

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 002
Issue: 2010 I-012**

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

All information above the line is for conference use only.

Title:

Employee Written Agreement for Employee Health Reporting

Issue you would like the Conference to consider:

Food workers working in a food establishment and preparing food while ill is a major cause of foodborne illness. The Food Code states that the Permit Holder is required to have employees and conditional employees report information about their health as it relates to diseases transmissible through food. There is no provision for documentation of this requirement, and, therefore, no accountability for compliance with this responsibility. The issue would require that the permit holder obtain a signed written agreement from employees and conditional employees.

Public Health Significance:

According to the Centers for Disease Control and Prevention, approximately 25% of foodborne outbreaks caused by viruses or bacteria may be attributed to infected food workers. Eighty-five percent of front line workers have no paid sick leave prompting many employees to continue to work while ill (ACORN, 2007.)

In 2007, thousands of Harris County restaurant patrons were potentially exposed to food handled by an employee infected with hepatitis A. This food worker handled ready-to-eat foods without using gloves or utensils, and it could not be verified that the employee followed appropriate hand washing procedures. In order to prevent illness among those who were potentially exposed, health officials administered a preventive vaccine to over 2,000 restaurant customers. This effort cost taxpayers \$70,000 in medication costs and required hundreds of staff hours.

The following paragraphs of Annex 3 of the 2009 FDA Food Code emphasize the importance of educating employees regarding their personal responsibility in reporting certain health conditions that have the potential of transmitting foodborne disease.

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.

Requiring food workers or conditional workers to sign a written agreement would remind and strongly emphasize to employees the importance of their responsibility in reporting these illnesses and symptoms and allow the person in charge to make the necessary decisions to exclude or restrict the employees. A written agreement would help promote open communication and reporting of illness and would educate staff on the health conditions they are required to report.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending that a permit holder keep signed documents on file at the establishment that inform and require employees and conditional employees to report illness transmissible through food.

Amend Section 2-201.11 Responsibility of Permit Holder, Person in Charge, and Conditional Employees to read:

(A) The PERMIT HOLDER shall require FOOD EMPLOYEES and CONDITIONAL EMPLOYEES to report to the PERSON IN CHARGE information about their health and activities as they relate to diseases that are transmissible through FOOD. The PERMIT HOLDER shall require that each FOOD EMPLOYEE and CONDITIONAL EMPLOYEE sign a written agreement in a form approved by the Regulatory authority such as in Annex 7 form 1-B. The signed forms shall be retained at the facility and made available at the time of inspection upon request. A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report the information in a manner that allows the PERSON IN CHARGE to reduce the RISK of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE:

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
2010 Issue Form**

**Internal Number: 003
Issue: 2010 I-008**

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

All information above the line is for conference use only.

Title:

Wild Harvested Mushrooms

Issue you would like the Conference to consider:

There are currently no standards by which a Regulatory Authority can certify that individuals who collect, inspect and sell wild harvested mushrooms are competent in mushroom identification.

Section 3-201.16 Wild Mushrooms of the FDA Food Code does not provide adequate guidance to Regulatory Authorities for the regulation and enforcement of the collection and sale of wild harvested mushrooms.

While this certification program is still in draft form, we would request CFP's support to proceed with this project for future adoption in the FDA Food Code Annex 3.

Please see attachments (State of Maine):

Wild Mushroom Partnership Proposal

List of Wild Mushroom Species Approved for Sale

Maine Wild Harvested Mushroom Certification Manual

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 certify 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 the following language be placed in Annex 3 of the FDA Food Code Section 3-201.16 to present as a model that states can adopt or modify to develop and implement a wild harvested mushroom certification program for their state.

3-201.16 Wild Mushrooms.*

(A) Except as specified in section B, mushroom species picked in the wild shall be identified and found to be safe by a certified mushroom identifier whose competence has been verified and approved by the regulatory authority through the successful completion of a wild mushroom identification course provided by either an accredited college.

university or a mycological society. An individual must be certified in the identification of each mushroom species they wish to harvest, buy or sell. An individual who wants to be approved as a certified wild mushroom identifier shall successfully complete a written exam approved by the regulatory authority. That individual shall have on file a current certificate issued by the regulatory authority acknowledging successful completion of the exam.

~~(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 identification expert.~~

(B) This section does not apply to:

(1) Cultivated wild mushroom species that are grown, harvested, or and processed in an operation that is regulated by the FOOD regulatory agency that has jurisdiction over the operation; or

(2) Wild mushroom species if they are in packaged form and are the product of a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.

(C) Requirements: Wild mushroom species must always be identified while in their fresh state.

(1) At least one party in the initial sales transaction of wild mushrooms must be certified to identify wild harvested mushroom species.

(2) Broker or Wholesaler shall retain records identifying the following information for a period of 90 days:

a) Latin binomial and common name of the mushroom species.

b) Name and address of person who harvested the wild mushroom.

c) Name and certificate number of the person responsible for identifying the wild mushrooms.

d) Quantity of each wild mushroom species purchased from individuals.

(3) Eating Establishments and Food Establishments shall retain records identifying the following information for a period of 90 days.

a) Latin binomial and common name of the mushroom species.

b) Name and certificate number of the person responsible for identifying the wild mushrooms.

c) Quantity of each wild mushroom species purchased from individuals.

(4) Point of Sale: Identification tag must be visible at point of sale stating the above information except quantity of mushrooms and must include the language, "Wild harvested mushrooms must not be eaten raw and should be thoroughly cooked".

(5) Consumer Advisory: A consumer advisory shall inform consumers by brochures, deli case of menu advisories, label statements, table tents, placards, or other effective written means that wild harvested mushrooms may cause allergic reactions, stomach upsets, or other effects.

Submitter Information:

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Attachments:

- "Wild Mushroom Partnership Proposal"
- "List of Wild Mushroom Species Approved for Sale"
- "Maine Wild Harvested Certification Manual"

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Partnership Agreement to Establish a Wild Foraged Mushroom Training and Certification Program for Maine

Background and Rationale for Partnership Agreement

Last summer Maine had two, separate, wild mushroom poisonings involving the consumption of wild mushrooms obtained from a local forager by Maine chefs. Both individuals developed severe vomiting and dehydration and required emergency medical intervention at a local hospital. Presently the FDA and Maine Food Code inadequately address the collection and sale of wild mushrooms and enforcement thereof. The 2001 Maine Food Code states:

3-201.16 Wild Mushrooms.*

(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is identified by the Latin binomial name in the fresh state by a person with local mushroom picking experience and training recognized by a national mycological organization.

Enforcement of this section is not possible because a certification process was not developed and implemented. The Maine Food Code requires that restaurants and retailers purchase all products for sale from an approved source. There is currently no training program for foragers recognized by a national mycological organization, therefore the Department must be able to assure accountability and public safety with regard to the identification, sale, purchase, preparation and service of wild foraged mushrooms.

To date, no progress has been made on this retail food issue. The Conference of Food Protection has not developed the comprehensive regulations needed by the States. Proper education and/or certification of foragers, and training of chefs and other retail resellers to enable them to distinguish edible from poisonous mushrooms are necessary to ensure the safety of those eating wild foraged mushrooms.

In November of 2008, a wild mushroom task force comprised of a diverse group of mushroom experts, foragers, restaurant representatives and state government overseers was convened to address the need to bring structure to the world of wild foraged mushroom sales in Maine. This joint task force feels strongly that foraging of wild foods to sell has a long accepted tradition in Maine, and is not a tradition that the committee feels should be prohibited. Rather than prohibit the sale of wild foraged mushrooms the task force proposes to develop rules, supported by training and certification that will enable wild mushroom foraging to continue while ensuring the safety of the buying public.

1. Statement of Agreement to Establish Partnership:

The state of Maine Department of Health and Human Services (DHHS) Health Inspection Program in cooperation with the Maine Mycological Association, Maine Department of Agriculture (DAFRR), Northern New England Poison Control, Maine Restaurant Association, and other interested stakeholders agree to establish a partnership related to the training and certification of foragers of wild foraged mushrooms and the chefs of restaurants and retail sellers purchasing wild foraged mushrooms in order to increase assurance that the general public will be adequately protected from avoidable mushroom poisoning incidents.

2. Partnership purpose and goals:

The purpose of this partnership is to draft regulations to clarify the process related to the sale of wild foraged mushrooms in the state of Maine. More specifically, the regulations will:

- Make clear the process needed to establish and maintain certification as a wild mushroom forager in order to sell or barter wild mushrooms on a retail or wholesale basis and,
- Detail the training needed for personnel of retail establishments including restaurants, farmers markets, and retail stores, in order for them to purchase wild foraged mushrooms for resale. There is no intention to regulate the sale of cultivated exotic mushrooms through this program, e.g. cultivated maitake, oyster, lion's mane, etc.

a. **This agreement covers the period of** two years from the date of final signature and may be extended as agreed upon by the parties.

b. **The anticipated outcomes of this partnership are to:**

- Draft language to revise the Maine Food Code as required to establish the parameters under which wild foraged mushrooms may be purchased and sold in Maine and to detail a process for training and certification of foragers and purchasers of foraged mushrooms for resale to the public.
- Establish an accepted list of wild mushrooms approved for collection and sale under the certification program in the state of Maine.
- Develop a curriculum, a training manual, and processes to train and certify foragers and retail buyers of wild foraged mushrooms in the skills needed to recognize approved mushrooms. Foragers will be trained in methods of harvesting mushrooms in a sustainable manner.

- Develop a state-sanctioned exam for certification of chefs, foragers, brokers, buyers and sellers of wild foraged mushrooms upon successful completion of the training program.
- Establish and staff a series of training seminars to carry out the goals of this program. The seminars will be self-supporting using the income generated through tuition charges.

3. Program areas and activities for the Partnership:

a. Program area for the partnership include:

1. This program will cover the state of Maine. As there are no other wild mushroom certification programs available, this program will serve as a model for Northeastern states. This project will benefit food retail operations, foragers, brokers, FDA and regulatory agencies throughout the Northeastern region by training and certifying wild mushroom foragers, chefs and brokers to safely identify an approved list of wild foraged edible mushrooms. This section of the Maine Food Code is not currently enforceable and this program will allow enforcement.

b. Cooperating Agency/organization/public contacts:

1. Maine DHHS
Lisa Brown
Program Manager
Health Inspection Program
2. Maine DAFRR
Steve Giguere
Program Manager
Division of Quality Assurance and Regulation
3. Maine DHHS
Laurie Davis
Health Inspector
Health Inspection Program
4. Maine Mycological Association, Greg Marley, Michaeline Mulvey
5. University Of Maine (UMO), School of Biology and Ecology, Dr Seanna Annis, Associate Professor of Mycology
6. Maine Restaurant Association, Dick Grotton, President
7. Northern New England Poison Control Center (NNE), Karen Simone, PhD, Director
8. Dan and Candyce Heydon, forager/brokers
9. Rick Tibbetts, forager/broker
10. Selected representative restaurant chefs and owners
11. Selected representative experienced foragers, David Spahr, Barbara Skapa

12. Northeast Mycological Federation. Dr. Seanna Annis as Maine Mycological Assoc. representative.
13. North American Mycological Assoc. Michaeline Mulvey as Maine Mycological Assoc. representative.

c. Statutory basis for Partnership Agreement:

1. FDA:
 1. FDA Model Food Code & Food Code Supplement
2. Maine
 1. Title 22 Chapter 562 Camping Areas and Eating Establishments.
 2. Title 7 Section 482 Manufacture and sale prohibited.

4. Responsibilities:

Joint:

1. The parties will conduct joint planning meetings to come to a consensus position on the issues and opportunities presented by sale of wild foraged mushrooms in Maine and the need to protect the buying public from the potential for the consumption of a toxic species.
2. Subcommittees will be formed to work out details of drafting regulations, determining a list of approved species, developing training curricula and materials.
3. Joint efforts of the stakeholders will be needed to develop and coordinate a training and certification program funded by tuition and certification fees.
4. If successful, this program will seek to form cooperative agreements with other states also required to enforce similar regulations, but without the mechanisms needed to support compliance and enforcement.

Maine DHHS/DAFRR, Health Inspection Program/ Division of Quality Assurance and Regulations:

- Provide the expertise needed to revise the Maine Food Code to reflect the efforts of this partnership and come into compliance with food law 3-201.11A food shall be obtained from sources that comply with law.
- Act as certifying body for foragers and buyers of wild foraged mushrooms.
- Provide the structure and temporal consistency needed to insure the Wild Mushroom Training and Certification Program is perpetuated beyond the efforts of the current committee.

Maine Mycological Association and University of Maine:

- Provide expertise to develop a list of approved mushrooms in coordination with area foragers and restaurant personnel.
- Assist in the development of training curricula and materials as needed.
- Develop a specific manual of approved mushrooms, look alikes and potentially

toxic species for use in the education of foragers and retail sellers of wild foraged Maine Mushrooms.

- Provide training personnel to carry out the curriculum to all interested participants on a minimally semi-annual basis.

Maine Restaurant Association:

- Provide leadership and coordination between the efforts of this partnership and those member establishments in Maine with interest in the use of wild foraged mushrooms.
- Act as a communication arm in informing membership about the efforts of this partnership.
- Provide resources and logistics needed to carry out the training program including monies for training material development, room for trainings and other supportive efforts.

Northern New England Poison Control Center:

- Provide expertise and input regarding toxicology and protection of the public as related to the use of edible wild foraged mushrooms.
- Provide resources as needed to support development and printing of a manual for training on approved edible wild foraged mushrooms.

State-wide wild mushroom foragers and wholesale brokers of foraged mushrooms.

- Provide expert input regarding foraged species for inclusion on approved list.
- Act as a resource to link the partnership with area foragers.
- Assist in development of training curriculum and materials.

5. Resources planned to carry out partnership (estimated):

Development of Mushroom ID Manual.....	\$ 750.00
Marketing and registration of training program.....	\$ 500.00
Printed Material	
-Other printed materials.....	\$ 250
-Wild Foraged Mushroom Manual.....	\$ 8,000.00
Payment of Training staff.....	\$ 1500.00
Travel expenses.....	\$ 500.00
Total.	\$ 11,500.00

Income Potential;

In kind donation of time and expertise*.....	\$
Mushroom Manual sales beyond use for training.....	\$16.00 per copy
Tuition from trainings (est. \$75/attendee x 20/session x 4 sessions)	\$5,000
Requested FDA support.....	\$5,000

*Maine state employees, UMO specialist, NNE Poison Control and Maine Restaurant Assoc personnel time are in-kind donations

6. Assessment mechanisms:

Foragers and others completing a mushroom identification training program will be tested for knowledge gained and retained by completing identification of approved wild foraged mushroom species. Scores on tests will be used to assess training effectiveness. Numbers of restaurants and retail establishments completing training will be used as one method to assess the breadth of the program statewide. Feedback from foragers and retailers completing a training seminar will be gathered as a means of fine-tuning the training curricula and materials.

7. Signatures of responsible parties:

List of Wild Mushroom Species Approved for Sale

Ranking

1- easy to identify and prepare

2 – caution in identifying, requires special care in preparing

3 – only expert identifiers can collect, multiple steps to prepare for eating

Edible Mushrooms for Cooking

<u>Latin Binomial</u>	<u>Common name</u>	<u>Other common names and comments</u>	<u>Ranking</u>	<u>Comments</u>
<i>Agaricus arvensis</i> <i>Agaricus campestris</i>	Horse mushroom Meadow mushroom	Pink bottom, field mushroom	1	Look-alikes: A. Xanthodermus (yellow), Lepiotaceae and Amanitaceae (white spored) Complex of species
<i>Armillaria mellea</i> complex	Honey mushroom	Includes A. mellea and A. ostoye	2	Needs to be cooked thoroughly, boil 5 minutes Do not collect from conifers , okay from hardwoods
<i>Boletus bicolor</i>	Two color bolete		3	Caution for identification, must be distinguished from look-alikes
<i>Boletus edulis</i>	Cep	Porcini, king bolete	2	
<i>Calvatia cyathiformis</i>	Dark-spored puffball		1	should be purple spored puffball
<i>Calvatia gigantea</i>	Giant puffball		1	bland for restaurant use but may be found at farmers markets

<i>Cantharellus cibarius</i>	Golden chanterelle	Chanterelle, pfifferling	1	
<i>Coprinus comatus</i>	Shaggy mane	Shaggy ink cap	1	Very short shelf life
<i>Craterellus cornucopioides</i>	Black trumpet	Horn of plenty, black chanterelle, Formerly called <i>C. fallax</i>	1	
<i>Craterellus ignicolor</i> , <i>C. xanthopus</i>	Yellow foot chanterelle	Flame-colored chanterelle	1	
<i>Craterellus tubaeformis</i>	Trumpet chanterelle	Winter chanterelle	1	Can be spelled <i>C. tubiformis</i> , some recognize <i>C. infundibuliformis</i> as a synonym
<i>Grifola frondosa</i>	Hen of the woods	maitake	1	
<i>Gyroporus castaneus</i>	Chestnut bolete		2	Caution for identification
<i>Hericium spp.</i> complex	Lion's mane, comb tooth	club tooth	1	Includes <i>H. americanum</i> , <i>H. ramosum</i>
<i>Hydnum repandum</i> <i>Hydnum umbilicatum</i>	Hedgehog	Sweet tooth	1	formerly <i>Dentinum repandum</i> and <i>D. umbilicatum</i>
<i>Hypomyces lactifluorum</i>	Lobster mushroom		1	
<i>Laccaria ochropurpurea</i>	Purple gilled laccaria		2	Caution for identification
<i>Lactarius deliciosus</i> complex	Orange latex milky	saffron milky	1	includes <i>L. thynios</i> and <i>L. deterrimus</i> – <i>L. deliciosus</i> is old name and the European sp.
<i>Laetiporus</i>	White		2	Caution, Cannot be collected from conifers. Must be

List of Wild Mushroom Species Approved for Sale

<i>cincinnatus</i>	pored chicken mushroom			collected young.
<i>Laetiporus sulphureus</i>	Chicken of the woods	Sulphur shelf, chicken mushroom	2	Caution, Cannot be collected from conifers. Must be collected young.
<i>Lepiota procera</i>	Parasol mushroom		3	Expert to identify, requires extra training. Many similar mushrooms, poisonous Amanitas or Lepiotas can be mistaken for it.
<i>Lepiota rachodes</i>	Shaggy parasol		3	Expert to identify, requires extra training. Many similar mushrooms, poisonous Amanitas or Lepiotas can be mistaken for it.
<i>Lepista nuda</i>	Blewit		3	Caution for identification, requires extra training. Difficult to identify, can be confused with purple Cortinarius species.
<i>Marasmius oreades</i>	Fairy ring mushroom	scotch bonnet faux mousseron	2	Cannot be collected from golf courses or pesticide-treated lawns, can be confused with <i>Clitocybe dialbatra</i> and <i>Inocybe umbratica</i>
<i>Morchella elata</i>	Black morel	Burn Morel	2	Caution for cooking: Needs to be well cooked
<i>Morchella esculenta</i>	Blond morel	Yellow morel	2	Caution for cooking: Needs to be well cooked
<i>Pleurotus ostreatus</i>	Oyster mushroom		1	
<i>Pleurotus populinus</i>	Oyster mushroom		1	
<i>Polyporus squamosus</i>	Pheasant back	Dryad's saddle	1	Useable when young and tender
<i>Stropharia rugosoannulata</i>	Wine cap stropharia	King stropharia	2	
<i>Tricholoma</i>	White	Matsutake	2	

<i>magnivelare</i>	matsutake			
Mushrooms for possible medicinal uses				
<u>Latin Binomial</u>	<u>Common name</u>	<u>Other common names and comments</u>		
<i>Ganoderma lucidum</i>	Ling chih / Reishi		1	
<i>Ganoderma tsugae</i>	Reishi	Hemlock varnish shelf	1	
<i>Inonotus obliquus</i>	Chaga, clinker polypore	Birch clinker	1	
<i>Trametes versicolor</i>	Turkey tail		2	

Maine Wild-Harvested Mushroom Certification Manual

Manual Overview

INTRODUCTION

- **Maine's Wild Harvested Mushroom Certification Program**
 - **Maine's Foraging Tradition**
 - **Traditional Use of Wild Mushrooms**
 - **The Federal Food Code and State Regulation of Food Safety**
 - **The Need for Certification of Commercial Mushroom Foragers**
 - **Who Needs to be Certified?**
 - **The Levels of Certification**
 - **Process for Implementing a Commercial Wild Mushroom Foraging Certification System**
- **Current Regulations and Rules Governing the Commercial Harvest of Wild Mushrooms in Maine.**
- **Commercial Mushroom Forager Certification Process.**

PART I. BACKGROUND INFORMATION

WHAT IS A MUSHROOM? WHY ARE MUSHROOMS IMPORTANT?

- **Introduction to the Fungi**
- **The Importance of Fungi in the Environment**
- **The Different Types of Mushrooms**

ANATOMY OF MUSHROOMS

- **General shapes of mushrooms**
- **The Parts of a Mushroom**
- **Pictorial Glossary of Mushroom Features**

HOW TO IDENTIFY MUSHROOMS

- **What do I need to Know?**
- **How to Collect for Identification**
- **What Equipment do I Need?**
- **The Steps to Identify an Unknown Mushroom**

NOMENCLATURE

- **Why Names are Important**

- **Scientific Names versus Common Names**

MUSHROOM TOXICITY

- **The History of Mushroom Poisoning**
- **The Extent of the Problem in Modern Times**
- **The Range of Mushroom Toxins**
- **Who Typically Gets in Trouble and How to Avoid Joining the Ranks**

Expectations FOR A CERTIFIED FORAGER

RESPONSIBLE COLLECTING

- **Collecting for a Sustainable Mushroom Supply**
 - **Protection of the Habitat**
 - **Avoiding Overharvesting**

Whose Land is it?

- **Access to Open Land in Maine**
- **Commercial Foraging on Public and Private Lands**
- **Securing Permission to Collect- “Ask First”**

Responsible Sales Practices

- **Education of Buyers/ Final User**
 - **Proper storage**
 - **Proper / Safe Preparation**

COLLECTION AND STORAGE OF WILD MUSHROOMS

- **Harvesting Mushrooms in Good Condition**
- **Collecting Techniques**
 - **Separation of Mushroom Species for Safety**
 - **Ensuring a High Quality Product**
- **Grading and Storage of Wild Mushrooms**

RECORD KEEPING

- **The Regulations**
- **Tips for Good Record Keeping**
 - **Foragers**
 - **Brokers**
 - **Chefs and Retailers**

PART II. THE MUSHROOMS

**MUSHROOMS APPROVED FOR COMMERCIAL COLLECTION AND SALE
IN MAINE**

LEVEL I MUSHROOMS (Alphabetical by Genus)

LEVEL II MUSHROOMS (Alphabetical by Genus)

LEVEL III MUSHROOMS (Alphabetical by Genus)

PART III. APPENDICES

- **Additional resources for Mushroom Identification**
 - **Mushroom Field Guides**
 - **Online Resources**
 - **Mushroom Associations and Groups**

DRAFT

Species Format

Name: Species binomial
Accepted Common Name
Other Common Names in Wide Use

Introduction and History of Use

Description:

Narrative Description

Typical size:

Cap: Size

Color:

Shape

Texture

Spore-bearing surface type (gills, pores, teeth...)

Color

Unique features

Stem: Size

Color

Shape

Texture

Ring +/-

Cup +/-

Flesh: Color and texture

Spore print color:

Habitat / Ecology

Certification Manual

Color: White to cream

Shape: Convex to almost flat

Surface Texture: smooth, becoming scaly with age.

Spore-bearing surface:

Gills: Free of the stem and closely spaced;

Color: maturing from grayish white to pink to reddish to dark brown.

Stem: Size: 3-5 inches long and up to 7/8 in. wide.

Color: White

Shape: equal to tapering upward

Texture: smooth and firm

Ring: Present, membranous and fragile

Cup: Absent

Flesh: Cream to white with mild odor of almonds sometimes present.

Spore print color: Dark bittersweet chocolate brown

The Horse mushroom caps are often 4-7 inches in diameter, but caps up to 10 inches are not uncommon. The cap is white to cream with occasional pale tan markings, tightly rounded in the button stage and becoming broadly convex and finally almost flat in maturity. At times the cap will stain or age pale yellow. The stalk is 3-5 inches long and up to 7/8 inch in diameter, generally equal or tapering toward the cap, with a distinct and membranous ring and occasionally, a broader base. Horse Mushroom gills are grayish to cream-colored in the button stage but then undergo the same color transformation as many *Agaricus*, becoming reddish brown and finally very dark brown. The flesh is firm and cream to white colored. The faint scent of almonds often accompanies this mushroom.

Habitat / Ecology: Horse Mushrooms are saprobes growing on the dead organic matter in coarse lawns, pastures and other open grassy ground such as the shoulders and medians of roads and highways. Occasionally it can be found fruiting on the ground in open woods. Often found fruiting in rings or arcs.

Occurrence / Season: The Horse mushroom frequently fruits in small numbers in late June and early July in a wet summer. The heaviest and most consistent fruiting comes in the mid-late autumn and ends with the onset of a hard freeze. The occurrence from year to year is not predictable and this mushroom is infrequent in both unusually dry and unusually wet years.

Look Alikes: **Edible:** *Agaricus macrosporus* is primarily a European mushroom seen occasionally in Maine growing in association with Spruce. It is of very similar size but

lacks any yellowing color and is usually associated with trees, especially spruce.

Agaricus silvicola and *A. abruptibulbous* These two woodland species are very similar in appearance and habitat. Both are taller with a thinner stalk and smaller cap with a fleshy, pendulous ring on a long slender stalk. Each species has a swollen or bulbous stem base, though it is more pronounced in *A. abruptibulbous*. In addition the scent of sweet almond is often stronger than in *A. arvensis* in the flesh. Both are recognized as good edibles.

Toxic: *Agaricus placomyces* is a smaller, more slender member of this group generally found growing with trees and with dark scales on the cap and the tendency to bruise bright yellow, especially at the base of the stem. Odor is disagreeable or chemically. Causes moderate to severe gastrointestinal distress when eaten.

Amanita bisporigera and *A virosa*, Destroying Angels contain potentially deadly phallotoxins. This is a pure white mushroom with free white gills, giving a white spore print and the stalk with a fleshy pendulous ring and a swollen base with a cup-like volva. It is a mycorrhizal mushroom growing in association with trees. The Destroying Angels are among our most toxic mushrooms!

Collection / Preservation: Collect firm young caps before they fully open for the best combination of appearance, flavor and durability. Older mushrooms are more strongly flavored, but much more fragile and prone to rot. Sell or use within a several days for the best results. The immature button stage has a longer storage life than the mature mushrooms. Preserve this species by either drying or sauté and freezing. Mature mushrooms can be chopped and cooked down into a sauce Duxelles.

Preparation / Use History: Given the close relationship between the Horse Mushroom and the cultivated Button mushroom, Crimini and Portabella, it is not surprising that it will lend itself to any recipe featuring its cultivated cousins as well as the closely related Meadow Mushroom. It has long history of use in both Europe and North America in a multitude of dishes, from soups to stews, and eggs to pizza.

Caveats / Potential Risks: The yellow staining *Agaricus* species, including *A. arvensis* have been shown to concentrate certain heavy metals from their environment into the fruiting body tissue. For this reason, care must be taken to avoid collection of these mushrooms from contaminated ground including the shoulders and medians of heavily traveled highways. In addition, avoid collections from agricultural lands, golf courses or other landscaped areas where chemical treatments are used or suspected as the mushrooms can become contaminated.

Summary: The Horse mushroom is a common inhabitant of grassy landscape and is notable for its large stature, squat, stolid appearance, white to cream color and the distinctive transition of the free gills from cream to pink to very dark brown. The white stem has a large membranous ring and lacks any signs of a cup. This common, widely eaten mushroom fruits in the summer and fall and has been a favored edible of many

mushroomers for generations.

DRAFT

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 001
Issue: 2010 I-011**

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

All information above the line is for conference use only.

Title:

Signage Requirement on Reporting of Employee Health Conditions

Issue you would like the Conference to consider:

The *Food Code* requires the Permit Holder to inform employees of their responsibility to report health issues related to illnesses transmissible through food. It is insufficient to inform employees once of their responsibilities. After the initial information is provided, there must be continual reinforcement of their obligations to report. A requirement should be added to the *Food Code* for signage to be posted as a reminder and reinforcement of their obligation to report illnesses.

Public Health Significance:

According to the Centers for Disease Control and Prevention, approximately 25% of foodborne outbreaks caused by viruses or bacteria may be attributed to infected food workers. Eighty-five percent of front line workers have no paid sick leave prompting many employees to continue to work while ill (ACORN, 2007.)

In 2007, thousands of Harris County, Texas restaurant patrons were potentially exposed to food handled by an employee infected with hepatitis A. This food worker handled ready-to-eat foods without using gloves or utensils, and it could not be verified that the employee followed appropriate hand washing procedures. In order to prevent illness among those who were potentially exposed, health officials administered a preventive vaccine to over 2,000 restaurant customers. This effort cost taxpayers \$70,000 in medication costs and required hundreds of staff hours.

The following paragraphs of Annex 3 of the 2009 FDA Food Code emphasize the importance of educating employees regarding their personal responsibility in reporting certain health conditions that have the potential of transmitting foodborne disease.

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.

Requiring persons in charge of food establishments to post a sign would remind and strongly emphasize to employees the importance of their responsibility in reporting these illnesses and symptoms. Such an employee health sign would help promote open communication and reporting of illness and would educate staff on the health conditions they are required to report.

Education of employers and employees regarding reporting of certain health conditions is the focus of a current Health Impact Study in Connecticut funded through the Environmental Health Specialist Network (EHSNet.) A pilot to this study noted a 20% increase in employer notification to employees of the obligation to report health symptoms after managers received educational brochures and signs notifying employees of their responsibility to report certain health conditions. Furthermore, the number of employers who asked employees who reported ill if their symptoms included diarrhea and vomiting increased 44% and 36 %, respectively.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending that a sign be posted to reinforce and remind employees to report health illnesses that are transmissible through food. (See attached sample sign from the Texas Department of State Health Services).

Amend Section 2-103.11 Person in Charge by adding Paragraph (N) to read:

(N) "A sign is posted in a place conspicuous to employees, in a form approved by the Regulatory authority describing a food service employee's responsibilities to report certain health conditions as described in Subparagraphs 2-201.11 (A)(1),(2) and (3) to the permit holder."

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Attachments:

- "Food Employee Reporting Sign"

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.

Attention Food Employees

Report to your supervisor immediately

If **you** have any of the following symptoms caused by illness or infection:

- ◆ Vomiting
- ◆ Diarrhea
- ◆ Jaundice (yellowing of eyes and skin)
- ◆ Sore throat with fever
- ◆ Infected wounds or lesions with pus (on hands, wrist, or exposed body parts)

If **you** or a household member have been diagnosed by a doctor with:

- ◆ Norovirus
- ◆ Hepatitis A
- ◆ Salmonella typhi (typhoid fever)
- ◆ Shigellosis
- ◆ E. coli O157:H7 (or other shiga toxin- producing Escherichia coli)

You could make your customers sick

Reporting your illness or symptoms is mandatory under:

***Texas Food Establishment Rule 229.163(d)
25 Texas Administrative Code (TAC) §229.163(d)***



Texas Department of State Health Services
Food Establishments Group
www.dshs.state.tx.us/foodestablishments

**Conference for Food Protection
2010 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:

USFDA Recall Policy Revision

Issue you would like the Conference to consider:

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:

Current Classification System from FDA web site for Industry:

Recall Classifications

- Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- Market withdrawal: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to

tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

These classifications are vague and difficult to understand. What is a "reasonable probability"? Furthermore both the FDA and the USDA, which uses the same definitions, are inconsistent with their application. A recall of chili with beans that was found to contain some pebbles was recalled as a Class I. Other than a chipped tooth, is there a problem of public health significance? A more recent recall for pieces of plastic in shaved steaks was a Class II. Last year, a slaughterhouse was found to be mistreating "downer" cows. This was an administrative violation, as there was no evidence that cattle with BSE entered the food supply. Nevertheless, millions of pounds of products containing beef from that plant were subjected to a Class II Recall at an extraordinary cost to industry in spite of virtually no health risk. Many more examples can be found, all pointing to a lack of clarity and understanding of how recalls should be classified.

Public Health Significance:

Rapidly removing adulterated products from commerce reduces the odds of consumption and subsequent illness. Clear concise guidelines will allow industry to focus efforts when food needs to be rapidly recalled. An understandable system will allow the public to gain confidence in the food supply and recall system, creating better cooperation and opportunities for clear communication. Administrative guidelines that tie the classification of a recall to the specific actions required of each layer of industry will greatly improve efficiency and enhance cooperation between industry and federal and state regulators

Recommended Solution: The Conference recommends...:

that a letter be written to the FDA urging creation of a committee/task force to redesign the administration of food recalls. The committee should include FDA, USDA, State Public Health, academia, and industry, including primary and secondary producers, brokers, and distributors.

The following model is offered as a starting point for the revised administrative guidelines to be developed by the committee/task force. There are only three categories, each with an expanded definition and actions required of industry:

Class I:

Definition: Consumption is likely to start, increase, or continue a FBI outbreak, or, a reportable FBI Agent is involved: C.Bot, HepA, Giardia, Listeria, Vibrio, Salmonella, Shiga+ E coli, Shigella, Campylobacter, or Vibrio.

Actions: Immediate response (within 24 hrs.), contact customers, public notification, destruction of product

Class II:

Definition: Consumption, at worst, may result in short illness treatable with over-the-counter meds - or - the consequences may be more serious (an allergic reaction) but few persons would be affected.

Actions: Next business day response, pull product from distribution and other suppliers, notify public.

Class III:

Definition: Administrative issues only - or - the consequences of consumption are minimal

Actions: no customer or public contact, pull product from distribution

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Attachments:

- "FDA 2009 Regulatory Procedures Manual, Chapter 7/21CFR"

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.

Chapter 7 RECALL PROCEDURES

This chapter contains the following sections:

Section	Topic	Page
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7-4	RECALL ENTERPRISE SYSTEM	7-3
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7-1 PURPOSE

This chapter provides policy, definitions, responsibilities, and procedures for agency units to initiate, review, classify, publish, audit and terminate recall actions. It implements 21 CFR Part 7 Subpart C – Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibilities. (See also Investigations Operations Manual, Chapter 8, Recall Activities.)

7-2 BACKGROUND

Recalls are an appropriate alternative method for removing or correcting marketed consumer products, their labeling, and/or promotional literature that violate the laws administered by the Food and Drug Administration (FDA). Recalls afford equal consumer protection but generally are more efficient and timely than formal administrative or civil actions, especially when the product has been widely distributed.

Manufacturers and/or distributors may initiate a recall at any time to fulfill their responsibility to protect the public health from products that present a risk of injury or gross deception, or are otherwise defective. Firms may also initiate a recall following notification of a problem by FDA or a state agency, in response to a formal request by FDA, or as ordered by FDA.

All agency units are expected to follow the requirements of this chapter. Some deviation from the procedures may occur in the initiation of device recalls ordered under section 518 of the Federal Food, Drug, and Cosmetic Act, corrective action programs (recalls) involving radiation emitting medical devices and electronic products, infant formula recalls, human tissue recalls, or other situations as they arise.

Guidelines delineating the responsibilities of industry in conducting recalls are in 21 CFR 7.40-7.59. An additional document titled “Product Recalls, Including Removals and Corrections - Industry Guidance” is available on the Internet at the FDA web site. It is designed for all FDA regulated industry and provides guidance both in the conduct of recalls and in the information needed by FDA to classify, monitor, and assess the effectiveness of a recall.

7-3 SUMMARY OF FDA RESPONSIBILITIES AND PROCEDURES

The FDA recall program gives recalls the proper attention at all levels of the agency and provides adequate resources to process, to classify, and to publicize recalls in a timely manner. FDA responsibilities are summarized below. This chapter is arranged according to the following outline:

1. Initiation of a Recall. Includes voluntary, FDA requested, and FDA mandated.
2. Classification and Strategy. FDA formalizes the recall action by reviewing the information, including the recall strategy provided by the firm, assessing the health hazard presented by the recalled product, and classifying the recall.
3. Notification and Public Warning. FDA notifies the firm of the classification and necessary changes in its recall strategy, including the need for press releases for those recalls conducted voluntarily. The agency notifies the firm of FDA requested or mandated recalls and the need for publicity. FDA publishes all recalls on the FDA Internet site and ensures that the public is warned about products that are hazardous to health. FDA provides recall information to other federal and state government agencies and to foreign governments.
4. Monitoring and Auditing the Recall. FDA develops and implements a recall audit program to ensure that the recall action has been effective.
5. Termination of a Recall. FDA determines when a recall should be terminated and, upon such determination, provides written notification of termination to the recalling firm.

Finally, FDA will take appropriate regulatory action or other measures when the firm fails to recall violative product or when a recall action fails. These actions will be taken in consultation and coordination with the district compliance branch, the appropriate center recall and compliance staffs, OE/DCMO, and when indicated, the Office of Chief Counsel, when:

1. a firm refuses to recall or sub-recall after being requested to do so by the FDA;
2. a firm fails to complete a recall in a timely fashion; and,
3. the agency has reason to believe that a recall strategy is not effective

7-3-1 Responsibilities Of The Office Of Enforcement/Division Of Compliance Management and Operations (HFC-210)

OE/DCMO is the agency's headquarters contact and focal point for information, advice, and direction for field recall operations and remains involved with each recall throughout its process. If required, OE/DCMO may direct appropriate follow up actions by the field. OE/DCMO, with the district coordinators and Center Recall Unit (CRU) evaluates firms' recall performance. The recall staff encourages timely district and industry action on recalls. In the case of FDA requested recalls, as well as all Class I recalls for which the ACRA has not delegated classification authority to center directors, OE/DCMO is the liaison between the districts, the CRUs and the ACRA. The recall staff reviews and makes recommendations to the ACRA regarding concurrence with the Action Memoranda. OE/DCMO will forward its recommendation to the ACRA within one working day unless additional or supplemental review

of the health hazard evaluation or recall classification or status is required. OE/DCMO periodically reviews all agency recall activities to ensure that current policy and procedures are being applied to recalls and recommends changes as appropriate. OE/DCMO informs OE/DCIQA (Division of Compliance Information and Quality Assurance) of recalls that may affect government agencies, and, in turn, OE/DCIQA informs the appropriate government agencies of such recall information, when applicable. OE/DCMO evaluates the overall effectiveness of recall activities. OE/DCMO communicates trends, common causes of recalls, control weakness, etc., to units having the need for this information.

7-3-2 Responsibilities And Procedures – Office Of Enforcement/Division Of Compliance Policy (HFC-230)

OE/DCP reviews and resolves compliance policy issues related to recalls. The division reviews recall action memorandums when requested by OE/DCMO, particularly when a policy issue has been identified. OE/DCP provides written response to OE/DCMO.

7-3-3 Responsibilities and Procedures – Office of Enforcement/Division of Compliance Information and Quality Assurance (HFC-240)

OE/DCIQA receives recall information from OE/DCMO when the identified consignees include government agencies. OE/DCIQA forwards the information, as appropriate, to the applicable government agencies. Such sharing of information supports the Government-Wide Quality Assurance Program (GWQAP).

7-4 RECALL ENTERPRISE SYSTEM

The Recall Enterprise System (RES) is an electronic data system used by FDA recall personnel to submit, update, classify, and terminate recalls. Districts will not capture and track Market Withdrawals or Safety Alerts in the RES system. The classification types of Market Withdrawal and Safety Alert in RES were designed to allow centers to use these selections for field recommendations placed in RES that were believed to be recalls by districts. Actions by firms determined to be Market Withdrawals or Safety Alerts by the districts prior to RES entry should not be entered into RES.

Basic recall guidance and procedures remain essentially unchanged from those used prior to the initiation of RES. RES User Guides contain the detailed information needed for the use of RES. Electronic copies of the guides have been provided to field and center recall coordinators. The RES application currently has some help information available for each screen. Additional detailed guidance will be developed and added to the application.

The RES increases efficiency in processing recall information by:

1. allowing field coordinators to input recall information via an on-line, Intranet system;
2. combining five separate documents for a recall event into a single system, allowing users to build a record of the entire recall by entering information as it becomes available thus reducing preparation time and providing consistency throughout the agency;
3. reducing duplication of efforts between the Field Offices, OE, the centers, and Office of Public Affairs;

4. increasing communication of recall information between the field, headquarters, and the appropriate center(s) offices;
5. providing a central, searchable database to more efficiently track information and generate and disseminate reports of recall activities;,
6. using a uniform Health Hazard Evaluation (HHE) form or a form equivalent to the HHE form to promote consistency in evaluating potential health hazards and/or risks agency-wide while supporting wider use of electronic precedent health hazard assessment files to expedite recall classifications; and,
7. Providing the public with “real-time” information about the FDA recall process

The information entered in RES is gathered from various sources, including the field, the firm, ORA and the CRU. ORA is the business owner for the RES database.

ORA/OE/DCMO maintains other documents relevant to these actions on their website at: www.fda.gov/Safety/recalls/industry_guidance

7-5 INITIATION OF A RECALL

A manufacturer or distributor may voluntarily initiate a recall at any time. Under certain urgent situations, FDA may request that a manufacturer or distributor recall a product. Under certain authorities, FDA may mandate a recall.

7-5-1 Firm Initiated Recalls

In summary, if a recall is firm initiated, the agency will obtain and review the information provided by the recalling firm under 21 CFR 7.46(a). This includes reviewing and suggesting changes to the firm’s recall strategy, to its recall communication, and to its press release (if necessary). The agency will conduct a health hazard evaluation (HHE), (precedent HHEs or written classification policies may be used), classify the recall, and advise the firm in writing of the assigned recall classification. The letter to the firm will recommend any appropriate changes in the firm's recall strategy, advise the firm that its recall will be placed on the FDA web site and, when appropriate, otherwise publicized, such as issuing a press release or talk paper and posting on MedWatch. FDA will also assign audit checks as appropriate, monitor the effectiveness of the recall communication, correction or removal, verify appropriate product disposition, and terminate the recall.

The district:

1. submits a Recall Alert;
2. gathers information about the recall. It may conduct an establishment inspection and collect samples of the recalled or other suspect products;
3. submits a Recall Recommendation and other information about the recalled product to the appropriate center;
4. offers guidance to the recalling firm;
5. monitors the recall; and,

6. terminates Class II and III recalls and recommends termination for Class I recalls.

The above district activities are described as follows.

1. ***Recall Alert***

The district, as soon as possible, but preferably within 24 hours, after learning of a recall either planned or in progress, should notify the appropriate CRU and OE/DCMO Recall Operations Staff (HFC-210). The district should submit this Recall Alert through RES by completing, at a minimum, all the fields identified in Attachment A, and may submit any other information at the same time. Additionally, the district will scan and e-mail or fax to the CRU a copy of the recalling firm's recall communication and press release, if any.

A copy of the press release is also to be forwarded to OE/DCMO and to the OPA Field Liaison. Alerts have not been required for device recalls under section 518(e), biologics recalls for which CBER issued an "alert to possible recall," and corrective action program (CAP) recalls involving radiation emitting medical devices and electronic products. These exemptions will continue under RES.

OE/DCMO will promptly notify the ACRA of significant recall actions and will provide copies of recall documents where appropriate

2. ***Recall Recommendation and Related Information***

The district must submit a complete Recall Recommendation (RR) through RES within five working days after submitting the recall alert or as soon as the recalling firm has provided the information necessary for the RR. When the information is submitted through the RES system, it automatically alerts the appropriate CRU and OE/DCMO via e-mail. See Attachment B for guidance on the information required by the CRU to review and classify the recall. The district may submit the Recall Alert and Recommendation up to 10 working days after the district learns of a "completed" recall.

- a. In conjunction with the recall recommendation, the district will submit to the appropriate CRU, as soon as possible:
 - i. legible copies of all labeling, including operations manuals, brochures, flyers, or any other product related literature that will aid in determining the violation and evaluation of the product problem;
 - ii. product specifications, formulation and related documents;
 - iii. FDA and/or state laboratory worksheets and/or the firm's pertinent quality control or analytical records for all products involved;
 - iv. if the district does not have a physical sample to demonstrate the defect and the potential hazard, other documentation of the justification for recall, such as a copy of the FDA-483 documenting serious violations of GMPs, or epidemiological evidence; and,
 - v. if not previously submitted at time of the Alert, a copy of all of the recalling firm's communications to the CRU. For potential Class I recalls, also forward a copy to OE/DCMO.

This material should closely follow the submission of the RR and should be submitted by the fastest means possible, for example, by scan delivered via e-mail, by fax, or by guaranteed overnight delivery.

If there is insufficient information to submit an RR, the district recall coordinator should telephone or email the appropriate CRU and OE/DCMO for advice on a course of action.

b. **Notes:**

- i. When requested by OE/DCMO or the CRU, submit a Recall Recommendation for a product removal as a result of actual or alleged tampering with individual unit(s) where there is no evidence of manufacturer or distributor responsibility. The district should recommend the action be classified as a market withdrawal as, although the situation may present a health hazard, there is no one identified as responsible for the violation. This will allow documentation and monitoring of specific corrective actions meeting the market withdrawal definition but considered significant to the agency.
- ii. FDA regulated products manufactured by U.S. firms for foreign distribution and which are in violation of United States laws will be processed, classified, and published the same manner as domestic recalls.
- iii. FDA regulated products manufactured by foreign firms recalled in the U.S. will be processed, classified and published (including entered in RES) the same as products manufactured in the U.S. If the U.S. Agent initiates the recall on behalf of the foreign firm, the U.S. Agent gets copies of the FDA correspondence on the recall. However, if the US agent refuses (or, otherwise fails) to initiate the recall and the foreign firm performs the notification to its first line distributors, then the foreign firm is the recalling firm and receives the classification and termination letters from the ACRA, center or district.
- iv. If the CRU or OE/DCMO finds the RR information lacking in any way, either may request that the district obtain the additional information. This may be done by telephone, email, or the electronic return of the recall record with comment.

3. ***Establishment Inspection***

The district will contact the firm to obtain recall information and, in the case of recalls that have been classified as or appear to be class I or significant class II recall situations, an establishment inspection should, in addition to other activities, determine the root causes of the problem and document violations for possible regulatory action if appropriate corrective action is not being implemented, and evaluate overall compliance. See the IOM Chapter 8 – Recall Activities for guidance in conducting recall related inspections.

The establishment inspection should, in addition to other activities:

- a. Obtain the recalling firm's proposed recall strategy [21 CFR 7.46(a)], if not previously submitted by the firm.

- b. Collect copies of all labeling associated with the product.
- c. Obtain complete distribution of all shipments of the suspect lot(s), including complete names and addresses of all foreign consignees.
- d. Obtain supporting documentation that will assist the agency in identifying and evaluating the problem such as product complaints, product specifications and test results, including the methods used to obtain the results.
- e. For medical device recalls, obtain marketing status of the device being recalled, that is, 510(k) or PMA number(s), or preamendment device with proof of status.
- f. Assess the root causes of the problem. Determine how and when the problem occurred and how and when it was discovered. Obtain the firm's corrective action to prevent future occurrences.
- g. Verbally apprise management that the district office should be consulted prior to the reconditioning or destruction of any returned product. Management should also be advised that FDA must witness or otherwise verify product disposition. Prior to initiating an establishment inspection, district personnel should determine whether similar complaints have been entered into FACTS. For devices, search CDRH's MAUDE database or contact CDRH's Division of Surveillance Systems, Information Analysis Branch (HFZ-531) to retrieve complaints. For drugs, contact CDER's Division of Compliance Risk Management and Surveillance, (HFD-330) regarding complaints reported in the Drug Product Defect Reporting system. Center offices managing other reporting systems may be contacted where applicable to a particular problem.

In many recall situations, the firm's production facility may differ from the recalling facility, typically a headquarters or corporate office. In these cases, the monitoring district will contact the district where the violation occurred and request an inspection of the responsible establishment. The investigating district, in turn, should keep the monitoring district informed of the inspectional progress and findings.

Usually during this initial contact, the center has neither evaluated the health hazard nor classified the recall. In that case, the district office should not urge the firm to expand or reduce its recall efforts. In all discussions of violative or potentially violative products with the responsible firm, avoid any misunderstanding that FDA is formally requesting recall action. FDA requested recalls may be authorized only by the ACRA or by center directors delegated that authority.

If the recall has been completed before FDA's knowledge of it, district personnel should obtain documentation of actions taken to dispose of or recondition the recalled products. This documentation may include processing records or laboratory analysis, process validation protocols and reports, signed destruction receipts, salesperson's written receipts, corporate official's signed statement on firm's stationery, etc. The district should update RES with the recommendation and termination information within 10 days of learning of the recall.

If the responsible firm is out of business or is unable to conduct an effective recall for any reason, the district should notify the CRU and OE/DCMO. The district and the CRU

should develop an appropriate course of action to recommend to the ACRA. In significant situations involving a serious health hazard, this could involve issuance of press to notify the public and/or FDA notifying consignees directly.

4. *Official Samples*

The district must determine the need for an official sample, either physical or documentary. Typically collect samples when they best demonstrate the defect and potential hazard. The decision to collect an official sample is a district management prerogative unless required by specific headquarters' initiated assignments, or the occasional direct request from the CRU or OE/DCMO. Samples collected should document interstate movement as well as the violation.

5. *Guidance to the Recalling Firm*

The monitoring district office will offer guidance to the recalling firm and will assist the firm in composing the text of recall communications to consignees so that the product will be promptly removed or corrected. The communication should be brief and to the point. It should clearly identify the product, potency, dosage, type, model and/or lot number(s), contain a concise statement of the reason for the recall, the known or potential hazard(s), the initial shipping date, and instructions for consignees to follow in handling the recall. If the depth of the recall is to the retail, hospital, physician or consumer level, the recalling firm should instruct its direct accounts to contact any sub-accounts that may have received the product. The subaccount should then instruct its additional accounts that they should sub-recall to the proper level and if they supplied any additional sub-accounts that all of the sub-accounts should recall to the proper level. See Exhibit 7-4 for a model letter. The possible need for bilingual or multilingual communications should be explored with the firm.

The instructions should also request direct accounts that are involved in further distribution of the recalled product to promptly initiate recall communications with sub-accounts. The written recall communication to sub-accounts should be in addition to any other means of communication, such as monthly sales bulletins, manufacturer representative visits, or recorded phone messages on order taking equipment. These actions may aid in a sub-recall effort, but they are an inadequate communication of the recall.

Ensure that the recalling firm flags the envelope containing a recall letter, mailgram, telegram, or other type of message as "URGENT DRUG (or FOOD, BIOLOGIC, DEVICE, etc.) RECALL (or CORRECTION)." Letters should be sent first class and, where appropriate, with proof of receipt (e.g., by certified mail).

Letters to direct accounts and sub-accounts should include a postage-paid, self-addressed post card, envelope, or other arrangement to enable the consignee to report the amount of the product available and its disposition. If none of the product is on hand, the letter should direct that the consignee submit a negative report. It should stress prompt return of the card or other report. (See Exhibits 7-4, 7-5, 7-6, and 7-7 for model letters, envelopes, and cards.)

7-5-2 FDA Requested Recall

An FDA request that a firm recall a product is ordinarily reserved for urgent situations. The request is directed to the firm that has primary responsibility for the manufacture or marketing of the product when the responsible firm does not undertake a product recall on its own initiative. FDA requested recalls are most often classified as Class I. Generally, before FDA formally requests recall action, the agency will have evidence capable of supporting legal action, i.e. seizure. Exceptions include situations where there exists a real or potential danger to health, or in emergency circumstances such as outbreak of disease involving epidemiological findings. The completion of either a firm initiated or FDA requested recall does not preclude FDA from taking further regulatory action against a responsible firm.

The Associate Commissioner for Regulatory Affairs (ACRA) approves all FDA requests for firms to conduct recalls, except that in some cases certain center officials are also authorized to approve FDA requested recalls (see SMG 1410.412). SMG 1410.412 indicates that, for medical devices assigned to their respective organizations, the Director, Deputy Director, and certain other officials, in CDRH, CDER and CBER, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 USC 360h(e)), that have been delegated to the Commissioner. In those cases, the center director is responsible for appropriately advising the ACRA. In all cases of FDA requested recalls, the center director must concur with Action Memoranda required to be submitted to the ACRA.

FDA requested recalls may begin with various communications between the field and headquarters units, but will be implemented by submitting an Alert and a FDA Requested Recall Recommendation in RES in the same manner as for voluntarily initiated recalls. All data and documentation related to the problem, as indicated above under the Recall Recommendation and the Establishment Inspection paragraphs, will be obtained and submitted to the CRU. The CRU will process the recommendation as outlined in the following paragraphs on Recall Classification and Strategy and submit an Action Memorandum to the ACRA through OE/DCMO.

DCMO will review the Action Memorandum and promptly prepare and forward a recommendation to the ACRA.

If the center's recommendation is approved by the ACRA and the letter to the recalling firm signed, the ACRA or his/her designee will notify the firm by letter of FDA's determination of the need to immediately begin a recall. The letter will specify the violation(s), health hazard involved, and recommended recall strategy. It will provide any other instructions appropriate to effectively conduct the recall.

When the district receives a copy of the letter sent to the responsible firm by either the ACRA or a center director, district personnel should verify the firm's receipt of the letter and make arrangements to visit and/or inspect the firm as soon as possible. Coordination with the center Recall Unit, Office of Criminal Investigations, or other offices may be necessary in special situations.

NOTE: FDA requested recalls for radiation emitting electronic products may not always follow this procedure. See Attachment E for special instructions.

The district office will offer the same guidance to the recalling firm as outlined above and will

assist the firm in arranging the text of recall communications to consignees so that the product will be promptly removed or corrected.

7-5-3 FDA Ordered Recalls

Various sections of the law authorize FDA to order a firm to recall a product. Each is discussed separately below. If the recall is FDA ordered, the agency will issue a written order to the firm to recall. This order should state the violation and the section of the Act or regulations that gives FDA the authority to order the recall. It should clearly describe the product, lots, serial numbers, etc. to be recalled and provide a time frame for the firm's reply.

FDA ordered recalls often have timeframes and procedures specified by regulation. The district should familiarize themselves with these before proceeding with assistance to the firm. The center compliance office normally takes the lead in negotiations with firms on FDA ordered recalls. The district should plan its strategy with direction from the center.

1. *Mandatory Device Recalls*

Under Section 518(e) of the Act, if the agency finds that there is a reasonable probability that a device intended for human use would cause serious adverse health consequences or death, FDA has the authority to order the manufacturer, importer, distributor, retailer, or any appropriate person to immediately cease distribution of the device, to immediately notify health professionals and device user facilities of FDA's order, and to instruct such professionals and facilities to cease use of the device. The Secretary delegated the authority to issue Section 518(e) orders to the Center Directors and Deputy Center Directors and to the Directors and Deputy Directors of the Offices of Compliance in the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health (21 CFR 5.411). Such orders must have the concurrence of the Office of Chief Counsel (see procedures in Attachment G). The implementing regulations are found in 21 CFR 810. After giving the party subject to the order an opportunity for a regulatory hearing, FDA must either vacate the order or amend it to include a recall of the device.

2. *Mandatory Recall of Biological Products*

The National Childhood Vaccine Injury Act of 1986 amended the Public Health Service Act (PHS Act) to provide recall authority for biological products (42 U.S.C. 262). If a determination is made that a batch, lot, or other quantity of a product licensed under the PHS Act presents an imminent or substantial hazard to the public health, the Secretary has the authority to issue an order for its immediate recall.

3. *Mandatory Recall of Human Tissue Intended for Transplantation*

On November 21, 2004, FDA issued regulations requiring human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; record keeping; and the establishment of a quality program (GTP final rule 69 FR 68612). FDA promulgated the new regulations under the legal authority of section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). The regulations at 21 CFR 1271.440 include a provision for orders of retention,

recall, and/or destruction, and a new provision for orders of cessation of manufacturing in certain circumstances. Such orders are intended for use in situations when needed to prevent the introduction, transmission, or spread of communicable diseases. HCT/Ps subject to the provisions in 21 CFR 1271.440 include, but are not limited to bone, ligaments, skin, dura mater, heart valves, corneas, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen and other reproductive tissue. The regulations at 21 CFR 1271.440 do not apply to vascularized organs such as livers, hearts, and kidneys, human milk or any tissues currently regulated by FDA as human drugs, medical devices, or licensed biological products. See RPM Chapter 5, Order of Retention, Recall, Destruction, and Cessation of Manufacturing Related to Human Cell, Tissue, Cellular and Tissue-Based Products (HCT/Ps), for detailed procedures.

4. *Infant Formula*

The Infant Formula Act of 1980 and its 1986 amendments mandate that an infant formula manufacturer promptly notify the Secretary if the manufacturer has knowledge that reasonably supports the conclusion that an infant formula shipment may not provide the required nutrients or may be otherwise adulterated or misbranded.

If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately recall shipments. It is a prohibited act [Section 301(s)] for a manufacturer of infant formula who engages in a recall to fail to request that retailers post notice of recall for a length of time specified by the Secretary and to fail to report to FDA every 14 days on the progress taken to implement the recall. Guidelines delineating the responsibilities of industry in conducting mandatory infant formula recalls are in the 21 CFR, Part 107, Subpart E.

5. *Interstate Milk Shipments*

The FDA does not ordinarily classify or audit interstate milk shippers (IMS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the state(s). The FDA district office in which the recalling firm is located must be ensured that all states involved in an IMS plant's recall are participating in ensuring removal of the product from commerce and that, when appropriate, states issue warnings to protect the public health. In the event that FDA determines that the states are unable to effect the recall actions necessary, the agency will classify, publish, and audit the recall, including issuance of a public warning when indicated.

7-6 RECALL CLASSIFICATION AND STRATEGY

The Center Recall Unit (CRU):

1. initiates a health hazard evaluation;
2. finalizes a recall strategy;
3. classifies the recall and, for Class I recalls, prepares an Action Memorandum for Center Director or his/her designee concurrence before forwarding it to OE/DCMO and the ACRA; and,

4. updates RES with classification, audit strategy, and any recommendations, and posts the information to the Internet.

7-6-1 Health Hazard Evaluation

The agency will conduct or obtain health hazard evaluations (HHE) for each recall scenario. Precedent HHEs will be used where the product is identical or similar with basically the same defect or violation as a recall action previously classified. Precedent HHEs will be re-evaluated and updated periodically. Established precedent recall policies such as those established by CDRH may also be used.

Upon receipt of each recall recommendation or other information, from any source, which indicates a recall may be necessary, the CRU determines whether an up-to-date health hazard precedent exists covering the situation. If not, it forwards the appropriate information to the Center Health Hazard Evaluation Committee for review. Additional information received during the progress of a recall should also be forwarded to the committee for timely health hazard reevaluation.

The Health Hazard Evaluation Committee in each center should use the Health Hazard Evaluation Worksheet (Attachment D) to record their evaluations. This evaluation will take into account the factors listed in 21 CFR 7.41(a) and Attachment D1 of this chapter. The health hazard evaluation form must be prepared by knowledgeable center personnel and should reflect their written concurrence. The HHE committee may use a precedent health hazard evaluation in lieu of conducting a new HHE for a similar situation. It is the responsibility of the HHE Committee to ensure itself that all reviewers are familiar with the intent of the evaluation.

The HHE Committee will complete, endorse, and forward the health hazard evaluation form to the center recall unit within two (2) working days after receiving a recall recommendation unless additional information is required. It is the responsibility of the HHE Committee to notify the CRU when further information is needed. If the recall recommendation indicates that the product is no longer in distribution channels, they will complete, endorse, and forward the HHE to the CRU within five (5) working days.

The Health Hazard Evaluation Committee must promptly reevaluate the initial health hazard when additional data regarding injury, illness, medical, or scientific findings is received by the center. Where additional data are being received on a continuing basis, the committee is to routinely meet and reevaluate the health hazard at least biweekly.

The CRU should coordinate their review with other centers when necessary. Any questions about lead center responsibility or jurisdiction should be promptly referred to OE/DCMO.

7-6-2 Classification Process

For ongoing recalls, the CRU will normally classify recalls within two days after receiving the health hazard evaluation or confirming the classification through precedent review. They will add classification information to the recall document in RES and transmit the classification electronically to the monitoring district and OE/DCMO.

The CRU will then review, correct, edit or add information necessary for the FDA Recall web page and then submit it for updating. (The actual updating will occur automatically, once daily, at midnight, so all updates from the previous day will be available the following morning.)

The ACRA has approval authority for all Class I recalls. However, the ACRA has delegated approval of certain Class I recalls to center directors. This has been done to streamline the recall classification process in the center, expedite the handling of the recall by industry and FDA district offices, and in certain situations, to have it universally understood that these recalls represent potentially serious to life-threatening health hazards. The center director may further delegate within the center compliance office the authority for review and classification of recall actions previously established by the ACRA as Class I. Specifically, for CFSAN, this includes precedent situations such as *Listeria monocytogenes*, salmonella species, various allergens, and pathogens in ready to eat foods.

The CRU will prepare the recall Action Memorandum in all situations requiring ACRA or center director approval. Attach copies of the following: health hazard evaluation, the firm's or FDA's recommended recall strategy, FDA audit program, and the initial recall recommendation. As appropriate, attach product analytical results, medical records, evaluations, etc., which are pertinent to the hazard evaluation and subsequent recall classification. In the case of FDA requested or ordered recalls, propose a course of action in the memorandum to be taken if the firm elects not to recall. Submit the Action Memorandum to the center's compliance director for review and concurrence in all Class I recall recommendations prior to submission to the center director. The center director approves all Action Memoranda required to be submitted to the ACRA for concurrence with Class I recommendations and FDA requested recalls.

OE/DCMO may review the Action Memo and discuss it with the CRU before submitting it to the ACRA. When the center and ORA/OE disagree on aspects of a recall or when the ACRA believes the health hazard evaluation or recall classification warrants additional medical review, OE/DCMO may request that an ad hoc committee be formed to review and recommend changes to the health hazard evaluation or recall classification.

NOTE: FDA will normally evaluate, prepare, and approve necessary action memorandum on infant formula manufacturers' notifications submitted in compliance with section 412 of the Act within five calendar days.

The CRU may classify Class II and III recalls without management review. However, unusual and/or potentially high profile recall issues should be brought to center management's attention.

7-6-3 Classification Notification And Routing

When the ACRA approves the Recall Action Memorandum, the center and the district office is informed by OE/DCMO (via phone) of the ACRA's decision. The classification letter when signed by the ACRA will be mailed to the firm by DCMO. Distribution copies of the final approved documents will be sent to the center and the district office as soon as they are available. The original action memorandum with appropriate signatures and comments will become a permanent part of the center's recall file.

When the CRU receives the ACRA approved Action Memorandum and letter to the recalling firm, the CRU will update the RES recall application, including the center Internet Release page. The classification information is then transmitted to the district and OE/DCMO, and the updated information for the FDA website is forwarded for posting.

7-6-4 Recall Strategy

Each recall is unique and requires its own recall strategy. The CRU will review the firm's recall strategy for voluntary recalls and will develop a strategy for FDA requested recalls. The recall strategy includes the type notification and depth of the recall. It also contains the depth and level of audit checks and the need for public warning. Recall strategies are based on the individual recall circumstances and are not necessarily dependent on the recall classification.

For FDA requested recalls, the center's compliance director ensures that the regulatory strategy cited in the recall recommendation and the action memorandum is supportable in the event the firm refuses the ACRA's request to recall or fails to complete the recall effectively or in a timely manner.

If the agency approves an industry Corrective Action Program (CAP) for a radiation emitting electronic product, the agency will notify the responsible firm that its CAP is classified as a recall and will stress the need for prompt corrective action. These corrective actions are taken to correct either product defects or non-compliance with standards. (See Attachment E, Recalls of Radiation Emitting Electronic Products)

1. *Elements of a Recall Strategy*

As specified in 21 CFR 7.42(b), a recall strategy should include a statement on and the reasons for recommending the desired option under each of the following elements:

- a. Depth of recall. The recall may extend to the consumer or user level, the retail level, or the wholesale level.
- b. Public warning. In urgent situations, consideration should be given to the need for a press release that could be nationwide or to affected geographical areas only. In some cases, special communication with specific segments of the population (e.g., physicians, pharmacists, veterinarians, and hospitals) may be appropriate. When the CRU believes that there is a need for a FDA press release or a Talk Paper, in addition to the FDA Recalls web page posting, they should coordinate with the appropriate press officer on OPA's Media Relations Staff (HFI-20). Similar Information may also be posted on Med Watch.
- c. Effectiveness Check Level. This includes the method(s) to be used for and depth of recall effectiveness checks.

The recall strategy should consider the disposition of recalled products (e.g., carcinogenic products) when normal disposition means, landfill, crushing, denaturing, etc., are inadequate.

2. *Recall Strategy Review or Development*

In reviewing or developing a recall strategy, the CRU should take into account the health hazard evaluation, type or use of the product, the ease in identifying the product, the degree to which the product's deficiency is obvious to the consumer or user, the amount of product remaining unused in the marketplace, distribution pattern, validated salvage or rework plan, and the continued availability of essential products.

For firm initiated recalls the CRU will review and change as indicated or concur with the firm's recall strategy and the district's recommendations for the FDA audit program. For firm initiated recalls, center coordinators should obtain current assessment of recall effectiveness from the field. The center will communicate recommended changes in the firm's recall strategy and effectiveness checks and the FDA audit program to the District Recall Coordinator and OE/DEMO and update RES.

For FDA requested recalls the CRU will develop a recall strategy and include it in the center's Action Memo.

FDA may have to conduct the recall when a responsible firm is out of business or is unable to conduct a recall for any reason. The CRU, working with the involved district, will consult with OE/DCMO about strategy to implement recall action by FDA.

The CRU, when necessary, will develop an interim strategy to cover the time between notification of a known or potential health hazard and completion of a final formal strategy. Interim strategies are frequently part of recalls conducted for radiation emitting devices and electronic products, and for device recalls requiring replacement of components or software that must be developed.

The interim strategy will indicate the immediate actions to be taken on the part of the responsible firm to ensure prompt warning to the appropriate depth of distribution. Such warning must identify the hazards involved and the steps to be taken to minimize exposure to the product hazard pending completion and implementation of the recall strategy. The District Recall Coordinator and the CRU should discuss any corrections/modifications to the recall strategy, as necessary, for follow-up and correction by the recalling firm PRIOR to completing the recall classification in RES. If these corrections are not made prior to classification, the recalling firm may interpret the center's classification as acceptance of their inappropriate recall strategy.

7-7 NOTIFICATIONS AND PUBLIC WARNING

7-7-1 Reports And Reporting Procedures

1. *Identification of Recall Documents*

All units referencing recall actions should identify them by the RES generated "Record Event Number." After classification, the recall number(s) may be added, but the primary identification will still be the Record Event Number. This will allow all FDA personnel operating in the RES to immediately locate the required recall record.

2. *Status Reports*

District recall coordinators will update the status of recall actions in RES when they become aware that a recalls status has changed from "ongoing" to "completed" to "terminated." They will so advise the CRU, which will then update the FDA web page by reposting the recall record.

For certain Class I recalls and Class II recalls, when required by the audit program, the district office will send a weekly progress report to the CRU and OE/DCMO until the recall is completed or until advised otherwise by OE/DCMO.

Monthly or bi-monthly status reports on recall actions within the districts are not required by headquarters, but may be prepared at the discretion of district management for district recall operation monitoring purposes only.

3. *District Notification to the Recalling Firm*

The monitoring district, upon receiving the recall number, classification, and recall strategies from the center, will then promptly prepare and send a notification letter to the firm stating the agency's position with respect to the recall. Prior to issuing the recall notification letter, the district may notify the recalling firm by telephone of the recall classification and its posting on FDA's website.

This letter will provide the recall number(s), the classification of the recall, an agency assessment of the firm's recall strategy, i.e., type of notification, depth of recall, and level of effectiveness checks, as well as any suggested strategy revisions. It will indicate FDA's determination to verify returned product disposition by stating that the district office should be notified prior to the initiation of reconditioning or destruction of recalled products and that such action should be witnessed by an FDA investigator. (An alternative means, such as verification by appropriate state or local officials, may be used.) The letter should also inform the firm that the recall has been posted on the FDA website. The letter should encourage proper corrective action, and request periodic status reports from the recalling firm as described in 21 CFR 7.53(b). The letter should include a statement that failure to conduct an effective recall could result in either seizure of the violative product or other legal sanctions under the FD&C Act or related statutes.

The notification letter should be prepared for the signature of the district director or his/her delegate. It should also include the name and telephone number of the district's recall coordinator to assist the firm in answering any questions related to the recall classification.

A sample Notification Letter is attached as Exhibit 7-7. This exhibit serves only as a model. These letters should be written on a case-by-case basis and tailored to each unique recall situation.

In situations where there is an urgent need for a more prompt notice, i.e., FDA requested recalls, Class I recalls, or pending FDA press release, the district office will visit or telephone the firm, and follow-up with a confirmatory letter as appropriate.

In instances where the recall is terminated at the same time it is classified, the district will prepare a combination notification/termination letter to the firm. This letter will provide the recall number(s), the classification of the recall, and indicate that FDA considers the recall terminated. A sample Notification/Termination letter is attached as Exhibit 7-10.

4. *Audit Check Reports*

Report all recall audit checks on form FDA 3177, Recall Audit Check Report. See Exhibit 7-12A for a copy of the report and Exhibit 7-12 for the audit check report instructions.

7-7-2 Notification Of Other Governments And Agencies

OE/DCMO is responsible for maintaining contacts and notifying headquarters organizations about significant recalls. These include the Center Recall Unit, Division of Federal State Relations (DFSR), Office of International Programs, Media Relations Staff in the Office of Public Affairs, and the Division of Compliance Information and Quality Assurance (DCIQA) in the Office of Enforcement. In emergency recall situations, DCMO will keep FDA's Emergency Operations center apprised of recall status. DCMO advises the USDA, DOD, and other federal government agencies of recalls in which they are involved. DCMO also advises government officials in Canada and Mexico of recalls, in accordance with existing MOU's and CUMCIG (Canada-United States-Mexico-Compliance Information Group).

1. Notification of State and Local Officials

District offices should consider appropriate notification to state and/or local officials of recall actions that may be pertinent to them. The districts should also consider requesting necessary assistance from state and local officials either in conducting or auditing recalls.

DFSR informs State and local officials by electronic mail system of selected recalls presenting serious health hazards, where intense publicity is anticipated, and/or where state assistance is requested. DFSR also distributes other publicity prepared by the Office of Public Affairs (HFI-3), to these officials.

2. Foreign, Military, and Other Federal Government Distribution

The district coordinator should submit a list of foreign, military, and other federal government consignees to OE/DCMO in RES with the Recall Recommendation submission, or, if this information is known at the time, with the 24 hour alert.

OE/DCMO notifies the Office of International Programs (OIP) of all Class I recalls where product was distributed to foreign countries except Canada. OE/DCMO informs International Relations Staff (IRS) of specific foreign consignees. OE/DCMO also responds through IRS to all requests for recall information from American embassies.

OE/DCMO notifies Canadian food, drug, and device regulatory authorities of every recall, in accordance with established communication agreements. They inform Canada of recalls of products shipped to Canada and of recalls of Canadian products in the United States.

OE/DCMO notifies IRS of recalls of imported products to expedite locating all importers of the violative product.

OE/DCMO notifies the USDA, Food Safety and Inspection Service (FSIS) and the Food Nutrition Service (FNS) of recalls of FDA regulated products that have been distributed to any USDA agency that may have involvement with the school lunch program.

3. Responsibility and Procedures - OC, Office of International Programs, (HFG-1)

For all Class I recalls involving foreign consignees other than Canadian, OIP/IRS summarizes and transmits essential information to the appropriate counterpart agency

in the foreign country. It provides a copy of the foreign notification to the CRU and OE/DCMO.

At the request of OE/DCMO, OIP/IRS contacts appropriate counterpart foreign agencies to have them contact foreign manufacturers or distributors in order to determine name(s) and location(s) of United States importers of the firm's product(s) found to be violative and under recall in the United States. It provides foreign agency responses to OE/DCMO.

OIP/IRS coordinates the development of responses to foreign embassy inquiries with the centers and OE/DCMO.

OIP/IRS provides the CRU and OE/DCMO with foreign counterpart agency responses regarding the effectiveness of recall actions, so that the effectiveness of the recall notification to foreign consignees may be properly evaluated.

4. *Responsibilities and Procedures - Division of Compliance Information and Quality Assurance (HFC-240)*

OE/DCMO notifies the Division of Compliance Information and Quality Assurance (DCIQA) when medical products under recall (Class I and Class II) have been distributed to any federal agency and advises about impending Class I and other serious recalls of drugs and devices shipped to the Department of Defense (DOD), Department of Veterans Affairs (DVA), or General Service Administration (GSA) facilities.

DCIQA uses established systems and relationships with DOD, DVA, and the GSA to provide information or obtain cooperation relative to drugs, biologics or devices shipped to these agencies and presenting serious health risks.

DCIQA notifies appropriate federal purchasing agencies (DVA, GSA, and DOD) of all Class I recalls and of those Class II recalls of medical products which have been distributed to federal agencies. They receive and coordinate Class I recall audit check data from other government agencies and forward the data to OE/DCMO.

7-7-3 Public Warning

All industry product removal or corrective actions classified by the agency as recalls will be posted on FDA's Recalls and Safety Alerts web page. All recall alerts and recommendations submitted to the CRUs will, unless determined by the CRU at the outset to be market withdrawals or non-classifiable, be immediately posted by the CRU on FDA's Recalls web page. These recall postings will then be updated by the CRU as they are classified and/or when significant changes, recall extensions, etc., are provided by the district coordinators or otherwise brought to the attention of the CRU. Additionally, the Office of Public Affairs (OPA) web page manager will update the recall document with Internet addresses for any press statements issued either by FDA, a state agency, and/or the recalling firm.

It is FDA's policy that press releases issue for Class I recalls unless specific circumstances indicate that a press release would not be beneficial to the public. Publicity may be issued by either the recalling firm or by FDA. Agency policy gives the recalling firm the first opportunity to prepare and issue publicity concerning its recall. The field recall coordinators will work with the

recalling firm to prepare a press release. The OPA Media Relations Staff, the CRU and/or OE/DCMO Recall Staff are available to provide assistance. The CRU will also assist the OPA Media Relations Staff, along with the district recall coordinator and OE/DCMO, in the preparation of FDA publicity.

If hazardous products contain defects that require extensive design and/or test time to ensure both the firm and FDA that a certain recall or corrective action program is appropriate, the agency will require prompt, preliminary communication to consumers/users to prevent unnecessary injury.

District recall coordinators will promptly provide (electronically if possible) copies of all recalling firm or state agency issued press releases to the OPA Field Liaison Officer, the FDA Website Management Staff, the CRU and OE/DCMO. The Website Management Staff will update the recall website URLs to link users to the press releases.

When appropriate, the CRU will forward press releases and/or other recall documents for posting on the center's and/or the MedWatch website.

Additionally, notices or warnings may be issued to health professionals, trade associations, etc., for the purpose of alerting these populations to either serious health hazards or other situations deemed to be in the public interest.

1. Responsibilities and Procedures – Associate Commissioner for Public Affairs

- a. Advises the ACRA on the appropriateness of publicity for all recall actions;
- b. When a recall's strategy includes FDA publicity, prepares and issues publicity with the assistance of the appropriate center, district, and OE/DCMO. Obtains ACRA concurrence on all recall publicity;
- c. Alerts the appropriate home district of the expected release of publicity;
- d. Through the Media Relations Staff (HFI-21), ensures that recall actions are included in the FDA Enforcement Report until such time as the Internet portion of RES is made available to the public on FDA's website, and the agency concludes that the Enforcement Report may be discontinued. Specifically, the staff will:
 - i. Complete the recall entry for the FDA Enforcement Report upon receipt of the recall classification and number(s) from the CRU;
 - ii. Coordinate the development of the draft and final report with the CRUs and OE/DCMO.
 - iii. Distribute the report to ORA headquarters and field offices, the press, other federal government agencies, consumers, and the CRUs.

Note: As soon as the Internet portion of RES is released to the public, recall information provided by the field and centers will be uploaded on a real time basis onto a FDA web page without OPA involvement with one exception. The Website Management Staff will be provided press releases from recalling firms and/or state agencies. The link to the press release will then be provided on the specific recall web page.

- e. In cooperation with the CRU and OE/DCMO, prepares "Talk Papers" on high interest recalls that do not warrant a press release;
- f. Evaluates the effectiveness of recall publicity and, if determined to be inadequate, initiates action to ensure effective notice; and,
- g. Handles or coordinates responses to all media calls regarding recall situations.

7-8 MONITORING AND AUDITING RECALL EFFECTIVENESS

This section includes the following subsections:

7-8-1 Recall Effectiveness

It is the recalling firm's responsibility to determine whether its recall is progressing satisfactorily. The firm has an obligation to conduct effectiveness checks as part of its recall strategy. Effectiveness checks assist in the verification that all known, affected consignees have received notification about a recall and have taken appropriate action.

In some instances, a recalling firm may be unable to check the effectiveness of its recall. This could occur when a recall extends to the consumer-user level, the confidential business records of a firm's customers are not accessible, wholesalers, distributors, or retailers do not cooperate, or, because the urgency of the situation requires an all-out effort. In such cases, FDA will directly assist in this activity and, where necessary, seek assistance from cooperating state and local agencies.

Furthermore, the FDA recognizes that effectiveness checks also serve an audit function, and the agency reaffirms its policy of closely monitoring recalls and assessing the adequacy of a firm's recall efforts. Therefore, as part of its audit responsibilities, FDA will selectively conduct audit checks separately from the effectiveness checks of the recalling firm.

7-8-2 Managing FDA's Audit Program

1. *FDA Recall Audit Program Development*

The CRU reviews the district recommendation and finalizes the FDA audit program for the recall.

In Class I or other significant recall situations, the CRU should regularly review and update the audit program to ensure its adequacy and to reflect changes in the health hazard evaluation, classification, effectiveness of firm's recall, etc.

Factors in Audit Program Development include:

- a. Special procedures for monitoring the recall at the firm
- b. Level and type of audit checks to be conducted
- c. Special reporting requirements

OE/DCMO concurs in the use of personnel resources for audit checks for ORA.

2. *District Responsibilities*

In summary, the districts:

- a. Issue audit check assignments (monitoring district)
- b. Complete assigned audit checks (monitoring and other districts)
- c. Notify the CRU and OE/DCMO of progress on recalls and ineffective recalls

The monitoring district director has the overall responsibility for ensuring that the FDA audit program is implemented. The recall coordinator and appropriate supervisory personnel are responsible for the day-to-day management of a recall. They will ensure that the firm's status reports are received and reviewed in a timely manner and that the disposition of recalled products is monitored or verified. They will ensure adequate progress and timely completion of the recall by telephone or establishment visit, as appropriate.

If the monitoring district office encounters unreasonable delays by the recalling firm in conducting the recall, an administrative or legal action should be recommended to the appropriate center compliance branch. The CRU and OE/DCMO should be kept informed of such recommendations.

3. *Audit Check Issuance*

Normally within 10 days of issuance of the firm's recall communication, the monitoring district will issue audit check assignments at the level in the FDA audit program. Exceptions to the ten day time frame would be made for Class I situations when the recall is to the consumer/user level and it is critical that the agency be certain that the products are off the market or that consumer/users have been notified of the recall action. Audit checks are often issued within 24-48 hours after the district learns of a precedent class I food recall. Exceptions to the 10 day time frame are also to be expected in certain radiation emitting devices and electronic product recalls. In these cases, follow CDRH recommended strategy. When the district considers the 10-day requirement inappropriate, they should recommend to the CRU a new date for issuing the audit checks. The monitoring district must provide specific instructions as appropriate when issuing an assignment to another district office. The assignment should be flagged "Request for Audit Check--Class I or II, Audit Check--Level A, B, C, or D". (See Exhibit 7-11 for format). The district should forward a copy of Class I audit check assignments to the CRU and to OE/DCMO.

4. *Audit Check Completion*

The district receiving audit checks assignments should consider them high priority and should accomplish them as soon as possible. Submit copies of audit check reports to the monitoring district. If possible, complete assignments within 10 working days from receipt of the assignment. For Class I recalls, provide audit check reports to the monitoring district at least once a week or more often if so directed.

Visits, rather than telephone calls, are preferable for Class I recall audit checks. Visits are also preferred for Class II audit checks. However, resource restraints may make it necessary to conduct the audit checks by telephone. Ineffective telephone audit checks may need to be followed by a visit to ensure effectiveness of the recall action. Exceptions to Class I and II audit checks will be made only when circumstances indicate that such checks will be of no significant value in FDA's audit of the recall. Audit checks are not normally performed for Class III recalls. However, the responsible district and CRU must consider the need for such checks in each recall situation.

The issuing district will evaluate audit check reports when received to ensure that they are adequate and then retain them. If insufficient information has been collected, the issuing district recall coordinator will advise the endorsing supervisory investigator.

It is the responsibility of the receiving district to notify the issuing district of circumstances which will adversely delay the completion of the assignment. Copies of any such communication should automatically be forwarded to the CRU and to OE/DCMO (HFC-210).

5. *Conducting Audit Checks – Direct and Sub-Accounts*

The extent of follow-up and information obtained from consignees of recalled products depends on several factors, including the depth of the recall and the type of recall action requested such as return, field correction, or destruction.

Prior to conducting audit checks for complicated or significant recalls, the district may either prepare information handout sheets or copy the recalling firm's recall communication so that copies may be left with consignees.

a. **No Sub-Recall Indicated.**

When sub-recall is not indicated by the consignee, determine how and when the consignee was notified of the recall and whether the consignee followed the recall instructions. If the consignee failed to follow instructions and recalled product is being held for sale or use, the investigator should request immediate compliance with the instructions. If the consignee has not received the recall notification, give the consignee a copy of the recall information to perform the requested recall action.

b. **Sub-Recall Indicated.**

Where sub-recall is indicated by the consignee, determine how and when they received the notification. If the consignee conducted a sub-recall, determine and report in detail the quantity of product involved, the timeliness of the action, and other data pertinent to the sub-recall. If the consignee has not received notification of the recall, provide the consignee with all pertinent recall data. If the consignee has elected not to conduct the sub-recall action, request that recall instructions immediately be followed, including notification of sub-accounts. Provide any assistance or guidance needed by the consignee to get a sub-recall underway.

c. **Sub-Recall Refusals.**

If the direct or sub-account refuses to initiate recall promptly, the district performing the audit check will advise the monitoring district, OE/DCMO, and appropriate CRU of the situation, and indicate what additional steps the district is taking to achieve a

satisfactory sub-recall. Options for consideration include meetings between district management and top management of firms, notification of consignees directly, reporting to State and local officials, recommendation for FDA requested recall, and initiation of administrative proceedings or enforcement actions.

d. **Responsibility.**

The district in which the direct or sub-account is located is responsible for convincing the consignee to conduct an effective sub-recall or for recommending administrative or legal action, if indicated, to achieve compliance. The monitoring district, the CRU, and OE/DCMO should be kept advised of such recommendation.

e. **Injury/Illness/Data.**

Injury/illness reports or other product related complaints should be reported promptly (separately from the audit check report) to the monitoring district and OE/DCMO.

The monitoring district should inquire whether or not the adverse event (s) has/have been reported to FDA through programs such as MedWatch.

6. ***Ineffective Recall***

If at any time during FDA audit of the recall it is apparent that the recalling firm's recall effort is ineffective, the monitoring district should discuss the situation with the firm. Such additional contact can be made by visit, telephone, letter, facsimile, etc., depending upon the circumstance. Determine what action the firm intends to take to improve its recall efforts such as issuance of additional recall communications, etc. A model letter regarding ineffective recalls is attached as Exhibit 7-8. This type of letter should be developed by the district on a case-by-case basis working closely with the CRU.

If, after this notification, the firm is unwilling to extend or modify its recall, the monitoring district will notify the CRU and OE/DCMO of the situation and recommend appropriate action. Actions to be considered include actions such as FDA-requested recall, initial or further public warning, multiple seizures, and injunction.

7-8-3 **State Audits**

1. ***Purpose***

A state recall audit (state audit) is an audit of the effectiveness of a recall, which is conducted by a state at FDA's request. State audits may be used in highly complex recall situations or during urgent public health events, or where it is otherwise in the best interest of public health for FDA to call upon its regulatory counterparts at the federal, state, or local levels for assistance. State audits enhance FDA's capacity to determine the effectiveness of a recall, and assure that FDA's and state(s)' efforts are timely, efficient, and documented so that a timely evaluation can be made and additional follow-up activities can be considered when necessary.

2. ***When State Audits are Considered***

FDA may consider state audits in any of the following situations:

- a. The volume of audits approved by center(s) demonstrates the need for state help to accomplish audit check activities in a timely manner. (“Timely” is based on the health risk of the product subject to the recall.)
- b.. FDA is receiving numerous complaints about recalled product still on retail shelves after a firm has issued a recall notification or public warning.
- c. FDA determines that the recall is ineffective based on audit check results.
- d. The recalling district determines that an ineffective recall letter may be necessary.

3. ***Planning and Initiation of a State Audit***

The District Recall Coordinator for the recalling firm will make the initial recommendation to ORA/OE Recalls (OE Recalls) and the Center Recall Unit (CRU) for state audit assistance. When the need for state audits is identified, OE Recalls will convene and lead a recall operational planning group that includes representatives from OE Recalls, the recalling district, CRU, OPA, DF SR and DFI.

The recall operational planning group will determine the state audit procedure and strategy (see Strategy for State Audits below). This group may have to work within an Incident Command System structure depending on the situation surrounding the recall.

The District Recall Coordinator for the recalling firm should coordinate the recall strategy by issuing a state audit assignment to the participating state(s) within their own district. Issuance of assignments may also involve other District Recall Coordinators, DF SR and/or OE Recalls when multi-district assistance is needed.

When multi-district assistance is required, DF SR will request state assistance according to RPM 7-7-2 (“Notification of Other Governments and Agencies,” “1. Notification of State and Local Officials”).

4. ***Strategy for State Audits***

The state audit strategy should include, but is not limited to, determining:

- a. What consignees have done to discontinue the use and/or distribution of all intact containers of recalled product and the segregation of these products from those products not subject to the recall.
- b. The methods distributors use for handling and/or disposing of undistributed recalled products in their warehouse.
- c. Whether distributors have communicated recall instructions to their consignees, and, if so, by what mechanism (e.g., phone, letter).
- d. How users may identify (or have identified) recalled products; especially when the products do not have a lot code printed on the individual unit.

A state audit can be conducted by a personal visit, telephone call, or other timely means of communication.

5. ***Reporting Audit Results***

a. General

The recall operational planning group will determine who will receive and evaluate the state audit forms. Original FDA audit checks assigned for the recall should continue to be performed and completed per the original recall audit plan. Separate reports should be prepared to document FDA's audit results and each individual state's audit results, for use in preparing an overall, comprehensive report.

b. Reports by States

States will be encouraged to use FDA audit check forms (Form FDA-3177), however, this is a voluntary system. If state chose not to document their audit check results on FDA Form-3177, FDA will request specific information from the states so that FDA can determine the effectiveness of the firm's recall. States will be asked to return audit forms to their local, assigning district office, or provide sufficient information to determine recall effectiveness if they did not use the audit check form.

c. Reports by Districts

All district offices will return state audit check forms or equivalent information to the recalling district office's recall coordinator.

The recalling district should send periodic progress reports, weekly if possible, to the CRU and OE Recalls.

State activities performed in FDA districts other than the recalling firm's district shall be coordinated by the assisting FDA districts' recall coordinators to minimize duplication of activities by the states and FDA.

6. *Follow-up to State Audits – Recall Expansion, Ineffective Recall Letter, etc.*

a. Recall Expansion

If a recalling firm expands its recall, the recalling district will coordinate new audit assignments with OE Recalls and CRU concurrence.

b. Additional state audits

Additional state audits may be considered during the course of the recall.

c. Issuance of Ineffective Recall Letter

If state audits reveal an ineffective recall, the recalling district should consider issuance of an ineffective recall letter as per RPM Chapter 7 with the concurrence of the CRU and OE Recalls.

d. Public Information

The recall operational planning group will update and relay public information to all relevant offices, as necessary.

7. *Revisions to this Procedure*

Each recall presents its own set of circumstances, many of which change on a constant basis, therefore modifications to these recommended procedures based on the nature of any specific recall may be considered by the recall operations planning group handling the current recall, where necessary. These modifications should be documented by OE Recalls as approved and should then be communicated to the recalling district office as accepted.

8. ***Relationship of this Procedure to CFR Part 7***

These procedures are intended to supplement, not replace, those cited in 21 CFR Part 7.

7-9 RECALL TERMINATION

FDA will terminate a recall when the monitoring district office determines that the recalling firm has completed all recall activity, including monitoring and final product disposition. The district should advise the recalling firms that FDA will not terminate a recall until the firm has brought the product into compliance or disposed of it in an acceptable manner. The district will notify the recalling firm by letter that FDA considers the recall terminated. See Exhibit 7-9 for a Model Recall Termination Letter.

Termination of a Class I recall and a Safety Alert requires center concurrence. When the monitoring district concludes that such a recall or Safety Alert has been completed, the district recall coordinator will enter the information required for termination in RES on the "Summary and Termination" page. This page includes fields to provide the: complete reason for recall, quantity recovered or number of units corrected, product disposition, root cause of the problem, section of the law violated, preventative action taken by the firm, legal action by FDA, and name and date of district official approving the termination recommendation. When all required fields have been completed, the coordinator clicks on "continue" at the bottom of the page, which brings up the Summary and Termination validation page. After verifying that all data is correct, clicking on the "Save/Send Termination Recommendation" button will send an email to the CRU recommending termination.

Upon receipt of the termination recommendation email, the CRU will access RES, review the termination information and, if in agreement with the recommendation for termination, provide concurrence in RES (at the bottom of the Summary and Termination page) by inserting the name of the concurring center official. The CRU will change the "recall status" field to "terminated" and click on the "Save/Send Termination Concurrence" button which updates the recall action and generates an email to the district and OE/DCMO advising that the recall is terminated.

Center approval is not required for Class II or III recall terminations. Field coordinators will follow the same basic procedure as outlined above for Class I recalls, but will just change the "status" field to indicate "terminated" and click on the "Save/Send ClassII/III Termination" button. The RES then generates an email to the center and OE/DCMO that the recall has been terminated by the district.

As a rule, FDA should terminate the recall within three months after the firm completes the recall. If the district feels that the recalling firm is unable to ensure that violative goods will not reenter channels of distribution, the district should consult with the CRU and/or OE/DCMO for

the best course of action.

NOTE: Before any FDA approval or concurrence is provided to plans for the disposition of recalled products, the district must follow established procedures governing the coordination of toxic wastes/product disposal programs with other federal or state agencies.

The information provided in the Summary/Termination portion of the RES recall record is very important as it not only provides finality to the recall process but provides information used by headquarters to determine trends and to identify or evaluate new problem areas in manufacturing, processing, etc.

7-10 ATTACHMENTS, EXHIBITS, AND APPENDIX

Note: For each recall action, the RES provides a single record that is initiated at the beginning of the recall with an Alert. The record is continually updated in order to provide information for the Recall Recommendation, Classification, FDA website posting, any updates, and finally, Termination. The RES requires submission of some information not previously required. As the RES is finalized, detailed instructions will be provided for district and center coordinators. At the present time, the information provided or requested in the following attachments remains pertinent and appropriate for all steps of the recall process.

ATTACHMENTS:

- A Recall Alert Information
- B Recommendation for Recall Classification
- B1 Recommendation for Recall Classification and Termination
- C Recall Termination or Recommendation for Termination
- D Health Hazard Evaluation Worksheet
- D1 21 CFR 7.41(a) Guidance to Health Hazard Evaluation Committees
- E Recalls of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control Of Chapter V Of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly The Radiation Control For Health And Safety Act Of 1968 (RCHSA)
- F Recalls of Infant Formula
- G Recalls of Medical Devices, Section 518(e)
- H Methods for Conducting Recall Effectiveness Checks

EXHIBITS:

- 7-1 Model Effectiveness Check Letter (Industry)
- 7-2 Model Effectiveness Check Response Format (Industry)
- 7-3 Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry)
- 7-4 Model Recall Letter (Generic, All Centers)
- 7-5 Model Recall Return Response Form
- 7-6 Model Recall Envelope
- 7-7 Model Notification of Classification Letter (FDA to Recalling Firm)
- 7-8 Model Recall Ineffective Recall Letter
- 7-9 Model Recall Termination Letter
- 7-10 Model Combined Recall Notification of Classification and Termination Letter
- 7-11 Request for Audit Check Format

- 7-12 Audit Check Report Instructions/Explanation By Section
- 7-12A Audit Check Report
- 7-13 Weekly Class I Recall Status Report (Optional)

APPENDIX:

- A Forms/Attachments for State Audits

Attachment A – Recall Alert Information

Submit the information listed below to the CRU and OE/DCMO via RES:

- Product(s) Description
- Codes
- Recalling Firm
- Short Reason for Recall
- District Awareness Date
- Recall Initiation Date, with Type Initial Firm Notification
- Recall Status
- Voluntary or FDA Mandated Pick Lists, with Date

Attachment B - Recommendation for Recall Classification

Update and transmit the electronic record in RES with the required information necessary for the CRU to review and classify the recall. RES will, via Outlook Email, automatically notify the appropriate center and OE/DCMO personnel of the recommendation through established Outlook lists. Guidance for information to be included in the recommendation is as follows:

1. Product Description (INT), Trade Name, and Product Usage fields- (Product Details and Center Specific Pages)

- a. For each product, provide as applicable: Pertinent labeling to identify the product to include the product name (brand and generic) and the intended use or indications. Model and/or catalog numbers which further define the exact product. Describe how it is packaged such as box, flexible plastic, glass bottle or vial; the type such as tablet, sugar coated, or liquid, capsule, or powder; strength; sizes; form; route of administration; shipping or unit package. Provide a brief description of the product and its use. If product labeling does not indicate how the product is to be used, and the health hazard is dependent on use, consult the firm's catalog, the Red Book, or similar sources for the information.

If a drug product, indicate Rx or OTC and include the NDA/ANDA and NDC or UPC codes. For medical devices, obtain and include the 510(k), IDE, or PMA numbers as well as any related Corrections and Removals numbers.

If it is determined that the product must be examined physically for health hazard evaluation and/or to determine the efficacy of the corrective action, collect and ship an appropriate sample to the designated unit via the most expeditious and practical means available. Notify the center of the time, how sent, and estimated time of arrival.

- b. For each product give: brand name; name, address, and type of responsible firm on label; number and description of private labels. Submit a complete copy of all labeling (including product inserts or information sheets) to the appropriate CRU by an expeditious method, such as Facsimile, Federal Express, or Overnight Mail, depending on the circumstances involved.

2. Code Information (RES Product Details page)

Code Information (INT) field - List all lot and/or serial numbers, product numbers, packer or manufacturer numbers, sell or use by dates, etc., which appear on the product or its labeling.

3. Recalling Firm/Manufacturer/Responsible Firm (for the violation) – (RES Firm/Contact Details pages)

Recalling Firm Information fields:

FEI field- provide FEI number and click search. If the firm is in the OEI, the firm name and address is provided. Complete any fields not automatically populated. If FEI is unknown, or does not exist, type in "unknown" in the FEI field and then fill in all following

information fields. Under the “Comment” box, identify the type of firm, i.e., manufacturer, importer, broker, repacker, own label distributor.

Manufacturer Information field – Same as FEI field! In the “Comment” box, add any information to clarify relationships with either the recalling or responsible firm.

Responsible Firm Information field – Same as FEI field! In the “Comment” box explain the firm’s relation to the product such as processor, contract sterilizer, distributor, component supplier, etc.

4. Reason for Recall Recommendation (RES Event Details pages)

Complete Reason for Recall field - provide detailed information as to how the product is defective and violates the FD&C Act or related statutes. Refer to the IOM Chapter 8, Subchapter 810 for inspectional guidance.

- a. Include any analytical findings in qualitative and/or quantitative terms, indicating whether firm, FDA, State, or private firm analysis. Indicate the analyzing laboratory. Explain all State involvement in the recall, including sample collection or analysis, recall agreement or initiation, recall monitoring, and product disposition.
- b. Provide inspectional (GMP) or other evidence where appropriate.
- c. In cases where a veterinary drug product is being recalled due to subpotency of active ingredients prior to labeled expiration date, provide the following information:
 1. The firm's stability testing plan (including analytical methodology) which established the labeled expiration date.
 2. Specific batch numbers in the stability studies and assay values that are the basis of the firm's recall.
 3. Potency specifications which the firm uses for recall purposes.
 4. Final assay values for the active ingredients which were the basis of the initial release of the batch.

It should be noted whether or not information regarding stability data on file with the firm and the Quality Control procedures used by the firm to determine the potency of the active ingredients, is available in the EIR.

Root Cause field - provide any information available which identifies circumstances which resulted in, or contributed to, the problem which resulted in the recall.

Type of Injury Field – List in chronological order any complaints, injuries, or associated problems with the recalled product(s). Note: specific reference to MDRs and Corrections and Removals Reports are reported elsewhere.

5. Volume of Product in Commerce (RES Event Details page)

Quantity Manufactured field – This calls for the total “event” quantity for the product or products recalled.

Quantity Distributed field (Internet) – This is the total of all products distributed and should be the sum of quantities distributed for all product(s). Note: Each product has its own field for quantity of product distributed.

Manufactured From field – Provides dates.

Expected Life - This could include products such as pacemakers, which have a calculable life span.

Shelf Life - This primarily references perishable foods but may also be used for medical devices, biologics, and certain drugs.

NOTE: If the recommendation is for a FDA Requested Recall, assure that there is, in fact, product remaining in commerce before preparing and submitting the recommendation.

6. Distribution Pattern (RES Event Details page)

Distribution Pattern field (Internet) – This field is to provide the public with the general area of distribution such as, “Distributors in 6 states: NY, VA, TX, GA, FL and MA; the Virgin Islands; Canada and Japan”. The term “nationwide” is defined to mean the fifty states or a significant portion of them scattered across the United States. The six United States territories, Guam, Puerto Rico, American Samoa, Virgin Islands, and the Canal Zone, are to be reported separately.

Consignee Details fields

List of Consignees or Comments – This field should be used to list U.S. government, military and/or civilian units/agencies to which product(s) has been distributed. This would include the Defense Personnel Support Center (DPSC), DOD Hospitals, Department of Veterans Affairs (DVA), USDA (especially any product which may reach the school lunch program), or other government agency sales/distribution. If the consignee list is long, it may be submitted separately through the district R&E Coordinator to OE/DCMO. Indicate whether these were direct or contract sales. If there have been contract sales, report the contract number, contract date, and implementation date. Any discussion of product sales, products expected to remain on the market at time of recall, or related topics may be included in comments. (This information is not published on the Internet)

Number of Domestic Consignees – Provide number

Number of Foreign Consignees – Provide Number

Chart - As best you can, check off the types and approximate number of consignees in the chart.

7. Firm’s Recall Strategy (RES Event Details page)

Recall Strategy field - If the firm was advised of FDA findings and the problem was discussed with them, report its reactions and recall plans in detail. Similarly, if the firm advised FDA of the problem, report and explain the firm's own analytical results and/or information that resulted in the firm's decision to conduct a recall. Obtain the date that the firm realized the need for recall. (Firm Awareness Date on Start Recall page). Describe the firm's planned recall strategy, comment on its adequacy from the district's viewpoint, and evaluate the firm's ability to complete an effective recall. Sections 7.42 and 7.46 of 21 CFR, Part 7 - Enforcement Policy, Subpart C, provide information to be obtained from the firm for CRU evaluation. The firm's strategy should address the depth of the recall, the consideration of a public warning, and an appropriate effectiveness check program. It should also include the firm's intended course of action when an account which distributed the recalled product is found out of business. Include date recall was initiated, if already underway. If product is to be removed from the market place and recovered, its final disposition should be identified. Provide details of any

publicity issued or to be issued by FDA, the firm, the state, or local government.

8. Firm Officials/FDA Contact/Public Contacts (RES Firm/Contact Details page)

Most Responsible Individual field - Provide name, address, and phone number (if available) for the most responsible corporate individual for the recalling firm. If someone other than the most responsible corporate official, or the FDA contact person, are to receive the original or copy of recall classification or termination letters, provide the name(s) under the "Comment" box.

Recall Contact field – list the name, address, phone number, email address, fax number, etc. of the person that is the FDA contact for recall operations.

Public Contact field – list for the recalling firm, either a person or staff such as "Public Relations Staff" that can handle contacts from the public. Include name, address, phone number, facsimile, and email address as applicable.

9. District Audit Program (RES Event Details page)

Effectiveness Check Level field – Provide the firm's planned or district recommended effectiveness level. .

Audit Check Level field – Provide the district's recommended audit check level, i.e. the level that the district believes will satisfactorily verify the recall's effectiveness.

Audit/Effectiveness Check Modification box - This box should be used to provide any modifications to the recommended levels, e.g. "Recommend level C (10%) audit checks at distributor accounts and level D (2%) not to exceed five sub accounts of each distributor audited." Provide the firm's recall effectiveness history when recommending low levels of, or no audit checks, and monitoring of recall status from the firm's own records. This box may also be used to provide the district's proposed program for monitoring the recall, including the time table for follow-up visits or firm contacts for reviewing the recall status. State what actions have already been taken by FDA such as inspections, sample collections, etc.

Attachment B1 - Recommendation for Recall Classification and Termination

Note: Under RES, this information will be a continuation of the electronic recall record and many of these fields will be pre-populated as the recall recommendation data is inputted. However, the following fields need to be completed to justify termination.

1. **Product:** See Attachment B.
2. **Codes:** See Attachment B.
3. **Recalling Firm/Manufacturer:** See Attachment B.
4. **Reason for Recall Recommendation:** See Attachment B.

5. Volume of Product in Commerce, Quantity Recovered, and Disposition:

Provide total volume of product distributed and under the recalling firm's control. Provide quantity of product recovered or corrected by the recalling firm. If no, or little product was found in the market, explain why (i.e., expired, short shelf life, rapid turnover, etc.). Indicate the recall was completed and provide verification of disposition or correction of recalled product.

6. **Distribution:** See Attachment B.

7. Firm's Recall Strategy:

Describe the level of distribution to which the recall was extended. Provide complete description of the firm's recall notification and/or correction efforts. List the number of consignees responding to the firm's notification. Provide effectiveness checks accomplished and their findings, and/or other means the firm has to document the recall effectiveness. Provide district conclusion as to the adequacy of the firm's actions. If known, indicate steps the firm has taken to prevent similar occurrences.

8. Violation:

Provide the section of law violated.

9. Preventive Action:

Provide the action taken by the firm to prevent recurrence of the violation.

10. District Audit Program:

Describe actions taken by FDA (inspections, sample collections, etc.). Provide details of any publicity issued. Provide results of any FDA audit checks or auditing of records at the firm. List any legal action planned or underway.

Attachment C - Recall Termination or Recommendation for Termination

A Recall Termination (Summary) or Termination Recommendation must be prepared and submitted for those recall actions not terminated at the time of classification. As indicated above under Recommendation for Recall Classification and Termination Format, the Summary and Termination page in RES is also an update to the continuous record. Class I recalls and Safety Alerts require Center concurrence for termination. Class II and III recalls and market withdrawals may be terminated at the district's discretion. RES requires the completion of all fields on the Summary and Termination page as well the recall status being "completed" and a date completed provided. Therefore update the recall record to contain the information listed above under Attachment B1. The district coordinator will have to determine that all applicable and required data is included before submitting the Class I "Recall Termination Recommendation" to the Center recall unit for concurrence. For Class II and III recalls, the district coordinator or other district personnel will prepare and submit, after coordinator review, the recall document to district management for concurrence. The name of the district manager approving the termination and the date of the approval is to be recorded in the recall record.

When the CRU concurs with the Class I recall or Safety Alert termination recommendation in RES, notice of that concurrence will be electronically sent to the field coordinator and OE/DCMO.

When the district obtains concurrence from district management for the termination of Class II and III recalls and so updates the RES recall record, the coordinator electronically notifies the CRU and OE/DCMO of the termination.

Attachment D - Health Hazard Evaluation Worksheet

Note: The following Health Hazard Evaluation Worksheet has been developed by the Agency. **This worksheet, or an equivalent form, is to be used by all Center Health Hazard Committee personnel to record HHEs.**

HEALTH HAZARD EVALUATION

1. **PRODUCT/IDENTIFICATION NUMBER/USAGE (e.g. unit, lot, serial number, catalogue number, order number, etc.)**
 2. **FIRM NAME, ADDRESS, IDENTIFICATION NUMBER(S)**
 3. **NATURE OF PROBLEM**
-

-
4. (a) **Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?**

- No
 Yes - Attach copies or explain

- (b) **Have any adverse reaction reports or other indication of injuries or diseases been reported for similar situations?**

- No
 Yes - Attach copies or explain

- (c) **Is the problem easily identified by the user?**

- No
 Yes

5. **What is the risk to the general population?**

- (a) **For products not bearing dosage information, what is the normal consumption of the product by the general population and the population most at risk.**

6. **What segment(s) of the population is most at risk and why?**

[e.g. entire population(animals/species), infants, children, elderly, pregnant women, women of child bearing age, nursing mothers, surgical patients, immune suppressed, clinical situations, food producing animals, non-food producing

animals, other].

(a) Is there any known/accepted off labeled use(s) that would increase or change the population at risk.

7. Within the population at risk, could individuals suffering from any particular conditions or diseases be more or less at risk and if so, why?

[e.g. Immune system debilities, diabetes, cardiac problem, concomitant medications, etc.]

8. What is the hazard associated with use of the product? Explain and cite literature references when applicable.

Life-Threatening (death has or could occur)

Results in permanent impairment of a body function or permanent damage to a body structure

Necessitates medical or surgical intervention to preclude or reverse permanent damage to a body structure or permanent impairment of a body function

Temporary or reversible (without medical intervention)

Limited (transient, minor impairment or complaints)

No adverse Health Consequences

Hazard cannot be assessed with the data currently available

Explanation:

9. What is the probability of an adverse event occurring?

Every Time Reasonable Probability Remote

Unlikely Unknown

Explanation:

Signature

Date

Signature

Date

Signature

Date

Recall Product: _____

MARKET ASSESSMENT

Note: This market assessment is to be done by the Center's medical staff when requested to do so by the Center Recall Coordinator. This assessment should not impact on the health hazard. This assessment will only be used to alert agency personnel to potential drug shortage situations.

Would removal of this product(s) cause a major disruption relative to the treatment/prevention of disease? ____ No ____ Yes* ____ Not Applicable

* Please identify any alternative treatments/procedures that are available.

Center Recall Unit Assessment of Recall

Conclusion: the degree of seriousness of the hazard [real or potential] to the population at risk?

- The product is violative and there is a reasonable probability that use of or exposure to the product will cause serious adverse health consequences or death. (Class I)
- The product is violative and use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences (life threatening/death) is remote. (Class II)
- The product is violative and use of or exposure to the product is not likely to cause any adverse health consequences. (Class III)
- The product involves a minor violation or no violations. (Market Withdrawal)

Signature(s):

Date:

Attachment D1 – 21 CFR Part 7, Guidance to Health Hazard Evaluation Committees

The Food and Drug Administration's recall policy (21 CFR Part 7) requires the conduct of an evaluation of the health hazard (actual or potential) presented by a product being recalled or considered for recall. The regulations (21 CFR 7.41(a)) specify the factors to be considered, among others, by the Health Hazard Evaluation Committee in making the health hazard evaluation. The purpose of the health hazard evaluation, in general, is to identify and document:

1. the population at risk,
2. conditions that may exacerbate or attenuate the risk of its occurrence,
3. the risk associated with the product under conditions of use (as labeled),
4. and the likelihood of the risk occurring in the future.

The purpose of these guidelines is to assist the Committee in the identification and documentation of the various factors listed in 21 CFR 7.41(a) that are to be considered in making the health hazard evaluation and to determine what additional data and information should be collected and evaluated during the recall either to confirm or revise the health hazard evaluation. The questions listed below are not all inclusive nor are they relevant to all recall situations. They are intended to focus attention on factors related to the significance of health hazards likely to be associated with a product being recalled or considered for recall.

7.41(a)(1) - Whether any disease or injuries have already occurred from the use of the product.

1. What is the name of the product (trade and generic) and what are its indications for use, where applicable?
2. What deaths, diseases, injuries, or other adverse reactions have already occurred in association with use of the product?
3. What documentation is there to support the association of the deaths, diseases, injuries, or other adverse reactions with the use of the product?
4. Was the product used in conformance with its labeled directions for use? (The Health Hazard Evaluation Committee should review product labeling for sufficiency in light of injuries). If not, did the deaths, diseases, injuries, or other specific adverse reactions result from product misuse?
5. If the product was used according to its labeled directions, were the associated diseases, injuries, deaths, or other specific adverse reactions due to a) product malfunction, b) product formulation, c) product quality (including potency, contamination, etc.), d) product design, e) inadequate directions for use, or f) other known or unknown causes? Specify.

7.41(a)(2) - Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard.

Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

1. Name the specific clinical conditions (e.g., diabetes, heart problems, etc.) which, if they exist, might render a person or animal more susceptible to experiencing a health hazard on exposure to the product.

2. How would these clinical conditions contribute to or change the risk of exposure to the products?
3. Could these clinical conditions mask or otherwise disguise the risk of exposure to the product?
4. What other products being used to treat these clinical conditions could contribute to or, conversely, lessen the risk of exposure to the product?

7.41(a)(3) - Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

1. What is the universe of users by segment of population and what is the relative frequency of use of each, if known. For example, what percentage of the product is used by infants or children?
2. Which segment of the population exposed to the products is at greatest risk of health hazard? Others above risk for "normals?"
3. Are any of the following high-risk groups likely to be exposed to the product?
 - a. Infants
 - b. Children
 - c. Elderly
 - d. Pregnant Women
 - e. Surgical patients
 - f. Others (specify)
4. For each of the high-risk groups identified, what is the anticipated frequency of exposure to the product?
5. In what setting is the product generally used (e.g., hospital, home, etc.)?
6. How frequently is the product used (e.g., daily, weekly, etc.) and what is the duration of use (e.g., one time only, for a month, over a lifetime, etc.)?
7. What percentage of the population at greatest risk is now under close medical supervision? Could everyone in this population be easily brought under observation? In practice, would all users be brought under medical supervision if this is needed?
8. What actions or medical interventions could reasonably be expected to decrease the likelihood of occurrence of the health hazard? For example, could patient monitoring detect the product defect before it causes any untoward health consequences and could patient monitoring entirely prevent medical injury?

7.41(a)(4) Assessment of the degree of seriousness of the health hazard to which the population at risk would be exposed.

1. Are the health hazards likely to be acute (lasting several days to a few weeks) or chronic (lasting weeks to months)?
2. Describe the degree of seriousness of the health hazard if it did occur, and which specific segment of the population might be at risk? Express in terms of the following:
 - a. Life threatening - death could occur
 - b. Severe - permanent significant disability
 - c. Moderate - transient but significant disability; permanent minor disability
 - d. Limited - transient minor disability; annoying complaints
 - e. None - no disability or physical complaints anticipated

7.41(a)(5) - Assessment of the likelihood of occurrence of the hazard.

1. How frequently have deaths, diseases, injuries, or other adverse reactions already occurred? How does the frequency of occurrence relate to the total extent of product exposure (e.g., number of devices implanted, number of prescriptions, etc.). How has this frequency been documented?
2. If deaths, diseases, injuries, or other adverse reactions have not already occurred, estimate the likelihood of occurrence in each segment of the population at risk.

7.41(a)(6) - Assessment of the consequences (immediate or long range) of occurrence of the hazard.

1. What are the immediate consequences of the health hazard?
2. What are the long-range consequences of the health hazard?
3. If the product being recalled or considered for recall is used to treat a medical condition, are alternate forms of therapy available?

SUMMARY OF HEALTH HAZARD EVALUATION

On the basis of the answers to the questions listed above and any others that relate to the associated risk, state the likelihood of the health hazard occurring following exposure to the product being recalled or considered for recall and the likelihood of exposure to a defective product in all users of the product.

In addition, include in the recommendation specific data and information that should be collected, how and by whom these should be collected and evaluated, and how frequently the health hazard should be reevaluated.

Attachment E - Recalls Of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control Of Chapter V Of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly The Radiation Control For Health And Safety Act Of 1968 (RCHSA)

Recalls conducted under Subchapter C are different from recalls conducted under the Food, Drug, and Cosmetic Act in that Subchapter C has mandated recall provisions written into the Act (Sec. 535(a)). The law requires a manufacturer, when he learns that a product he manufactures is either defective or not in compliance with a published performance standard, to notify the Secretary of Health and Human Services (delegated to CDRH Director), and to notify the first purchaser (and known subsequent transferees) of the defect(s) or noncompliance(s). Subchapter C is specific as to the method of notification and procedure, and also contains "repair, replace or refund" provisions.

Differences may be encountered in dealing with recalls of radiation emitting versus non-radiation emitting medical devices. For medical devices, recall procedures for electrical and mechanical problems generally follow the pattern outlined in this chapter for general recalls. However, both medical and non-medical electronic products follow a different procedure when recalled under Subchapter C for radiation defects or deviations from a radiation safety standard. For example, consider a piece of diagnostic x-ray equipment that displays a mechanical problem not covered by Subchapter C (e.g., instability resulting in the unit falling over). The recall is conducted under the standard recall procedure of recommendation by the field, evaluation and classification by the Center and the usual recall notification, monitoring, and termination by the field. If that same equipment displays a radiation related defect or a noncompliance with the diagnostic x-ray standard (21 CFR 1020.30), the recall falls under Subchapter C, and follows the pattern outlined below: (Note: The Health Hazard Evaluation Committee does not review recalls involving noncompliance with a standard because the significance of the hazard was considered when the standard was introduced).

Recalls Conducted Under Subchapter C of the Act:**1. Center for Devices and Radiological Health (CDRH) Learns of Defect or Noncompliance**

A manufacturer who discovers a radiation related defect or noncompliance is required by Subchapter C to immediately notify CDRH and submit a proposed corrective action plan (CAP). CDRH may also learn of defects or noncompliance from various other sources including establishment inspection, results from FDA field and laboratory testing, and review of reports required to be submitted by the manufacturer. CDRH will inform the manufacturer in writing of the defect or noncompliance and request the firm to propose a CAP as required by Subchapter C. In some cases, special field testing may be necessary in order to define the precise defect or noncompliance. These tests will be arranged by CDRH.

2. Opportunity to Refute Declaration or to Request Exemption from Notification Requirements

As provided by Subchapter C, a manufacturer has the opportunity to refute a defect or

noncompliance declaration (Section 535(a)(2)). The manufacturer is usually given 14 days to refute the Center's declaration or to request exemption from notification based on evidence that the defect or noncompliance is not such as to create a significant risk of injury, including genetic injury, to any person. The burden of proof lies with the manufacturer. If the refutation is accepted, or if the exemption is granted, the manufacturer is then exempt from the notification requirements and is relieved of responsibility to "repair, replace or refund."

3. Proposal of Corrective Action Plan by Manufacturer

If no request for exemption has been filed or if the exemption request was denied, the manufacturer must then submit proposals to CDRH for user notification and correction of defective or noncompliant product(s). The notification to users is required to be by certified mail to the first purchaser (or subsequent transferees, if known) and must be mailed within 14 days after CDRH approval. CDRH requires that return receipts be maintained for recall audit purposes. Manufacturers are also required to provide CDRH with copies of all notices, bulletins, and other communications to dealers, distributors, purchasers, or other transferees which they have issued as required by Section 535(d). These notifications to users are required to contain instructions for interim safe operation of the product until such time as corrections can be made.

4. Correction Action Plan (CAP) Review

Upon receipt of the manufacturer's proposed CAP, the Center will review that document for thoroughness and technical accuracy. The following are elements of a typical approved CAP:

- a. Product description (including all model and serial numbers used) and the total number of units of this product that are involved.
- b. Consignee list (foreign and domestic).
- c. Description of the defect (including all reports, documents, memos, etc., of meetings, technical reviews, etc., which pertain to the analysis of the problem and the development of a "fix").
- d. Proposed steps to be taken to correct the product in the field and steps taken to prevent future occurrences.
- e. Proposed effectiveness checks to be conducted.
- f. Proposed date of completion and appropriate interim dates for design, fabrication, and implementation of the correction.
- g. Any and all injury/death investigations or reports.
- h. Pertinent complaints on file.

Some additional requirements may be included in a CAP if necessary. For example, a CAP may require that the recalling firm obtain a signed statement from their purchaser stating that corrections have been made or it may require that copies of service or work orders be held for FDA review.

In the event that the proposal is insufficient, the Center will request the additional data needed. When sufficient information has been submitted to the Center for review, the plan is evaluated and approved if it appears to be adequate.

5. Mechanics of Conducting Recall

CDRH will assign a recall number and issue a classification memo to the district and the Press Office (HFC-21) when the corrective action plan (CAP) and an approval letter is signed and issued to the recalling firm. CDRH will send copies of the CAP approval letter, the corrective action plan and the letter of non-compliance with the classification memo. The home district will then promptly obtain from the firm by phone or a visit any other information required for the Enforcement Report and the Initial Recall Notification message to the field. This will not affect the way the district processes recalls for X-ray assemblers and suntan lamp recalls. The home district office will still continue to submit a Recommendation for Recall for cases generated in the field. The districts will approve the corrective action plans for these cases, and submit a copy of the district approval letter with the Recommendation for Recall to CDRH for issuance of a recall number.

The timeliness of audit check issuance will depend on the progress of the CAP and may be determined by recall status reports received from the firm. Audit checks should issue when the recall is approximately 25% complete and continue throughout the completion of the recall. At the point when the recalling firm indicates by way of their status reports to the district that they have completed the recall action at 25% of their consignees, the field will issue a request for a portion of the required audit checks to affected districts. Upon receipt of the completed audit check reports from the districts, the home district Recall Coordinator will evaluate the audit checks to determine if the recall is effectively on-going. If apparently effective, the balance of the audit checks need not be requested until the recall is complete, or nearly so. Center consultation is available, if needed, in determining the effectiveness of the recall at the 25% complete mark.

The recalling firm must, in its CAP, provide a target date for completing the recall. The time span is typically six months to one year. If the firm does not or is not likely to complete the recall within the specified time, a Warning Letter should be issued to the firm. The firm may request a time extension to complete the recall. All such requests must be approved by CDRH.

If a request for extension is denied, the home district will send the firm a warning letter when the target completion date expires.

The home district will document unsatisfactory results of a CAP and/or other violations of Subchapter C by inspection and field testing. Bimonthly recall status reports will be sent to the Center recall unit and OE/DCMO by the home district.

At the conclusion of the recall, the home district will conduct a termination ("close-out") inspection at the recalling firm, terminate the recall appropriately according to classification, and prepare a recall termination letter to the firm. (See Exhibit 7-9).

6. Time Frames

The timeframes associated with electronic products recalls are considerably different than for general FD&C recalls. At the time the Center identifies a problem, the manufacturer is often unaware that any problem exists. Opportunity is provided to the manufacturer to examine and

possibly refute the Agency's evidence, or to request exemption, or to locate all products and to formulate a CAP. The time between declaration of noncompliance and CDRH approval of the CAP varies widely depending upon the product, the nature of the problem, and the thoroughness of the proposed correction.

Attachment F – Recalls of Infant Formula

Due to the susceptible nature of the population affected by infant formulas, the recall of a violative infant formula is to receive the highest agency priority.

Normally, within five calendar days, infant formula manufacturers' notifications submitted to FDA in compliance with the Infant Formula Act will be evaluated by the Center, action memorandum prepared, and the recall approved by the ACRA.

Other than the above timeframe, recalls of infant formulas are to be handled under the same procedures as other recalls with two important additions:

1. Section 412(f)(3) of the Act requires that the manufacturer post written notice of the recall of an infant formula at each retail establishment where the infant formula is sold. The content of such notices should be reviewed by the Agency prior to the posting, and the duration of posting should be part of the firm's recall strategy with agency concurrence. Audit checks should verify adequate posting.
2. Section 412(f)(1) of the Act requires that the manufacturer submit a report on the recall not later than 14 days after the initiation of the recall and at least every 14 days thereafter until the recall is terminated. The Agency is to review these reports at least once every 15 days.

Attachment G – Recalls of Medical Devices, Section 518(e)

Guidance Regarding Mandatory Recalls under Section 518(e) of the Federal Food, Drug and Cosmetic Act.

BACKGROUND

On November 28, 1990, the President signed into law the Safe Medical Devices Act (SMDA), which was intended to improve the Medical Device Amendments of 1976. The new law includes provisions designed to expand and strengthen FDA's authority to ensure that devices entering the market are safe and effective. The SMDA, by streamlining procedures and augmenting FDA's authority, refines premarket controls and adds postmarketing controls relating to medical devices introduced into interstate commerce.

One of these provisions is section 518(e), the so-called mandatory recall authority. Actually, section 518(e) requires a two step process involving an order to a firm to immediately cease distribution of a defective device and notify users to cease using it; and either vacating the order, or amending the order to require the product's recall. In the first step, if FDA finds there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA shall order the manufacturer, importer, distributor, retailer, or any appropriate person to immediately cease distribution of the device and to immediately notify health professionals and device user facilities of FDA's order, and to instruct such professionals and facilities to cease use of the device.

"Reasonable probability" means that it is more likely than not that an event will occur. "Serious adverse health consequence" means any significant adverse consequence, including those which may be either life-threatening or involve permanent or long-term injury, but excluding non-life-threatening injuries that are temporary and reasonably reversible. Injuries attributable to a device that are treatable and reversible by standard medical techniques, proximate in time to the injury, meet this latter definition.

After giving the party subject to the order in step 1, an opportunity for an informal hearing, FDA shall either vacate the order or amend it to include a recall of the device. The opportunity for an informal hearing is contained in the order in step 1. The hearing must be held not later than 10 days after the date of issuance of the order, in accordance with the procedures set out in section 201(y) of the Act and 21 CFR Part 16. Failure to request a hearing will generally result in an amended order requiring recall. The party subject to the order may also request, by written submission, review of an order without an informal hearing.

PROCEDURES:

These procedures are final publication of regulations implementing section 518(e).

Actions under section 518(e) may be initiated by the Center or recommended by the field. Factors to be considered when deciding to recommend a 518(e) recommendation are:

1. Does the hazard meet the criteria for a Class I recall situation, i.e., there is a strong likelihood that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death?

2. Are other administrative or enforcement actions more appropriate to address the problem? Seizure or detention may be a lesser agency burden and may address the health risk situation more effectively.
3. GMP issues alone will not support the contention that use of the device will cause serious adverse health consequences.

If the district office believes this threshold has been met, a recommendation should be submitted to OC, HFZ-300. Before the district submits a 518(e) recommendation, the firm should be fully apprised of our concern and have been given an opportunity to initiate corrective action.

The 518(e) recommendation should be in an organized Recall Recommendation format, and be flagged, "Recommendation for 518(e) Action". It should include the following:

1. The product labeling, and product advertising and/or newsletters to consumers, if pertinent.
2. The basis for determining that 518(e) criteria have been met, such as:
 - a. Any sample analysis that documents that the device does, or may, present a serious health hazard.
 - b. Any testing done which substantiates device failure, e.g., firm's in-house and/or FDA testing, independent studies, etc.
 - c. The number of known injuries and/or deaths as documented in the firm's files. Complete documentation of those events should be provided to support the 518(e) criteria. The firm's complaint, litigation and service files are valuable in obtaining this information.
 - d. A summary of complaints and description of those complaints such as 20 complaints of electrical shortage, 15 complaints of shock, 13 complaints due to over-infusion, 30 complaints of under-infusion. To say that there are 300 complaints may indicate a problem, but does not necessarily indicate a serious health issue. Provide copies of significant or representative medical device complaints or service records, if available, and any significant correspondence with customers.
 - e. The EIR, if inspectional findings support the problem, especially if testing is inadequate.
 - f. Any pertinent manufacturing or recall history.
 - g. Date of the last visit to the firm, the reason for the visit, and any subsequent correspondence or communications. Is a limited update inspection needed or some other mechanism available to determine whether the hazard condition still exists? Be clear on the firm's regulatory history, conditions of approval of the device, etc., so the firm will not later argue that it did not have advance notice of the problems. It presents problems in demonstrating the case as a serious health risk if the case review has taken months.
 - h. Any other pertinent information to document that the device presents a hazard consistent with 518(e) criteria.
3. Because a hearing may take place quickly, include one extra copy of ALL information for the Office of Chief Counsel (OCC). All written materials which FDA will rely on for support at the hearing (for example, the EIR) must be turned over to the opposing side at least one day before the informal hearing.

Do not delay other regulatory actions (e.g., seizure) pending the 518(e) review. In addition, do not stop collecting data, as the issue can still potentially result in a trial, seizure, Congressional hearing, etc.

OC will convene a Health Hazard Evaluation Committee (HHE) to evaluate the information in the recommendation. If the HHE concludes that a 518(e) action is warranted, OC, with Chief Counsel concurrence, will prepare the order for signature of the Director, OC. The order will be faxed to the firm and the district. If the firm cannot receive facsimile transmissions, the order will be hand delivered by the district. In either situation, the district should seek an immediate determination from the firm as to its actions. If the order is not complied with, any product encountered should be administratively detained in accordance with the instructions in RPM Chapter 5, Section 5-4, "Administrative Detention of Devices", and appropriate regulations found in 21 CFR 800.55.

The firm is to provide periodic status reports to the district. The frequency of such reports will be specified in the order. Communications developed by the firm to implement the order must be submitted to CDRH for review and approval prior to distribution. The Center will work with the district and firm so that users comply with the order in a medically safe manner. The firm may need to immediately replace defective devices with equivalent devices, including those of a competitor. The Center will review all "emergency" or "urgent need" requests to permit continued use of the device on a case-by-case basis. We have found that there may be unique medical conditions for which there is no alternative to the device subject to the order. In those cases, we have permitted continued use of the device provided certain safety precautions are followed.

INFORMAL HEARING

The person receiving the order may, within the timeframe specified in the order, submit a written request to FDA for a regulatory hearing. The request must be addressed to the agency employee identified in the order. Ordinarily, FDA will require that the person named in the order submit the hearing request within 3 days of receipt of the order. When necessary, however, FDA may require that the hearing request be submitted in less than 3 days.

The informal hearing will be conducted as a regulatory hearing under 21 CFR Part 16. Following the hearing, the Hearing Officer will issue a decision to vacate the original "cease and desist" order, modify such order, or amend the order to require recall of the product. An ordered recall should begin on the date of the amended order to recall and, generally, should be at mid-stage in six weeks, and completed no later than three months from the recall's initiation.

The Office of Compliance (OC), CDRH, will make arrangements for the informal hearing including a conference room and stenographer. The hearing will be held in the Washington area. The Center will identify a hearing officer. The hearing will be held not later than 10 days after issuance of the order, unless both the person named in the order and FDA agrees that the hearing will be held at a later date. Such an agreement is unlikely because of the hazard presented by the device.

As soon as OC determines that a 518(e) action is appropriate, the field fact witnesses should

immediately prepare for possible testimony in anticipation of the informal hearing. Each should prepare a narrative memo of findings of facts pertaining to the device, i.e., inspectional findings, analytical findings, etc. The Office of Chief Counsel will need the narrative memo three (3) days before the hearing, and will follow-up with a telephone call to the CSO involved.

The Center will also be gathering documentary support and locating expert witnesses to testify at the hearing. Expert identification and preparation is a difficult and time-consuming process.

The field office should be alert to potential experts and provide their names to CDRH. A pre-meeting of FDA participants and CC will be held 1-2 days prior to the informal hearing, to discuss the issues and prepare our strategy for the hearing.

If a hearing is to be public, it will be announced on the public calendar. If FDA wants the hearing to be closed to the public, it must state one of the reasons contained in 21 CFR 16.60.

If the company wants the hearing to be closed to the public, the company must state its reason under 21 CFR 16.60 in its request for a hearing. The Hearing Officer will make the final determination as to whether a hearing is to be open to the public or closed.

If the person named in the order does not request a hearing within the timeframe specified in the order, the right to a hearing will be deemed waived. In such cases, FDA is free to amend the order to require a recall as it deems appropriate.

The person named in an order may, in lieu of requesting a hearing, submit a written request to FDA asking that the order be modified or vacated. The written request must be addressed to the agency employee identified in the order and must be submitted within the timeframe specified in the order. The agency official who issued the cease distribution and notification order will provide the requestor written notification of the agency decision to affirm, modify, or vacate the order within a reasonable time after completing the review of the request.

If the person named in a cease distribution and notification order does not request a regulatory hearing or submit a request for agency review of the order, or if after conducting a regulatory hearing or completing agency review of a cease distribution and notification order, FDA determines that the order should be amended to include a mandatory recall of the device with respect to which the order was issued, FDA will amend the order. The amended order will contain the requirements of the mandatory recall and the form of patient notification, if required.

The statute does not permit FDA to require the recall of devices in the possession of patients or individuals. However, FDA may require the firm to notify patients, if necessary. Patient notification should be used only where the device is in a home health care setting and notification to doctors would not be sufficient. Patient notification should be evaluated on a case-by-case basis, depending on the type of product being recalled. If a significant number of individuals at risk cannot be identified, FDA may use any technique at its disposal to notify such individuals, i.e., publicity section 705(b) of the Act.

Similarly, an amended order cannot include recall of a device from user facilities if FDA determines that the risk of recalling it from the facilities presents a greater health risk than the health risk of not recalling the device, unless the device can be replaced with an equivalent device by the recalling firm (including a competitor's product equivalent to the device).

Attachment H –Methods for Conducting Recall Effectiveness Checks

INTRODUCTION

In the Federal Register of June 16, 1978, (43FR26202), The Food and Drug Administration (FDA) issued as a final rule, Recalls (Including Product Corrections) - - Guidelines on Policy, Procedures, and Industry Responsibilities. Section 7.42 of these guidelines states that the recalling firm will ordinarily be responsible for conducting recall effectiveness checks. Such checks are for the purpose of verifying that the recalling firm's consignees have received notification about the recall and have taken appropriate action.

To assist the recalling firm in carrying out this responsibility and in accordance with section 7.42(b)(3) of the FDA recall guidelines, the following may be used as a guide on how to use different methods for conducting recall effectiveness checks. The methods described include mail, telephone calls, personal visits, and combinations of these alternatives.

METHODS

1. General

All the methods for conducting effectiveness checks have several common aspects: a consignee list, a common identifier, a questionnaire, and a procedure for recording responses.

A consignee list is to be prepared when a recall is initiated by a firm. Each of the consignees notified of the recall is a candidate for a recall effectiveness check. However, if there is suitable documentation that a consignee has been notified and has either made the proper disposition of the recalled product or has submitted a negative report on having the product, it may not be necessary to perform a recall effectiveness check at the consignee.

In order to facilitate the correlation of responses from consignees, each consignee could be assigned a unique number which would serve as an identifier. The consignee's zip code could be used as part of the number. The identifier would be put on any return mail card and provided on any telephone or personal visit list used for effectiveness checks. The number would provide easy match with the consignee list and the reconciliation of the consignee contacts and recall effectiveness.

Reconciliation of the effectiveness checks may be handled in numerous ways. It may be by computer or by a system as simple as preparing pressure sensitive labels for each consignee which contain the name, address, and identifying number assigned to that consignee. The number of labels required for each consignee will vary according to the recall method used, i.e. five labels for mailings (if two mailings are used), and two labels for telephone calls and personal visits. For all methods, one of the labels is to be placed on a 3 X 5 card to be used as the control. The second label is to be used for the consignee questionnaire.

As a questionnaire is returned and/or completed, it is placed with the control file card for the consignee for "logging in" purposes.

2. Mail

There are four elements to the use of mail:

- a. a letter to the consignee,
- b. an envelope prominently inscribed with “IMPORTANT RECALL INFORMATION INSIDE”,
- c. a questionnaire, and
- d. a self-addressed, stamped envelope for the consignee to return the completed questionnaire.

The letter to the consignee should state exactly state the reason for the recall, a complete description of the product being recalled or corrected, instructions regarding the disposition of the recalled product, and a request for cooperation in completing and returning the questionnaire. Exhibit 7-1 provides an example of the type letter that can be used. Exhibit 7-2 provides an example of the questionnaire to accompany the effectiveness check letter. It should be noted that the exhibit questionnaires are only examples and that actual circumstances may necessitate changes in the questionnaire wording. Some pretesting of the questionnaire prior to mass mailing is suggested.

In conducting a recall effectiveness check, there are certain basic questions that need to be asked. The purpose of these questions is to determine whether: the recall notification was received; the product involved was handled as instructed in the recall notification; the product was further distributed by the consignee before receipt of the recall notification; and, if so, were the additional consignees notified. Other questions may need to be asked depending upon the nature of the recall. Also, the design and format of the questionnaire may vary depending upon the method of contact to be used.

Exhibit 7-1
MODEL EFFECTIVENESS CHECK LETTER (INDUSTRY)Consignee
Name and Address

Date

(Pressure Sensitive
Label)

Dear Sir:

On (date), you were notified by letter that John Doe Company, Someplace, Somewhere 12345, is recalling (product name), container size, code number. All products were manufactured by John Doe Company and distributed solely under the manufacturer's label.

Recall of the product was initiated following a change in their formulation which resulted in products in distribution channels having the same brand name but different ingredients. The old formulation contained X and there is concern that consumers may receive the old formula. Use of the old formulation by some consumers represents a potential health hazard.

The recall notice from John Doe Company requested consignees (wholesalers and retailers) to discontinue selling their existing stock of the old formulations and return existing inventories of the recalled formulations to John Doe Company.

In order to advise the Food and Drug Administration about the effectiveness of this John Doe Company recall, you are requested to complete and return the enclosed questionnaire promptly using the prepaid self-addressed envelope.

If you have any questions or problems with this request, please call (name and telephone number).

Thank you for your cooperation.

Sincerely,

NOTE: If this letter is sent to distributors who may have further sold the product to other distributors or to retail outlets, the third paragraph should include the fact that the recall notice requested the direct consignees to conduct sub-recalls by notifying their customers of the recall situation.

Exhibit 7-2**MODEL EFFECTIVENESS CHECK RESPONSE FORMAT (INDUSTRY)**

Consignee Name and Address
(Pressure Sensitive Label)

Recall Effectiveness
Checks-Mail Method

JOHN DOE PRODUCT RECALL

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

DATE _____

1. Did your firm receive notification that the John Doe Company is recalling its _____ (Name) _____ product?

YES _____ NO _____

2. Did your firm receive shipments of the product being recalled?
(If no, please sign and return).

YES _____ NO _____

3. Do you now have any of the recalled product on hand? (Please check inventories before answering).

YES _____ NO _____

4. If the answer to question 3 is YES, do you intend to return the product to the John Doe Company as requested?

YES _____ NO _____

5. If the answer to question 4 is NO, please explain your intentions

6. Have you received any reports of illness or injury related to this product?

YES _____ NO _____
If yes, please provide details.

Name of person completing questionnaire:

Exhibit 7-3**MODEL EFFECTIVENESS CHECK QUESTIONNAIRE FOR TELEPHONE OR PERSONAL VISITS (INDUSTRY)**

Consignee Name and Address
(Pressure Sensitive Label)

JOHN DOE PRODUCT RECALL

After contacting the consignee and locating the person responsible for handling recall notifications and/or the product involved, an opening similar to the following may be used.

This is (Name of Interviewer). I am calling for (recalling firm) to check on the effectiveness of the company recall of (product description, including codes). On (date), (recalling firm) notified (how: letter, telephone, visit, mailgram, etc.), all firms which may have purchased (product) that all stock should be (returned, destroyed, modified, relabeled, etc.). I have the following questions to ask you about this recall:

DATE _____

1. Did your firm receive notification that (product name) products manufactured by John Doe Company are being recalled?

YES _____ NO _____

2. Did your firm receive shipments of the product being recalled? (If no, terminate questioning and go to the closing).

YES _____ NO _____

3. Do you have any of the recalled product on hand? (Please check inventories before answering).

YES _____ NO _____

4. If the answer to question 3 is YES, do you intend to return the product to the John Doe Company as requested?

YES _____ NO _____

5. If the answer to question 4 is NO, please explain your intentions

6. Have you received any reports of illness or injury related to this product?

YES _____ NO _____

If yes, please provide details.

Thank you for your cooperation.

And your name is _____

And what is your title please? _____

Interviewer _____

Date _____

IF RESPONDENT HAS ANY FURTHER QUESTIONS, ASK HIM/HER TO CONTACT THE
JOHN DOE COMPANY, SOMEPLACE, SOMEWHERE 12345

Exhibit 7-4
MODEL RECALL LETTER (GENERIC, ALL CENTERS)

<COMPANY LETTERHEAD>

URGENT: < *Insert FOOD, DRUG, MEDICAL DEVICE, BIOLOGIC, COSMETIC, etc.*> **RECALL**

<DATE>

<Contact name or Dept.>

<Firm Name>

<Address>

<City/state/zip>

Dear < >:

This is to inform you of a product recall involving:

<Insert: PRODUCT NAME, BRAND NAME, DESCRIPTION, UPC CODES, LOT NUMBERS>

See enclosed product label <for ease in identifying the product at retail/user level>.

This recall has been initiated due to <problem>. Use of <or consumption of> this product may <include any potential health hazard>.

We began shipping this product on <date> (or) This product was shipped to you on <date>. (If possible, provide consignee with shipping dates and quantities shipped.)

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter, or <Enclosed is a letter you should use in notifying your customers>.

[Your notification must include instructions on what customers should do with the recalled product.]

This recall should be carried out to the <wholesale>, <retail>, <consumer>, <user> level. Your assistance is appreciated and necessary to prevent <i.e. consumer illness or patient harm>.

Please complete and return the enclosed response form as soon as possible. If you have any questions, call <name and telephone number>.

This recall is being made with the knowledge of the Food and Drug Administration.

Enclosure(s)	Name Title
--------------	---------------

**Exhibit 7-5
MODEL RECALL RETURN RESPONSE FORM**

<COMPANY LETTERHEAD>

<insert product>
<insert lot numbers>

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the <date> letter.
- I have checked my stock and have quarantined inventory consisting of _____ <units or cases>.
- Indicate disposition of recalled product:
- returned (**specify quantity, date and method**)/held for return;
 - destroyed (**specify quantity, date and method**);
 - relabeled (**specify quantity and date**);
 - quarantined pending correction (**specify quantity**);
 - transfused – Blood or blood products (**specify date and quantity**);
 - implanted (**specify date and quantity**)
- I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**); <or>

Attached is a list of customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product? Yes NO

If yes, please explain: _____

Please check the appropriate box(es) to describe your business

- | | |
|---|--|
| <input type="checkbox"/> wholesaler/distributor | <input type="checkbox"/> retailer |
| <input type="checkbox"/> grocery corporate headquarters | <input type="checkbox"/> food service/restaurant |
| <input type="checkbox"/> repacker | |
| <input type="checkbox"/> manufacturer | |
| <input type="checkbox"/> pharmacy - retail | <input type="checkbox"/> hospital/medical facility |
| <input type="checkbox"/> hospital pharmacies | <input type="checkbox"/> medical laboratory |
| <input type="checkbox"/> Other: _____ | |

Name: _____
Title: _____
Tel. number: () _____

Firm name: _____
address: _____
city/state: _____

PLEASE FAX COMPLETED RESPONSE FORM TO Tel. # < >, ATTN: < >

OR MAIL TO: FIRM NAME AND ADDRESS

NOTE: This MODEL is intended to serve as guidance for recalling firms. It may not conform to your firm's recall strategy. Please make any appropriate modifications to the response form. **IT IS ADVISABLE TO SUBMIT THE PROPOSED RECALL LETTER AND RESPONSE FORM TO YOUR LOCAL FDA RECALL COORDINATOR FOR REVIEW, PRIOR TO ISSUANCE.**

Exhibit 7-6
MODEL RECALL ENVELOPE

FIRST CLASS MAIL

JOHN DOE
Somewhere, U.S.A. 12345

A. B. C. Pharmacy
Anywhere, U. S. A.

(red print) **URGENT: DRUG RECALL**

Exhibit 7-7**MODEL NOTIFICATION OF CLASSIFICATION LETTER (FDA TO RECALLING FIRM)**

Mr. John Doe, President
J. D. Laboratories, Inc.
Somewhere, U. S. A.

Re: Recall No. D-000-9

Dear Mr. Doe:

We agree with your firm's decision to recall (Product), Code Nos. _____
due to (Reason for Recall).

We have reviewed your action and conclude that it meets the formal definition of a "Recall." This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove your defective product from the market. This recall will be reported in an upcoming issue of the weekly FDA Enforcement Report.

It is suggested that you follow the FDA's "Enforcement Policy-Recalls (including Product Corrections) -- Guidelines on Policy, Procedures and Industry Responsibilities" issued June 16, 1978 in conducting your recall. Enclosed is a copy of this Enforcement Policy as well as a copy of the FDA's "Methods for Conducting Recall Effectiveness Checks."

This recall has been classified by the FDA as a Class ____ recall. This means (Insert Definition).

Our evaluation indicates that this recall should be conducted to the (Consumer or User, Retail, Wholesale, etc.) level and that level ____ effectiveness checks should be conducted by your firm. Level _____ effectiveness checks are (Definition).

In addition to your recall efforts, it is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped.

Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse. We, therefore, urge you to immediately begin making plans to destroy the product or recondition it to bring it into compliance with the law.

Either method should be done under the supervision of an investigator from this office.

(Note: The paragraph above may be modified to reflect concern about appropriate disposition of toxic materials.)

We request that you advise us within ten days of the steps you have taken or will take to ensure that the recalled merchandise is properly inventoried and maintained to prevent unintended use or shipment, and provide your proposed method of disposition of the returned goods.

In addition, we request that you submit to our (City) District office a recall status report at (Monthly or Bi-Weekly) intervals. These recall status reports should contain the following information:

- (1) Number of consignees notified of the recall, and date and method of notification
- (2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received
- (3) Number of consignees that did not respond
- (4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for
- (5) Number and results of effectiveness checks that were made
- (6) Estimated time frames for completion of the recall

These periodic status reports should be addressed to:
(The district will determine who receives the firm's responses.)

Our judgement regarding the effectiveness of your recall will largely be based upon your implementation of the enclosed recall guidelines. Please be advised that failure to conduct an effective recall could result in seizure of the violative product or other legal sanctions under the Federal Food, Drug, and Cosmetic Act (in other acts as appropriate).

Your response to this letter should be addressed to: (District Director).
Your cooperation in this matter is obviously important for the protection of the general public.

Sincerely yours,

District Director
_____ District

Enclosures

Exhibit 7-8
MODEL INEFFECTIVE RECALL LETTER

Mr. John Doe, President
J. D. Laboratories, Inc.
Somewhere, U.S.A.

Dear Mr. Doe:

This confirms our telephone conversation/visit with you that our audit of your firm's class _____ recall of (Product) indicates that the recall is ineffective at the (Distributor, Wholesale, Retail, etc.) level. This determination is based on the fact that: (detail all audit findings, for example):

1. Review of your submitted recall status reports found that (number and type of consignees) have not responded to your recall communication.
2. Review of documentation at your firm found that sub-recall was not initiated by (number) wholesale distributors.
3. Audit checks conducted by FDA found that ...

It is therefore reasonable to assume that the defective product could still be in the hands of these consignees.

It is requested that you advise us in (*) days of the steps you plan to take to rectify this situation.

(*) Two days for class I
Five days for class II
Ten days for class III

Sincerely,

District Director
_____ District

Exhibit 7-9**MODEL RECALL TERMINATION LETTER**

Mr. John Doe, President
J. D. Laboratories, Inc.
Somewhere, U.S.A.

Dear Mr. Doe:

The Food and Drug Administration has completed the audit of your firm's actions concerning the recall of (Product), (Code Number)(s), (Recall No.)(s). We conclude that the recall has been completed and there has been proper disposition of the recalled articles. Therefore, FDA considers the recall terminated.

This letter is not intended to imply that the FDA will not recommend civil or criminal legal action related to this matter. It does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate) in the future.

Sincerely,

District Director
_____ District

Exhibit 7-10**MODEL COMBINED RECALL NOTIFICATION OF CLASSIFICATION AND TERMINATION LETTER**

Re: Recall No. Z-000-5

Mr. John Doe
President
John Doe Enterprises, Inc.
4321 Enterprise Lane
Johnsontown, New York 12345-6789

Dear Mr. Doe:

This is to advise you that the Food and Drug Administration (FDA) agrees with your decision to (retrieve from the market to the retail, user, hospital, consumer, etc. level, or conduct a field correction of) (product), lot/code numbers due to (reason for action taken).

We have reviewed your action and conclude that it meets the FDA definition of a Class (I, II, or III) recall. This is a situation in which (quote appropriate classification definition from section 7.3(m) of Title 21 CFR). This recall has been posted on the FDA's recall web site. (When appropriate, a statement on the Center's suggested effectiveness check level and the firm's satisfactory completion of same may be added at this point.)

Information provided to FDA indicates that (the recall has been completed and there has been proper disposition of the recalled product, or your corrective action has been completed). Therefore, FDA considers the recall terminated.

This letter is not intended to imply that the FDA will not recommend civil or criminal legal action related to this matter. It does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate) in the future.

Sincerely,

District Director
_____ District

Exhibit 7-11
REQUEST FOR AUDIT CHECK FORMAT

Flag: "REQUEST FOR AUDIT CHECK - CLASS I, II, or III,
LEVEL A, B, C, or D"

Include the following Information:

1. Recall number
2. Description of product being recalled including model numbers
3. Codes: lot, or serial number(s)
4. Recalling firm/manufacturer
5. Reason for recall
6. Number, level, and type of audit checks to be conducted
7. Direct consignees, whenever possible
8. FEI# of recalling firm

Furnish the consignee district a copy of the firm's recall communication or quote appropriate portions of it so that the person performing the check can determine if the consignee has complied with the recalling firm's directions. When possible, include the name, title, and department to whom the recall communication was directed.

List any additional data required but not entirely included on the audit check report form. Provide any specific reporting instructions.

Exhibit 7-12**AUDIT CHECK REPORT INSTRUCTIONS/EXPLANATION BY SECTION**

NOTE: COMPLETE ONE FORM PER AUDIT CHECK; HOWEVER, PROGRAM DATA MAY COVER NUMEROUS AUDIT CHECKS.

1. Recall Information:
 - a. Recall Number - Enter the recall number assigned by the Center. If more than one number is involved, enter the lead number.
 - b. Recalling Establishment - Provide the name and address of the firm responsible for issuing the recall notification.
 - c. Recalled Codes - Provide the lot, batch, or serial number under recall.
 - d. Product - Provide the name of the product under recall. If numerous products are involved, use generic term, e.g., ice cream, dried fruit, etc.
2. Program Data:

Completion of Section 2 is required only if the credit sheet is to be used for program data reporting. Form FDA 2123 may also be used for reporting audit check data. If time is reported on either a FDA 2123 or another FDA 3177, check the box and do not complete Section 2.

 - a. Accomplishing District - Enter the code for the district conducting the audit check.
 - b. Home District - Enter the code for the home district of the recalling establishment listed in 1b.
 - c. Operation Code for Audit Checks - Operation 17, has been pre-printed.
 - d. Operation Date - Provide the date the audit check was conducted. When multiple checks are reported, use the date of the last audit.
 - e. Central File Number or FEI- Provide the CFN or FEI for the recalling establishment listed in Block 1b.
 - f. PAC Code - Enter appropriate PAC code.
 - g. Employee - Self-explanatory.
 - h. Provide a breakdown of the number of visits and phone audits conducted. Time for each type of check should be listed under the Hours column.
3. Audit Accounts: The form has been designed so that it may be used at the tertiary level of distribution, that is, as far down the distribution chain as consignees of secondary distributors.
4. Consignee Data: "Consignee" is the account at which the check is being conducted. Data requested is self explanatory.
5. Notification Data: Fill in appropriate blocks. Did consignee receive a specific written, verbal, or personal contact providing recall notification; from whom and when was notice received?
6. Action and Status Data: Self-explanatory
7. Sub-Recall Needed: Describe firm's sub-recall procedures in Block 10 or give reason for not conducting sub-recall. If firm has refused to sub-recall properly without justification, include district follow-up in Block 10 or separate memo.
8. Self-explanatory.
9. Self-explanatory.
10. Remarks: Provide all information not covered in 1-9 which aids in the evaluation of

recall effectiveness at this consignee.

The Recall Audit Check Report is to be signed by the individual conducting the check as well as the individual endorsing the report to the monitoring district.

Exhibit 7-12A
AUDIT CHECK REPORT

1. RECALL INFORMATION
 - a. RECALL NUMBER
 - b. RECALLING ESTABLISHMENT
 - c. RECALLED CODE(S)
 - d. PRODUCT

2. PROGRAM DATA (CHECK BOX IF PREVIOUSLY SUBMITTED) (DO NOT COMPLETE IF REPORTED UNDER FDA 2123)
 - a. ACCOMP DISTRICT CODE
 - b. HOME DISTRICT CODE
 - c. OPERATION CODE - 17
 - d. OPERATION DATE - MO DA YR
 - e. CENTRAL FILE NUMBER OF RECALLING ESTABLISHMENT
 - f. PAC CODE
 - g. EMPLOYEE - HOME DIST. POS. CLASS NUMBER
 - h. TYPE - VISITS/PHONE
OF CHECKS HOURS

3. AUDIT ACCOUNTS
 - a. DIRECT
PHONE NO _____
 - b. SUB-ACCOUNT (SECONDARY)
PHONE NO _____
 - c. SUB-ACCOUNT (TERTIARY)
PHONE NO _____

4. CONSIGNEE DATA Contacted by: Phone Visit Other
 - a. NAME OF PERSON CONTACTED, TITLE, & DATE
 - b. TYPE CONSIGNEE
 Wholesaler Physician
 Retailer Hospital Other
 Processor Pharmacy _____
 Consumer Restaurant
 - c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT?
 YES NO

5. NOTIFICATION DATA
 - a. FORMAL RECALL NOTICE RECEIVED?
(IF "NO" SKIP TO ITEM 6c)
 YES NO CANNOT BE DETERMINED
 - b. RECALL NOTIFICATION RECEIVED FROM:
 Recalling Firm
 Direct Account
 Sub-Account
 Other (Specify) _____

- c. DATE NOTIFIED
- d. TYPE OF NOTICE RECEIVED (e.g. letter, phone)

6. ACTION AND STATUS DATA

- a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? (IF "NO", DISCUSS IN ITEM 10, ACTION TAKEN UPON FDA CONTACT) YES NO
- b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION
- c. CURRENT STATUS OF RECALLED ITEMS
 - Returned Destroyed
 - Corrected None on Hand
 - Was Still Held For Sale/Use(*)
 - Held For Return/Correction(*)
- (*) = Ensure Proper Quarantine/Action
- d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED?

- Did Consignee Distribute to any other Accounts?
- (If "Yes give Details in "Remarks" or Memo) YES NO

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND.

9. INJURIES/COMPLAINTS

- IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?
- INJURY COMPLAINT
- ILLNESS NONE
- IF ANSWER IS OTHER THAN "NONE" REPORT DETAILS IN A SEPARATE MEMO TO MONITORING DISTRICT AND COPY TO OE/DCMO (HFC-210)

10. REMARKS (INCLUDE ACTION TAKEN IF PRODUCT WAS STILL AVAILABLE FOR SALE OR USE)

TO: _____ DATE: _____

ENDORSEMENT: _____

SIGNATURE OF SCSO OR RECALL
COORDINATOR: _____

SIGNATURE OF CSO/CSI: _____

DISTRICT:

DATE OF CHECK:

Exhibit 7-13**WEEKLY CLASS I RECALL STATUS REPORT (OPTIONAL)**

Districts monitoring certain Class I certain recalls may be requested to submit a weekly status report by either the CRU or OE/DCMO. (Weekly status reports may also be required for certain Class II recalls per the audit program.) When reports are requested, they should be prepared and submitted by close-of-business each Friday.

Data to be submitted may vary depending upon individual recall circumstances, but should usually contain the following points:

Subject: Status Report, Class I (or II), Recall No. _____

Product:

Recalling Firm:

I. Summary of Firm's Activities

1. Number and type of consignees notified, date and method of notification.
2. Number of consignees responding to the recall communication.
3. Number of consignees not responding.
4. Number and results of effectiveness checks made.
5. Significant problems firm is experiencing in the recall.
6. Any additional steps the firm is taking to complete the recall.

II. Summary of FDA's Audit Activities

1. Date and No. of audit checks assigned.
2. Number of audit checks completed.
3. Number of audit checks finding the recall effective.
 - a. Direct Accounts
 - b. Sub-accounts
4. Number of audit checks finding the recall ineffective.
 - a. Direct Accounts
 - b. Sub-accounts
5. Significant problems encountered during the checks.

Provide any additional information pertinent to Center and OE evaluation of the recall's progress or effectiveness.

Appendix A FORMS/ATTACHMENTS FOR STATE AUDITS

1. Form FDA 3177

Form FDA 3177 (Recall Audit Check Report), can be obtained by contacting the local FDA recall coordinator.

Follow the directions below to complete the form. NOTE: COMPLETE ONE FORM PER AUDIT CHECK.

Block 1. Recall Information:

- a. Recall Number: Leave Blank
- b. Recalling Establishment: Provide the name and address of the firm responsible for issuing the recall notification.
- c. Recalled Code(s): Provide the lot, batch, or serial number under recall.
- d. Product: Provide the name of the product under recall. If numerous products are involved, use generic term, e.g., ice cream, dried fruit, etc.

Block 2. Program Data: Leave Blank

Block 3. Audit Accounts: The form has been designed so that it may be used at up to the third level of distribution. Complete the appropriate block for your visit, if known.

Block 4. Consignee Data: "Consignee" is the account at which the check is being conducted. Data requested is self explanatory.

Block 5. Notification Data: Fill in appropriate blocks. Did consignee receive a specific written, verbal, or personal contact providing recall notification; from whom and when was notice received?

Block 6. Action and Status Data: Self-explanatory.

Block 7. Sub-Recall Needed?: Describe firm's sub-recall procedures in Block 10 or give reason for not conducting sub-recall. If firm has refused to sub-recall without proper justification, include district follow-up in Block 10 or separate memo.

Block 8. Amount of Recalled Product Now on Hand: Self-explanatory.

Block 9. Injuries/Complaints: Self-explanatory.

Block 10. Remarks: Provide all information not covered in 1-9 which aids in the evaluation of recall effectiveness at this consignee.

Signature Block: The Supplemental Audit Report is to be signed by the individual conducting the effectiveness check in the block noted "Signature of CSO/CSI"; as well as by the individual endorsing the report to the monitoring district.

2. Other Forms

If state personnel wish to use a different form to capture the information obtained during their recall audit visits, they should assure that at least the following information is obtained, plus any additional information requested by the monitoring or home FDA district office:

1. Name and title of person interviewed.
2. Was notification received, understood, and followed?
3. Date and method of notification.
4. Amount of recalled product on hand at time of notification.
5. Amount returned and the method of return.
6. Amount destroyed and method of destruction.
7. Amount presently on hand and its status (held for sale, awaiting return, etc.).
8. Date of anticipated return or destruction, and planned method (if applicable).
9. Was sub-recall conducted? (If so, obtain a list of consignees from which to select your sub-recall check locations).
10. Have injury reports or complaints been received? If so, report details.

3. Other Materials

FDA recall monitoring districts may provide state personnel with audit assignments (and level of recall effectiveness checks) in addition to any supporting recall materials, e.g., Press Releases, Technical Guidance, etc.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 022
Issue: 2010 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 - TCS Implementation Committee

Issue you would like the Conference to consider:

During the 2008 Conference for Food Protection Biennial Meeting, the TCS (Temperature Control for Safety) Implementation Committee was created and given the following charges as an outcome of Issue 2008 1-008:

1.) Send a letter to the FDA requesting that they monitor and subsequently post to the FDA website the following information:

- a. Any new or additional information that will assist regulators and industry in the implementation of the new PHF/TCS definition
- b. The finalized FAQ from the 2005 TCS survey
- c. The response document from NACMCF (National Advisory Council for Microbiological Criteria for Foods) on inoculation studies

2.) Work with the Conference to provide a link on the CFP website to the FDA information noted above.

This Issue presents the TCS Implementation Committee's report with supporting documents (Committee Roster and Letter to FDA) and requests acknowledgement of the report.

The TCS Implementation Committee worked to complete their charges by crafting the required letter with the appropriate requests.

Public Health Significance:

Food establishments are required to maintain certain foods at required temperatures unless the food item meets parameters that would prevent pathogenic microorganism growth or toxin formation. By changing the term "PHF" and replacing with "PHF/TCS food" clarifies that "time" and "temperature" have a role in preventing growth and encourage the use of science based food safety principles and programs. Additionally, the new definition recognizes the "Hurdle Concept" which shows that the interaction of several factors at levels that alone would not prevent or control growth, can prevent or control growth when used together.

The posting of the documents as requested by the committee to both the CFP and FDA web sites will allow all interested parties to have access to the necessary information in order to accurately apply the "PHF/TCS food" criteria.

Recommended Solution: The Conference recommends...:

acknowledgement of the TCS Implementation Committee's report and recognition of the efforts committee members put forth in completion of the charges issued by the 2008 Biennial Meeting.

Submitter Information:

Name: Adam Johnson, Chair
Organization: TCS Implementation Committee
Address: Supervalu7075 Flying Cloud Drive
City/State/Zip: Eden Prairie, MN 55344
Telephone: 952-947-3995 Fax:
E-mail: adam.johnson@supervalu.com

Attachments:

- "TCS Implementation Letter to FDA"
- "TCS Implementation Committee Final Report 2010"
- "TCS 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.

December 4, 2009

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

Dear, Mr. Smith

As you are aware, the mission of the Conference of Food Protection (CFP/Conference) is to promote food safety through collaboration and partnership among federal, State, and local regulatory agencies, the food industry, academia, and consumer groups.

On April 11-16, 2008, the Conference met in San Antonio, Texas. The three Councils deliberated a total of 114 issues. Of these, the Assembly of State Delegates (a group of representatives from 49 States, the District of Columbia and one territory) accepted 111. One of these accepted issues (2008 I-008) was to request your agency monitor and subsequently post to the FDA website the following information:

- Any new or additional information that will assist regulators and industry in the implementation of the new PHF/TCS definition
- The finalized FAQ from the 2005 TCS survey
- The response document from NACMCF on inoculation studies

CFP is aware that FDA has already published information on its website related to the items mentioned above. These include "Evaluation and Definition of Potentially Hazardous Foods", and "Potentially Hazardous Food: The Evolving Definition of Temperature Control for Safety". Links to these FDA webpages can now be found on the CFP website. In addition, a link to the 2009 report published by NACMCF on inoculation studies has also been placed on the CFP website. CFP applauds your efforts to clarify and standardize the information available to industry and regulators pertaining to the implementation of PHF/TCS requirements. We respectfully request that you continue these efforts, including the possible compiling and publishing of a list of FAQ's based on the 2005 CFP survey related to PHF/TCS and the placement of a link to the NACMCF report on inoculation studies on the FDA website.

Kevin Smith

December 4, 2009

This letter is being sent on behalf of the CFP TCS Implementation committee with the full knowledge and approval of CFP Conference Chair, David Gifford. FDA's support of and cooperation with the Conference through the years has resulted in an improved regulatory process and increased efforts toward food safety. The CFP Executive Board looks forward to continuing this same collaboration and partnership with the FDA in the coming years. With such a liaison, we expect to continue the great progress of the past.

Sincerely,

Adam Johnson
Chair, TCS Implementation Committee

**Conference for Food Protection
Committee Final Report**

COMMITTEE NAME: TCS IMPLEMENTATION

COUNCIL (I, II, or III): I

DATE OF REPORT: DECEMBER 4, 2009

SUBMITTED BY: Adam Johnson

COMMITTEE CHARGE(s):

Conference for Food Protection (CFP) Issue 2008 I-008 specified that CFP create a TCS Implementation Committee to work on the following:

- 1.) Send a letter to the FDA requesting that they monitor and subsequently post to the FDA website the following information:
 - a. Any new or additional information that will assist regulators and industry in the implementation of the new PHF/TCS definition
 - b. The finalized FAQ from the 2005 TCS survey
 - c. The response document from NACMCF on inoculation studies
- 2.) Work with the Conference to provide a link on the CFP website to the FDA information noted above.

COMMITTEE ACTIVITIES AND RECCOMENDATIONS:

Background:

During the 2008 CFP Meeting, the TCS Implementation Committee recommended that the FDA post on the CFP and FDA websites any new or additional information that will assist regulators and industry in the implementation of the new PHF/TCS definition.

Council 1 accepted Issue 2008 1-008 "Request Approval of the TCS Committee's Training Document" in which the TCS Implementation Committee was continued and the charges above were given.

Activities:

The committee first met in September of 2008 and consisted of 14 members with a breakdown of 3 State Regulatory, 1 Local Regulatory, 7 Industry Retail Food, 1 Federal Regulatory, and 2 Academia.

Based on a review of the committee charge it was recognized that there were significant web postings related to charges #1 and #2 that had already been posted. These included "Evaluation and Definition of Potentially Hazardous Foods", and "Potentially Hazardous Food: The Evolving Definition of Temperature Control for Safety". Links to these FDA web pages could also now be found on the CFP website. In addition, a link to the 2009 report published by NACMCF on inoculation studies had also been placed on the CFP website.

A letter was drafted and sent to the FDA requesting that they continue their efforts, including the possible compiling and publishing of a list of FAQ's based on the 2005 CFP survey related to PHF/TCS and the placement of a link to the NACMCF report on inoculation studies on the FDA website.

Recommendations:

Based on the significant related postings present on the FDA and CFP websites, it is recommended that the TCS Implementation committee be disbanded.

Requested Actions:

The TCS Implementation Committee will submit one (1) issue at the 2010 Conference based on the recommendation of the committee.

Issue: Report – TCS Implementation Committee

The issue will request that the Committee Report be acknowledged.

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

Casmir Tryba
Big Y Food Stores
Springfield, Mass.

Patrick Brown
Atlantic & Pacific Tea Co.
Montvale, NJ

Larry Kohl
Food Marketing Institute
Arlington, VA

Alan Tart
USFDA/CFSAN
Atlanta, GA

Susan M. Wallace
Johnson & Whales
Providence, RI

Richard Parker
HEB
San Antonio, TX

Steven Moris
Kansas Dept. of Ag
Topeka, KS

Mahipal Kunduru
Safeway
Pleasanton, CA

Richard Akin
Florida Div. of Hotels & Restaurants
Tallahassee, FL

Robert Brown
Whole Foods Market
Austin, TX

Diane Bernazzani
Mass Dept of Public Health
Jamaica Plain, MA

Michael Roberson
Publix Super Markets
Lakeland, FL

Marcel Elizondo
Austin/Travis County HHS
Austin, TX

Martin Bucknavage
Penn State University
State College, PA

COMMITTEE MEMBER ROSTER:

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

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
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Wallace	Susan M.	Member	Academia	Johnson and Wales University	265 Harborside Blvd.	Providence	RI	2905	(401) 598-1706	susan.wallace@jwu.edu
Tryba	Casimir M.	Member	Industry - Retail Food Stores	Big Y Foods, Inc.	2145 Roosevelt Avenue, P.O. Box 7840	Springfield	MA	01102-7840	(413) 504-4450	tryba@bigy.com
Parker	Richard	Member	Industry - Retail Food Stores	HEB	5105 Rittiman Rd	San Antonio	TX	78218	(210) 938-6514	parker.richard@heb.com
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Akin	Richard	Member	Regulatory - State	Florida Division of Hotels and Restaurants	1940 N. Monroe Street	Tallahassee	FL	32399	(850) 488-1133	rick.akin@dbpr.state.fl.us
Brown	Robert	Member	Industry - Retail Food Stores	Whole Foods Markets	550 Bowie Street	Austin	TX	78703	512-542-3043	Robert.Brown@wholefoods.com
Bernazzani	Diane	Member	Regulatory - State	Massachusetts Dept of Public Health/Food Protection	305 South Street	Jamaica Plain	MA	2130	(617) 983-6765	diane.bernazzani@state.ma.us
Roberson	Michael	Member	Industry - Retail Food Stores	Publix Super Markets, Inc.	P.O. Box 407	Lakeland	FL	33802-0407	(863) 688-7407 x32422	Michael.Roberson@publix.com
Elizondo	Marcel	Member	Regulatory - Local	Austin/Travis County Health & Human Services		Austin	TX		(512) 974-8068	Marcel.Elizondo@ci.austin.tx.us
Bucknavage	Martin	Member	Academia	Penn State University	438 Food Science Building	University Park	PA	16802	(814) 867-1839	mwb124@psu.edu
Tart	Alan	Member	Regulatory	CFSAN	60 8th Street NE	Atlanta	GA	30309	(404) 253-1267	alan.tart@fda.hhs.gov

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 023
Issue: 2010 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:

Report - Criticality Implementation and Education Committee

Issue you would like the Conference to consider:

During the 2008 Conference for Food Protection Biennial Meeting, the Criticality Implementation and Education Committee was created and given the following charges as an outcome of Issue 2008 1-022:

1. Develop a training program, educational information and identify issues of concern to all stakeholders.
2. Recommend revised terminology based on focus group consideration. The recommended revised terms will be forwarded for review and acceptance to the Executive Board by December 2008.

This Issue presents the Criticality Implementation and Education Committee's report with supporting documents (Committee Members and Training Document) and requests acknowledgement of the report.

The Criticality Implementation and Education Committee worked to complete their charges by providing training materials for the implementation of the new three-tiered criticality designation of Food Code provisions and corresponding definitions. The committee debated for three months in late 2008; yet was unable to come to a consensus on terms. Consequently, the Criticality Implementation and Education Committee sent to the Executive Board the recommendation of the majority (Priority, Foundation and Core), along with the recommendation of the minority (Priority 1, Priority 2 and Priority 3). The difficult charge to form a "focal group" without funding resulted in the committee itself acting as the "focal group".

Public Health Significance:

Food establishment operators are required to operate their facilities in a manner that receives, stores, prepares, packages, displays and sells safe food. There are many facets to the operation of the food establishments, but the ultimate goals are the prevention of foodborne illness and injury and to protect the consumer. The regulatory inspectors and industry must recognize, measure, and prioritize risks associated with each step of the operation. The US Food and Drug Administration Food Code has long categorized infractions or violations into two designations, "Critical and Non-Critical". The 2009 Food Code now goes further to break these two designations into three criticality designations

based on risk. Providing a training tool for all stakeholders becomes valuable as a means to incorporate the use of the new designations into action plans, intervention strategies, and effectiveness measures.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the Criticality Implementation and Education Committee's report and recognition of the efforts committee members put forth in completion of the charges issued by the 2008 Biennial Meeting.
2. Dissolution of the committee as it has completed the charges issued by the 2008 Biennial Meeting.

Submitter Information:

Name: Rick Barney, Co-Chair
Organization: Criticality Implementation and Education Committee
Address: Sweetbay Supermarket 3801 Sugar Palm Dr.
City/State/Zip: Tampa, FL 33618
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Attachments:

- "Criticality Implementation and Education Committee Final Report"
- "Criticality Implementation and Education Committee Members November 2009"
- "Re-Designation of Food Code Provisions Training Document"

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.

**2010 Conference for Food Protection
Criticality Implementation and Education Committee Final Report**

Committee Name: Criticality Implementation and Education

Council: I

Date of Report: December 4, 2009

**Submitted By:
Rick Barney and Deborah Marlow, Co-Chairs**

Committee Charges: Conference for Food Protection (CFP) Issue 2008 I-022 specified that CFP create a Criticality Implementation and Education Committee to work on the following:

1. Develop a training program, educational information and identify issues of concern to all stakeholders.
2. Recommend revised terminology based on focus group consideration. The recommended revised terms will be forwarded for review and acceptance to the Executive Board by December 2008.

Background:

During the 2008 CFP Biennial Meeting, the CFP Critical Item Committee and the FDA Criticality Workgroup separately proposed terms for a three-tiered violation system as a replacement for the two-tiered Critical and Non-critical violation designations found in previous editions of the FDA Food Code. These designations are based on a qualitative risk assessment conducted by the FDA Workgroup and reviewed by the Critical Item Committee.

Council 1 accepted Issue 2008 1-021 "Incorporation of the three tier criticality ratings". Council 1 also accepted Issue 2008 1-022 "Revisions to the Food Code Resulting from Re-designation" in which the Criticality Implementation and Education Committee was formed.

Committee Findings and Work:

The committee first met in September of 2008 and consisted of 39 members with a breakdown of 11 State Regulatory, 7 Local Regulatory, 9 Industry Food Service, 7 Industry Retail Food, 3 Federal Regulatory and 2 other. Having a December 2008 deadline, the committee proceeded quickly to propose new terms.

The following sets of terms were proposed to and from the committee.

- Essential, Sensitive, Fundamental
- Focal Point, Focal Foundation, Core
- Priority, Foundation, Core
- Class I, Class II, Class III
- Priority I, Priority II, Priority III
- High Risk, Medium Risk, Low Risk
- Red, Orange, Yellow
- Priority, Significant, Basic
- Level I, Level II, Level III
- Risk Factor (and Intervention), Critical, Good Retail Practices
- High, Med(ium), Low

- Critical, Key, Other
- Critical, Foundation, Basic
- Priority, Priority Foundation, Core

The committee also sought guidance in regard to “focal group” and learned from FDA (Dr. Jordan Lin in the Consumer Science Division) that...

1. *Focus groups and one-on-one interviews provide you with a range of opinion, not consensus. They are also good at explaining why and how people think about an issue. The Committee will then have to tease the conclusions out of the responses.*
2. *There are inherent biases in focus groups (not so much with one-on-one interviews) – some people like to talk more than others and some people are swayed by others in the group so not everyone will get equal time or provide unbiased opinions in a group.*
3. *Focus groups are usually done in person but could be done by conference call, provided certain things are done.*
 - a. *Set up an appointment when they are not rushed and give the individual the list of choices and the questions ahead of time (by e-mail, mail or drop off in person).*
 - b. *Stick closely to a scripted set of questions. We wouldn't have to be concerned about preconceived ideas or bias of the moderator in a focus group. This would also allow more than one individual to conduct interviews in different locations if they were careful to follow the questions exactly and not project their own opinion which may be biased.*
4. *The number of interviewees should be large enough to represent the divergent viewpoints in the group of stakeholders we are interested in.*
 - a. *Do we want to consider having representatives from the food service industry, retail food store industry, state agencies, local agencies, trainers?*
 - b. *Can you think of any other groups of stakeholders?*
 - c. *Dr. Lin suggested that 10-15 people be interviewed in each group.*
5. *The scripted questions should be short and very clear. Dr. Lin offered to review our proposal once it is put together. Possible questions include:*
 - a. *Rank the list of terms (provided beforehand) from #1 (most preferred) to #12 (least preferred). – We could also pare down the numbers of choices as a committee so they won't have so many to choose from.*
 - b. *Explain why you ranked the first one as #1 and the last one as #12.*
 - c. *Why did you like your top two choices?*
 - d. *How much does your top choice convey the importance or priority of that definition?*
 - e. *Can you think of any other term that would be better?*
6. *We need to have a prepared description of why we are interviewing these people for the interviewer to read.*
7. *We should put together a proposal and address the following issues:*
 - a. *Statement of the problem*
 - b. *Objectives*
 - c. *Methodology*
 - d. *Expected conclusion*

Based on this in-depth analysis of how a true focal group would and should function and due to the limited amount of time the committee had to fulfill its charge to the Executive Board by December 2008, the Committee determined to forgo an external group process and proceed using the knowledge and experiences of its committee members.

The committee (taking the sets of terms proposed) narrowed the list to five preferred, then to three preferred and finally to two preferred sets of terms. The final two preferred sets were “Priority, Foundation, Core” (PFC) and “Priority I, Priority II, Priority III” (P1, P2, P3). After a final vote of the committee, we had a majority (70%) of the committee for PFC and a strong minority (30%) for P1, P2, P3. Unable to come to a consensus the committee sent to the Executive Board our work and requested acceptance of the majority opinion.

The Executive Board recognized the effort of the committee and that the focus group requirement was unrealistic based on resources (time/money) as part of the original charge. The Board had a split vote (11 yes, 8 no, 2 abstentions) to accept the majority opinion; therefore, a letter was sent to the FDA indicating that CFP has no recommendation at this time. Since the FDA received no recommendation from the CFP, they used their original terms, Priority, Priority Foundation, and Core in the 2009 Food Code.

The committee did agree that while the terminology was important, even more important was providing educational tools and processes to best explain the changes and reasons around the change to the three-tiered system of violations.

The committee began work in two areas: first, to provide a PowerPoint training tool that can be used by all stakeholders in training and education; and second, to collect and develop a list of Frequently Asked Questions (FAQs) that can be added to various web sites to better explain the changes and practical uses of the three-tier criticality system.

During discussion it was noted by the committee that Food Code Section 8.405.11 Timely Corrections had not significantly changed to reflect the change from a two-tier to a three-tier criticality system. The committee felt that specifically calling out separate and distinct time standards for the three-tier designations was consistent with the intent of the 2009 Food Code and would, in essence, make it easier to learn, train, and understand prioritizing violations and corrections in regards to risk factors.

Requested Actions:

The Criticality Implementation and Education Committee will submit four (4) issues at the 2010 Biennial Meeting based on the recommendation of the committee. The issues are:

1. Final Report from the Criticality Implementation and Education Committee.
2. Criticality Implementation and Education Committee – Criticality Training Slides. Request the PowerPoint presentation titled “Re-Designation of Food Code Provisions” be approved and placed in a downloadable format under the “Conference Developed Guidance and Documents” section of the CFP website. “Re-designation of Food Code Provisions” PowerPoint Slides and Speaker Notes are included as an attachment to the issue.
3. Criticality Implementation and Education Committee – “Frequently Asked Questions” Document
Request the Committee developed FAQ Document be forwarded to the FDA and that the FDA provide answers available for stakeholders on or before June 30, 2010. “Frequently Asked Questions” Document is included as an attachment to the issue.

4. Criticality Implementation and Education Committee - Timely Correction of Violations

Request acceptance of revised language for Food Code, Section 8.405.11 Timely Corrections that will provide separate guidance for Priority and Priority Foundation violations.

The committee would like to thank twenty public health experts from the Tulsa Health Department (Stephen Day, Mark Garvey, Tanya Harris, John Hartman, DeBrena Hilton, Diane Howland, Karla Hutton, Larry Little, Betsy Mathai, Paige Nelson, Elizabeth Nutt, Rich Peterson, Bert Plants, Nate Richardson, Travis Splawn, Frank Strozier, Debbie Watts, Rebecca Williams, Kendra Wise, and Jaymee Zabienski) for their invaluable assistance in providing feedback to the PowerPoint tool after testing it a “in real life” training mode. The committee would also like to thank two of the trainers, Ruth Hendy and Lone Wenzel, from the Texas Department of State Health Services that reviewed the slides from a trainer’s perspective and provided comments.

Finally the committee would like to recognize all its members and thank them for their services.

Rick Barney Sweetbay Supermarket Tampa, Florida	Deborah Marlow TX Dept. of Health Services Austin, Texas	Geoff Luebke FL Restaurant and Lodging Tallahassee, Florida
Casmir Tryba Big Y Food Stores Springfield, Mass.	Paul Uhler USDA/FSIS Washington, D.C.	Debbie Watts Tulsa Health Dept. Tulsa, Oklahoma
Kendra Wise Tulsa Health Dept. Tulsa, Oklahoma	Jacqueline Owens Wisconsin Dept of Ag Madison, WI	Priscilla Neves MA Dept of Public Jamaica Plain, Mass.
Sheri Morris Penn. Dept. of Ag Harrisburg, Penn.	Steven Moris Kansas Dept. of Ag Topeka, Kansas	Jere Ferrazo Douglas County Health Dept. Omaha, NE
M. David Lawrence Fairfax County Health Dept. Fairfax, VA	David Reed Minn. Dept. of Ag St. Paul, Minn.	Ivory Cooper DC Dept. of Ag Washington, DC
Christopher Gordon VA Dept. of Health Richmond, VA	Angela Kohls Kansas Dept. of Ag Topeka, Kansas	Adam Johnson Supervalu Boise, Idaho
Cheryn Hargrave United Supermarkets Lubbock, Texas	Christine Andrews NSF International Fredericksburg, VA	Larry Kohl Food Marketing Institute Arlington, VA
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Gina Nicolson
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Todd Taylor
Ecolab/Kay Chemical
Greensboro, NC

Shirley B. Bohm
USFDA/CFSAN-OFS
College Park, MD

Recommendation for future charge;

The committee recommends that the committee be discharged because it has fulfilled its charges.

Committee Member Roster:

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

Attachment:

Criticality Implementation and Education Committee Members November 2009.

Criticality Implementation and Education Committee

Last Name	First Name	Position	Constituency	Employer	Address	City	State	Zip	Telephone	Email
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Re-designation of Food Code Provisions

By the 2008-2010 CFP Criticality
Implementation and Education Committee

Objectives of Criticality Implementation Training

- #1 – Explain the **three new definitions** and the **risk assessment process** used to define the level of risk of Food Code provisions and their relationship to preventing foodborne illness.
- #2 – Provide clear and concise **training** for regulators, operators and trainers in restaurants, retail food stores, institutions and vending with examples and how to communicate this information in an effort to reduce the incidence of foodborne illness and injury

Objectives of Criticality Implementation Training

- #3 – **Increase awareness and understanding of the changes** in compliance and enforcement sections of the Food Code related to the re-designated provisions
- #4 – Give different examples of where and how to **apply the new designations** of Food Code provisions in routine activities to achieve long term behavior change, including in training, active managerial control and inspections

Introduction to Re-Designated Food Code Provisions - History

- The usual inspection/enforcement system in a food establishment emphasizes reactive, rather than preventive measures for food safety
- Additional measures must be taken by operators and regulators to better prevent, eliminate or reduce the occurrence of foodborne illness and injury **before it occurs**
- The re-designated provisions focus attention on the level of risk for foodborne illness or injury for any violation in the Food Code

History of Changes

- Issues were submitted to CFP since 2000 to remove “critical” and “non-critical” designations of Food Code provisions and replace them
 - “Critical item” was defined as a provision of this Code, that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard.
 - There was misunderstanding about critical items being connected to HACCP
- 11 issues, 3 committees and 1 work group were established to work on the charges
 - In 2004, CFP charged FDA to develop alternative terms

History of Changes

- In 2008, FDA submitted a 3-tiered set of definitions to CFP to rank Food Code provisions by risk
- The definitions were used with a qualitative risk assessment process to rank the Food Code provisions by their risk (high, medium or low risk) of causing foodborne illness or injury
- The re-designated terms were incorporated into the 2009 Food Code

New Definition of Priority Item

■ “Priority Item”

- “**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.
- “**Priority item**” includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
- “**Priority item**” is an item that is denoted in this Code with a superscript – ^P.

Priority Item^P

- When a Priority Item in the Food Code is out of compliance, it has the highest risk of causing foodborne illness or injury
- Compliance with a Priority Item eliminates, prevents or reduces to an acceptable level, biological, chemical or physical hazards that **directly** cause foodborne illness or injury (see Annex C – What are common food safety hazards?)
- No other provision more directly controls the hazard
- There is a **quantifiable measure or critical limit** for each Priority Item
- The term Priority Item implies an importance and need for immediate correction.



New Definition of Priority Foundation Item

- **“Priority Foundation Item”**
 - **“Priority foundation item”** means a provision in this Code whose application supports, facilitates or enables one or more Priority Items.
 - **“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
 - **Priority foundation Item”** is an item that is denoted in this Code with a superscript Pf – ^{Pf}.

Priority Foundation Item^{Pf}

- A Priority Foundation Item is usually linked to a Priority Item and supports, enables or helps achieve it
- Active managerial control/industry control systems support the compliance of Priority Items, such as:
 - Conducting personnel training (See Annex A&B)
 - Monitoring and enforcing Priority activities
 - Providing necessary equipment, facilities, etc. to carry out Priority activities
 - Developing & carrying out HACCP plans when necessary
 - Maintaining documents or records as necessary
 - Labeling food for employees or consumers
- The term Priority Foundation links the provision to a Priority Item

New Definition of Core Item

- **“Core Item”**

- **“Core item”** means a provision in this Code that is not designated as a Priority Item or a Priority Foundation Item.
- **“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.

Core Item

- A Core Item is a good retail practice (GRP) which is not intended to control a particular hazard but hazards in general
- A Core Item has no superscript in the Food Code
- Core Items include:
 - General sanitation requirements
 - Sanitation Standard Operating Procedures (SSOPs)
 - Equipment design
 - Design & construction of facilities and structures
 - General maintenance & repair
 - Operational controls

Relationship between Priority Items and Imminent Health Hazards

- **Imminent health hazard:**

- A significant threat in an entire establishment that may endanger the public health which requires the operation to cease operation if immediate correction is not possible and to notify the RA
- Priority Items such as smoke or fire damage, flood, extended electrical or water outage, extended lack of hot water, sewage back-up, foodborne outbreaks, misuse of toxic substances, gross insanitary condition, etc.

- **Not all Priority Item violations are imminent health hazards**, only those that affect the operation of the entire establishment or a large part of that operation

Qualitative Risk Assessment Process

- A qualitative risk assessment is used to rank risk of foodborne illness or injury in very complex situations such as a food service/food store or provisions in the Food Code
- A qualitative risk assessment process considers:
 - The likelihood of causing foodborne illness or injury
 - The characteristics of the hazard (virulence and severity)
 - The size and/or number of outbreaks (infectivity or potential for illness or injury)
 - Any contributing factors (contamination, proliferation or survival) identified in previous foodborne outbreaks reported to CDC

What does this change to a risk assessment process mean to me?

- Food Code provisions are prioritized according to their risk of causing foodborne illness or injury (P, Pf or C)
- Using science-based reasoning for the new terms promotes:
 - Internal consistency in the Food Code
 - Objective, not subjective designations
- For further explanation of the ranking process, see:
 - Risk assessment decision making process
 - Public Health Reasons, Annex 3 of the Food Code
 - Published references in the Excel spreadsheet and Annex 2 of the Food Code, available at:
 - <http://fda.gov/Food/FoodSafety/RetailFoodProtection.default.htm>

What does this change to a risk assessment process mean to me?

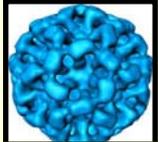
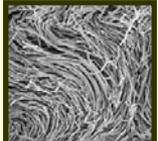
- It is possible to prioritize operational and regulatory food safety activities according to the level of risk provided by that violation
 - Priority Item – highest risk, direct connection to foodborne illness or injury
 - Priority Foundation Item – supports one or more Priority Items
 - Core Item – lowest risk, general good practices
- There is a recognized critical limit (quantifiable measure) to show compliance with the highest risk priority items

Risk Assessment Process

- The risk assessment process starts by identifying the food safety hazard(s) each provision in the Code will control
- Biological Hazards* include, for example:



- Vegetative bacteria
- Spore-forming bacteria
- Viruses
- Parasites



*** See Annex C for more examples and explanations of hazards in foods**

Risk Assessment Process

- Chemical hazards* include, for example:



- General chemical contamination (cleaning compounds, sanitizers, allergens, additives)

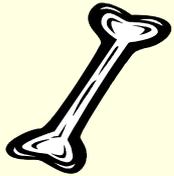


- Scombroid toxin (*B. proteus* breaks histadine down to histamine in certain temperature-abused fish)
- Ciguatera toxin (natural toxin in reef-fish)

*** See Annex C for more examples and explanations of hazards in foods**

Risk Assessment Process

- Physical hazards* include, for example:



Bone



Metal fragments

Bandage

Jewelry



Hair



*** See Annex C for more examples and explanations of hazards in foods**

Risk Assessment Process

Initial Evaluation

- After identifying the hazard associated with that provision, determine which of the 3 defined terms (P, Pf or C) most clearly describes this provision, e.g.,
 - Cook poultry to 165°F for 15 sec. (CL) destroys vegetative pathogens (Priority Item)
 - No date marking system used on RTE potentially hazardous/TCS food to limit shelf life and control *Listeria* (Priority foundation Item)
 - Floor in grill area dirty – general sanitation (Core Item)

Risk Assessment Process

Other Characteristics

- Determine if other characteristics of the hazard increase the risk:
 - Virulence where hazard has severe consequences - HIGH
 - high potential by ill food worker to spread hazard to food or patrons
 - more than one mode of transmissions (ingestion, inhalation, person-to-person)
 - shed at high levels (i.e., norovirus)
 - extremely virulent
 - low infectious dose (i.e., *Listeria monocytogenes*)
 - potential for secondary infection (e.g., Norovirus, *Shigella* spp., *E. coli* O157:H7)
 - extremely toxic chemical or natural toxin (i.e., *Clostridium botulinum*)
 - high incidence of hospitalization and death, (e.g., *Clostridium botulinum*, *Listeria monocytogenes*)
 - chronic sequelae possible (*E. coli* O157:H7, *Salmonella* spp., parasites)

Risk Assessment Process

Other Characteristics

- Assess characteristics of the hazard:
 - Virulence or severity of hazard - MEDIUM:
 - medium potential for ill food worker to spread hazard to food or patrons
 - medium infectious dose
 - unlikely secondary infection
 - high incidence of hospitalization but few deaths

Risk Assessment Process (cont'd.)

- Assess characteristics of hazard:
 - Virulence or severity of hazard - LOW:
 - low potential for ill food worker to spread hazard to food or patrons
 - low infectious rate
 - unlikely secondary infection (e.g., *Clostridium perfringens*, *Bacillus cereus*)
 - high incidence of illness but low incidence of hospitalization or death
 - mild symptoms
 - short duration

Risk Assessment Process

Other Characteristics

- Assess size & number of outbreaks based on infectivity of the hazard in the absence of control provided by the Code:
 - **High** – large outbreaks, large number of outbreaks
 - **Medium** – small outbreaks, small number of outbreaks
 - **Low** – individual cases, sporadic cases

Risk Assessment Process

- Identify relevant CDC contributing risk factors including contamination, proliferation or survival
- Revise the initial designation based on additional information
- Provide rationale for the decision and references that explain or support designation

What criticality changes were made in the Food Code?

- Three new definitions were added to Chapter 1:
 - Priority Item
 - Priority Foundation Item
 - Core Item
- Section 2-102.11(A) Demonstration (of Knowledge) was changed to say one of the ways the PIC could show compliance with the Code was by having no Priority Item (instead of critical item) violations during the current inspection
- A superscript (^P or ^{Pf}) is used to identify Priority or Priority Foundation Items in Chapters 2-8, Core Items have no superscript
- Five sections in Chapter 8 were amended to change Critical Item and/or Non-Critical Item to Priority Item, Priority Foundation Item and/or Core Item.

Chapter 8 Compliance & Enforcement

(8-401.20)

- **Section 8-401.20 Performance- and Risk-Based (inspection frequency)**
 - Prioritize and conduct more frequent inspections based on:
 - Food establishment's history of non-compliance with P & Pf items in the Code or HACCP Plan
 - Numerous or repeat violations of C items
 - This section of Chapter 8 is recommendation only and not enforceable

Chapter 8 Compliance & Enforcement

(8-403.10)

- **Section 8-403.10 Documenting Information and Observations (documentation on inspection forms)**
 - Document on an inspection report non-compliance with P and Pf Items
 - This section of Chapter 8 is recommendation only and not enforceable

Chapter 8 Compliance & Enforcement

(8-405.11)

■ Section 8-405.11 Timely Correction

- Correct P or Pf Items at the time of inspection
- Implement corrective actions for a required HACCP plan provision that is not in compliance with its critical limit (CL)
- The Regulatory Authority may agree to a longer time for correction (usually for Pf Items), not to exceed 10 days, based on the potential hazard and complexity of the corrective action
 - The P Item it supports must be in compliance using some other procedure, method, equipment, etc. for an extended period for compliance

Chapter 8 Compliance & Enforcement

(8-405.20)

- **Section 8-405.20 Verification and Documentation of Correction**
 - Record correction of P and Pf Items or corrected HACCP Plan deviations observed during an inspection on an inspection report
 - After receiving notification that a violation of a P or Pf Item or a HACCP Plan deviation has been corrected, the Regulatory Authority will verify and document correction of the violation
 - This Section of Chapter 8 is recommendation only and not enforceable

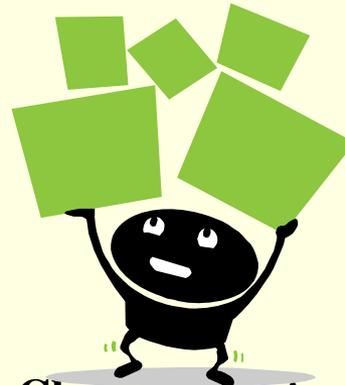
Chapter 8 Compliance & Enforcement

(8-406.11)

- **Section 8-406.11 Time Frame for Correction**
 - Correct C Items by a date and time agreed to by the Regulatory Authority but no later than 90 days after the inspection
 - The Regulatory Authority may approve a longer compliance schedule:
 - If it is provided in writing
 - If no health hazard exists or will result from the extended compliance schedule

Who can use the new terms?

- The new terms allow focusing and prioritizing of tasks, training* and corrective actions for the
 - Inspector
 - Person-in-charge
 - Trainer



* See Annex A – Effective Behavior Change and Annex B – Communication Techniques for training assistance

How can the new terms be used?

- New terms P, Pf and C:
 - Designations help identify issues for “Active Managerial Control”
 - They guide regulatory inspections and enforcement.
 - They aid trainers focus their courses on the most important food safety information for their students



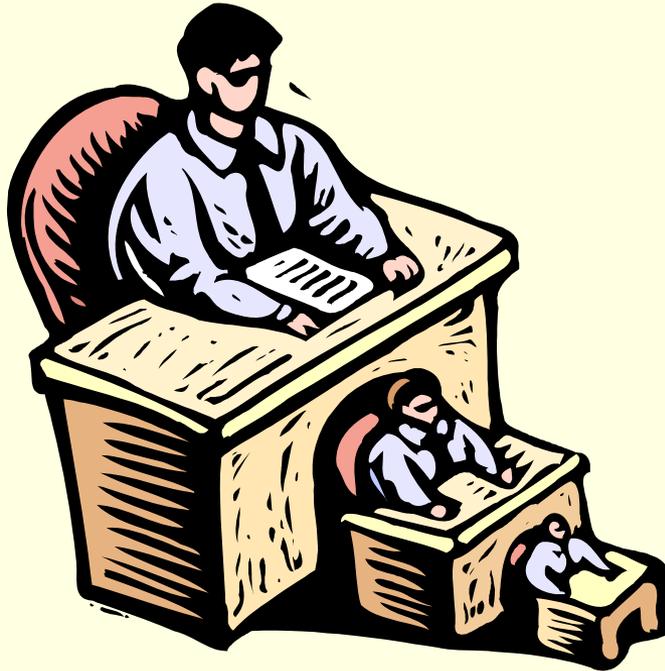
How can regulators, QA & 3rd party inspectors use the new terms?

- Increase frequency of inspections for establishments with history of non-compliance with P Items
- Do risk-based inspections that focus on P Items
- Require immediate correction or initiate correction of all P or Pf violations during inspections
- Use “teachable moments” to explain why P Items are most important
- Develop various options for correction of P Items
 - E.g., different methods for cooling, accomplishing no bare hand contact with RTE food, reheating
- Present inspection findings at exit interview based on level of risk (P Items first, then Pf Items and finally C Items if time permits)

Potential Uses - Compliance & Enforcement

- Develop intervention strategies for long term compliance for “P” items identified in inspection summaries, baseline surveys, foodborne outbreaks, etc.
- Amend state or local Food Code to reflect use of new terms
- Provide longer time for correction of Priority Foundation Items (if the P item it supports is controlled) and Core Items because of lower risk level
- Provide stakeholders with an explanation of the definitions and risk assessment process and their link to preventing foodborne illness and injury

How can the food industry use the new terms?



Shift attention to Priority Items in:

- Management systems
- Standard Operating Procedures
- Recipes
- Self inspections
- 3rd Party Audits

How can the food industry use the new terms?



They will help prioritize...

- Corrective actions for “out of compliance” inspection findings
- monitoring, walk throughs
- Training content for employees within food establishments
- Limited resources of time and money

How can the food industry use the new terms?



They can build in compliance for Priority Items....

- during Plan Review
- during construction
- during remodeling
- during training

How can food safety trainers use the new terms?

- Trainers can explain:
 - The new definitions, 3-tiered re-designation system with examples of each
 - Immediate correction of Priority Items because of direct connection to foodborne illness
 - Priority Foundation Items provide options to correct, manage and control Priority Items
 - Core Items are general good practices
 - How to prepare for accredited Food Protection Manager Certification examinations

What do you think about this?

Scenario #1

- **One day, a retail establishment was inspected and several violations were noted.**
 - Several holes in drywall of stockroom (pallets hit wall and made a hole)
 - Excess fly activity at open trash containers in outside receiving area

When I arrived at the location the following day, I found store personnel repairing and painting the dry storage area. Painting requires ventilation, therefore all receiving doors were propped open. Guess what? The excess fly activity that was once outside was now inside the stockroom and kitchen.

What do you think about this?

Scenario #1

- Do we consider implications and unintended consequences of our activities (opening door for ventilation allows flies to enter)?
- Were the holes in the drywall corrected before more serious violations were corrected (prioritizing risk, time for correction and cost of correction)?
- Were other priority violations (handwashing, time/temperature control, etc.) in compliance when maintenance repairs were made?

What is a risk-based inspection process?

- A risk-based inspection process:
 - Prioritizes inspection activities, corrections and enforcement based on risk of foodborne illness or injury
 - Focuses on factors that contribute more directly to foodborne illness or injury
 - Bases frequency of inspection on establishment type and history
 - Requires more inspection time when more P & Pf Items are present
 - Monitors critical limits to determine compliance with P Items

What is a risk-based inspection process?

- Corrective actions are confirmed for P & Pf violations at time of inspection (or later through a written confirmation)
- Explanations of the P & Pf link to foodborne illness or injury are offered to reinforce correct appropriate correction to operators
- Alternate options for correction are used to develop a risk control plan with the operator to achieve long term change (see Annex A for additional advice)

What is a risk-based inspection process?

- At the exit interview, an inspector can:
 - Discuss inspection findings with the operator based on the P & Pf risk
 - Confirm understanding of risk and correction with operator
 - Confirm timeline for correction of P & Pf violations

Examples of P, Pf and C Violations

- The following examples will provide the:
 - Violation of a P, Pf or C Item
 - Provision in the Food Code that, if Out of Compliance, will result in potential hazards in food that will cause foodborne illness or injury
 - Rationale or explanation of why/how violation of that provision is a P, Pf or C Item.



Priority Item Examples

Example of Priority Item^P Violation

- **Employee working with symptoms of vomiting**
 - Provision in Food Code: 2-201.11(A) Responsibility of Permit Holder, PIC & Conditional Employees
 - Correction – Employee reports symptoms to PIC and stop working, or
 - Provision in Food Code: 2-201.12(A)(1)
 - Correction – PIC excludes employee from work
 - Rationale – High numbers of pathogens, especially norovirus, contaminate food, clothing, surfaces, air (through aerosols) and cause illness when ingested

Example of Priority Item^P Violation

- **Employee working with uncovered, infected cut on finger**
 - Provision in Food Code: 2-201.11(A) Responsibility of Permit Holder, PIC & Conditional Employees
 - Correction: Employee reports to PIC or covers infected lesion with double, impermeable barriers (i.e., waterproof bandage or finger cot plus a single-use glove worn on top of that)
 - Rationale: Infected lesions with pus, typically contaminated with *Staphylococcus aureus*, can contaminate RTE food unless covered with double, waterproof barrier

Example of Priority Item^P Violation

- **No vigorous hand rubbing during handwashing**
 - Provision of Food Code: 2-301.12(B)(3) Cleaning Procedure
 - Correction: Rub vigorously with soap and water for 10-15 seconds
 - Rationale: Friction from rubbing hands together vigorously helps loosen soil on hands and reduces pathogen levels as they are rinsed off

Example of Priority Item^P Violation

- **Home-canned green beans served in a restaurant**
 - Provision in Food Code: 3-201.11(B) Compliance with Food Law
 - Correction: Discard and do not use home canned foods in a food establishment
 - Rationale: Home-canned green beans, a low acid food, are often inadequately processed which allows germination of *C. botulinum* spores and toxin formation

Example of Priority Item^P Violation

- **Employee using bare hands to make sandwiches**
 - Provision in Food Code: 3-301.11(B) Preventing Contamination from Hands
 - Correction: Use utensils or gloves to touch ready-to-eat food, not bare hands
 - Rationale: Ill or infected but asymptomatic employees can transfer pathogens from inadequately or unwashed hands to RTE foods such as sandwiches

Example of Priority Item^P Violation

- **Chef cooking chicken to 155°F for 15 sec.**
 - Provision in Food Code: 3-401.11(A)(3) Raw Animal Foods
 - Correction: Cook chicken to 165°F for 15 seconds
 - Rationale: Undercooking chicken which may be contaminated with bacteria will allow survival of pathogens

Example of Priority Item^P Violation

- **Cooking egg rolls that received a non-continuous (partial) cook to 145°F for 15 sec.**
 - Provision in Food Code: 3-401.14(D) Non-Continuous Cooking of Raw Animal Foods
 - Correction: If cooking process was interrupted and product cooled, it must have a final cook temperature of 165°F for 15 seconds
 - Rationale: The final heating process of 165°F for 15 seconds must overcome any pathogen growth resulting from normal contamination, cooling and cold holding.

Example of Priority Item^P Violation

- **5 gallons of chili made yesterday afternoon according to the cook now at 57°F in cooler at 9:30 am**
 - Provision in Food Code: 3-501.14(A) Cooling
 - Correction: Discard chili. In future, cool from 135°F to 70°F within 2 hrs., then to 41°F in a total of 6 hrs.
 - Rationale: Spore formers (*C. perfringens*, *B. cereus*) have had sufficient time in optimum temperature range to germinate and form toxins, or produce high levels of bacteria that may not be destroyed by reheating

Example of Priority Item^P Violation

- **RTE, PHF/TCS food (not exempted) was not date marked or, if date marked, was held for more than 7 days**
 - Provision in Food Code: 3-501.18(A)(1), (A)(2) & (A)(3)
RTE, PHF (TCS Food), Disposition
 - Correction: Discard food, begin using a date marking system and monitor for expiration
 - Rationale: *Listeria monocytogenes* can multiply at refrigeration temperatures, therefore time is the only control. If time is not used, food must be discarded.

Example of Priority Item^P Violation

- **Cooked chicken placed in bags, sealed (cook chill/ROP) and held for 30 days at 41°F**
 - Provision in Food Code: 3-502.12(D)(2)(e)(i) Reduced Oxygen Packaging without a Variance, Criteria
 - Correction: Discard food. In future, cook chill processed food must be stored at 34°F, if held for 30 days.
 - Rationale: If cooked chicken was re-contaminated or if spore formers were present before ROP packaging, the longer shelf life could allow growth and/or toxin formation

Example of Priority Item^P Violation

- **Using galvanized metal can to mix and store fruit juice punch**
 - Provision in Food Code: 4-101.15 Galvanized Metal, Use Limitation
 - Correction: Discard. Use glass, plastic or other safe metal (aluminum, stainless steel, etc.)
 - Rationale: Acid fruit punch will leach toxic tin from the galvanized can

Example of Priority Item^P Violation

- **Hot water dish machine does not achieve 160°F surface temperature on utensils (using temperature sensitive tape or max. registering thermometer)**
 - Provision in Food Code: 4-703.11(B) Hot Water and Chemical
 - Correction: Re-sanitize if temperature not achieved. Check wash and final rinse water temperatures, method of racking dishes (no masking), clear spray nozzles, etc. and correct as necessary
 - Rationale: Pathogens could survive on the surface of utensils and dishes

Example of Priority Item^P Violation

- **No backflow prevention device faucet with hose attached and end in bucket of mop water**
 - Provision of Food Code: 5-203.14(B) Backflow Prevention Device, When Required
 - Correction: Attach a backflow preventer such as an atmospheric vacuum breaker when hose is attached to faucet and no control valve is present
 - Rationale: Mechanical atmospheric vacuum breaker prevents backflow of waste water into water supply

Example of Priority Item^P Violation

- **Direct connection between building sewer line and drain line of ice machine storage bin and 3-compartment sink**
 - Provision of Food Code: 5-402.11 Backflow Prevention
 - Correction: Provide an air gap on the drain line between the drain/waste line and the ice machine and 3-compartment sink
 - Rationale: Air gap prevents possible backflow of waste water into ice machine and 3-compartment sink

Example of Priority Item^P Violation

- **Cans of bug spray stored on shelf with bags of chocolate chips**
 - Provision of Food Code: 7-201.11(A) Separation
 - Correction: Separate toxic chemicals from food products
 - Rationale: Drillage of toxic insecticide could cross-contaminate food or food contact surfaces to cause illness, injury or death

Example of Priority Item^P Violation

- **The active chemical ingredient used in a commercially manufactured hard surface sanitizer is not listed in EPA's 40 CFR 180.940.**
 - Provision of Food Code: 7-204.11 Sanitizers, Criteria
 - Correction: Use only EPA registered chemical sanitizers with an EPA Registration number on the sanitizer container's label.
 - Rationale: EPA has not evaluated and approved the sanitizer as safe and effective for use



Priority Foundation Item Examples

Example of Priority Foundation Item^{Pf} Violation

- **No designated person in charge (PIC)**
 - Provision of Food Code: 2-101.11(A) Assignment
 - Correction: Identify a PIC during all hours of operation
 - Rationale: A PIC facilitates management control systems (monitoring, verification, training, etc.) that ensure Priority Items are in compliance

Example of Priority Foundation Item^{Pf} Violation

- **PIC does not monitor employees for necessary handwashing**
 - Provision of Food Code: 2-103.11(D) Person in Charge (Duties)
 - Correction: It is the PIC's duty to monitor employees for handwashing at appropriate times
 - Rationale: There is no management procedure to control (monitor and verify) employee handwashing to prevent fecal contamination of food

Example of Priority Foundation Item^{Pf} Violation

- **Employees are not trained in food safety practices related to their job duties**
 - Provision of Food Code: 2-103.11(L) Person in Charge (Duties)
 - Correction: Communicate and educate employees about food safety in their jobs
 - Rationale: Training facilitates employees' understanding and application of Priority Items as they perform their duties

Example of Priority Foundation Item^{Pf} Violation

- **Paper towel dispenser empty at kitchen hand sink**
 - Provision in Food Code: 6-301.12(A) Hand Drying Provision
 - Correction: Monitor and refill as necessary
 - Rationale: Sanitary paper towels enable employees to properly dry their hands after washing and prevent using clothing to dry them

Example of Priority Foundation Item^{Pf} Violation

- **Food for sale packaged or re-packaged in-house not labeled**
 - Provision in Food Code: 3-602.11(A) Food Labels
 - Correction: Label package with common name of product, ingredient statement, any major food allergens, quantity, place of business and other information as necessary (claims, etc.)
 - Rationale: Proper labeling enables consumers to make informed decisions about consumptions of that food

Example of Priority Foundation Item^{Pf} Violation

- **Last date that molluscan shellfish were sold/served was not written on the tag**
 - Provision of Food Code: 3-203.12(B) Shellstock, Maintaining Identification
 - Correction: Train employees of responsibility to put that date on the tag
 - Rationale: Writing this date on the tag facilitates a traceback investigation in case of a shellfish outbreak to prevent other shellfish from that harvest area being consumed

Example of Priority Foundation Item^{Pf} Violation

- **5 gallons of chicken stock in stock pot at 110°F cooling in walk-in cooler for 1 ½ hrs. (put in cooler at 135°F)**
 - Provision of Food Code: 3-501.15(A)(1) to (A)(7) Cooling Methods
 - Correction: Use an appropriate cooling method or combination of methods to cool PHF/TCS food within required criteria (including shallow pans, smaller portions, blast chiller, stirring, ice stick, ice bath, etc.)
 - Rationale: Specific cooling methods that enable rapid cooling would allow product to safely meet cooling parameters

Example of Priority Foundation Item^{Pf} Violation

- **No date marking system used on RTE, PHF/TCS food (leftovers, opened containers of commercially processed foods) in the facility**
 - Provision of Food Code: 3-501.17(A) RTE, PHF (TCS Food), Date Marking
 - Correction: Date mark RTE, PHF/TCS food (not exempted) held more than 24 hrs. to show when 7 day shelf life has expired
 - Rationale: Use of a date marking system enables PIC to discard or use RTE, PHF/TCS product before high levels of *Listeria* are present

Example of Priority Foundation Item^{Pf} Violation

- **Acidifying sushi rice (to pH 4.1) to hold at room temperature without a variance**
 - Provision of Food Code: 3-502.11(C)(2) Variance Requirement
 - Correction: Variance application with HACCP plan required to show food is non-PHF/non-TCS food
 - Rationale: A variance with HACCP plan and appropriate record keeping enables PIC to verify that acidification and any necessary corrective actions have occurred with rice held at room temperature

Example of Priority Foundation Item^{Pf} Violation

- **Hot water temperature gauge shows sanitizing rinse at manifold in the warewashing machine is 170°F**
 - Provision of Food Code: 4-501.112(A)(2)
Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures
 - Correction: Check booster heater and water heater are operating at high enough temperature that that the temperature gauge is accurate
 - Rationale: Monitoring temperature at the manifold facilitates trouble-shooting to verify effective sanitization is occurring at the utensil surface

Example of Priority Foundation Item^{Pf} Violation

- **No thin probe thermometer, thermistor or thermocouple available to check hamburger patty cook temperatures**
 - Provision of Food Code: 4-302.12(B) Food Temperature Measuring Devices
 - Correction: Provide thin probe temperature measuring device
 - Rationale: A thin probe allows verification of the final cook temperature that destroys pathogens

Example of Priority Foundation Item^{Pf} Violation

- **Drinking water from a restaurant's private well is tested every two years**
 - Provision of Food Code: 5-102.13 Sampling
 - Correction: Well water must be tested annually according to state water quality regulations
 - Rationale: Testing well water for quality standards at a sufficient frequency enables PIC to verify its potability

Example of Priority Foundation Item^{Pf} Violation

- **Hot water at handwashing sink is 80°F**
 - Provision in Food Code: 5-202.12(A)
Handwashing Sink, Installation
 - Correction: Adjust water heater, mixing valve, etc.
to provide 100°F water for handwashing
 - Rationale: Maintaining 100°F water for proper
handwashing facilitates optimum temperature for
use of soap and more effective removal of food
soils and pathogens from hands

Example of Priority Foundation Item^{Pf} Violation

- **No handwashing sink in food preparation and dispensing areas**
 - Provision of Food Code: 5-204.11 Handwashing Sinks
 - Correction: Install convenient handwashing sink in the areas
 - Rationale: Nearby handwashing sinks facilitate handwashing when necessary to remove pathogens and soil from hands

Example of Priority Foundation Item^{Pf} Violation

- **Evidence of mice with no pest control plan in place**
 - Provision of Food Code: 6-501.111(C) Controlling Pests
 - Correction: Implement a pest control plan such as seal entry holes, place traps, remove harborage, and routinely inspect for water and food sources, as well as presence of pests
 - Rationale: A pest control plan enables PIC to systematically rid establishment of pests which may carry disease –causing organisms to the facility

Example of Priority Foundation Item^{Pf} Violation

- **Unlabeled spray container of green liquid**
 - Provision of Food Code: 7-102.11 Common Name
 - Correction: Label working containers of poisonous or toxic chemicals such as cleaners
 - Rationale: Labeling working containers of cleaners prevent mix-ups with food products or the wrong chemical and accidental ingestion of chemicals that can cause illness, injury or death

Example of Priority Foundation Item^{Pf} Violation

- **Safe handling statement not placed on label of fresh meat or poultry packaged in a meat market**
 - Provision of Food Code: 3-201.11(F) Compliance with Food Law
 - Correction: Add the safe handling statement to each consumer sized package of raw meat or poultry
 - Rationale: Information on the Safe Handling Statement enables consumers to safely handle and prepare meat and poultry and avoid foodborne illness



Core Item Examples

Example of Core Item Violation

- **Cook not wearing an effective hair restraint**
 - Provision of Food Code: 2-402.11(A)
Effectiveness
 - Correction: Food employees should wear hat, cap, net or other effective hair restraint
 - Rationale: Hair restraints prevent hair from falling into food and keep employees from touching hair and scalp to reduce hands as a vehicle of cross-contamination

Example of Core Item Violation

■ **Cartons of food stored on the floor**

- Provision of Food Code: 3-305.11(A)(3) Food Storage
- Correction: Store food on shelves, pallets, etc. six inches off the floor
- Rationale: Storing food off the floor allows good sanitation practices such as sweeping, mopping, inspection for pests and protecting food containers from splash.

Example of Core Item Violation

- **No drain board on 3-compartment sink for dirty dishes/utensils and air drying dishes & utensils**
 - Provision of Food Code: 4-301.13 Drainboards
 - Correction: Add drain boards or use nearby tables, counters or carts for soiled and clean items
 - Rationale: Proper design with drain boards promotes proper dishwashing procedures and sanitization

Example of Core Item Violation

- **Heavy grease build-up on sides of fryers and grill**
 - Provision of Food Code: 4-601.11(C) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils
 - Correction: Set up a cleaning schedule to prevent build-up of grease
 - Rationale: Good sanitation practices prevent conditions that contribute to pest problems

Example of Core Item Violation

- **Cold water faucet in mop sink leaks**
 - Provision of Food Code: 5-205.15 System Maintained in Good Repair
 - Correction: Repair or replace faucet to prevent leaking
 - Rationale: Leaking faucet provides water source for pests and erodes fixtures

Example of Core Item Violation

- **Garbage dumpster lids open outside**
 - Provision of Food Code: 5-501.113(B) Covering Receptacles
 - Correction: Close lids of dumpsters, grease barrels and garbage cans after each use
 - Rationale: Leaving waste containers uncovered allows flies, rodents and birds access to garbage and creates a nuisance

Example of Core Item Violation

- **Broken and missing floor tiles in prep area and toilet room**
 - Provision of Food Code: 6-201.11 Floors, Walls, and Ceilings
 - Correction: Replace broken and missing floor tiles
 - Rationale: Floors in good repair allow easy cleaning and good sanitation practices

Example of Core Item Violation

- **Missing grease filter in ventilation hood above grill**
 - Provision of Food Code: 6-202.12 Heating, Ventilating, Air Conditioning System Vents
 - Correction: Replace missing grease filter or close open space with a metal spacer
 - Rationale: Closing all openings in hood with grease filters or spacers prevents grease build-up in ductwork, a fire hazard and food source for pests

Example of Core Item Violation

- **Open space (1/3 inch) under back delivery door.**
 - Provision of Food Code: 6-202.15(A)(3) Outer Openings, Protected
 - Correction: Close off space with weather stripping, threshold sill repair, etc.
 - Rationale: Tight fitting doors prevent entry of pests

Example of Core Item Violation

- **No area designated for employees' personal belongings**
 - Provision of Food Code: 6-403.11 Designated Areas
 - Correction: Identify lockers, specific area or room where employees can safely store their coats, shoes, street clothes, purses, etc.
 - Rationale: Street clothes can potentially contaminate food, utensils, single-service articles, etc. if not properly stored

Example of Core Item Violation

- **Food employee wearing a watch and decorative ring**
 - Provision of Food Code: 2-303.11 Prohibition
 - Correction: Jewelry, except a plain wedding band, should be removed
 - Rationale: Food debris can accumulate around and under jewelry without notice and is not easily cleaned

What should you do now?

Scenario #2

You (manager or inspector) open the door of a walk-in cooler. You look around and notice:

- Dirty fan guards and dirty shelves
- Broken light covers
- Dirty floors
- Raw chicken (dripping) stored above an uncovered container of salad dressing
- Many leftovers including two 3-gallon stock pots full of refried beans at 40°F on lower shelf – not date marked and not covered

What should you do now?

Scenario #2

- First, identify & rank the violations according to risk level (P, Pf or C):
 - Priority Items
 - Raw chicken dripping over salad dressing - 3-302.11(A)(1)(b)
 - Disposition of undate marked RTE, PHF/TCS food not date marked - 3-501.18)
 - Priority Foundation Items
 - Refried beans cooled in 3 gallon stock pots - 3-501.15(A)(1-7) (DISCUSS)
 - No date marking system used – 3-501.17(A)
 - Core
 - Dirty fan guards & shelves – 4-601.11(C)
 - Broken light shield – 6-202.11(A)
 - Uncovered food – 3-302.11(A)(4)
- Next, immediately correct P items, then Pf items, then C items as able
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

What should you do now?

Scenario #3

It is 10:30 am. You are inspecting a nursing home kitchen and the first lunch will be served at 11:15.

- You notice the cook taking a tightly covered pan (product 6” deep) out of the reach-in cooler. She goes straight to the steam table and places the pan in it. She reaches down and turns on the steam table. You discover the pan is Spanish rice that was made five days ago according to the tag.
- The cook has no thermometer and the thermostat dial on the steam table is broken.
- You also hear her say to another cook that she started running a fever this morning and her throat was sore.

What should you do now?

Scenario #3

- First, identify & rank violations according to risk level (P, Pf or C):
 - Priority Item
 - Cook has not reported fever & sore throat to PIC (exclude for HSP in nursing home, restrict for others) – 2-201.11(A)(1)(d)
 - Reheating Spanish rice (verify final reheated temp. reached 165°F in 2 hrs. or before service) – 3-403.11(A)
 - Priority Foundation Item
 - No thermometer to measure food temps – 4-302.12(A)
 - Spanish rice in 6” pans – 3-501.15(A)(1) (method unlikely to meet cooling parameters, need to verify procedure for cooling)
 - Core Item
 - Broken thermostat in steam table – 4-502.11(C)
- Immediately correct P items, then Pf items, then C items
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

What should you do now?

Scenario #4

You walk into a kitchen. This is what you see.

- The cook is mixing the slaw and dressing with his bare hands
- The back door is propped open so it will not close and there are a lot of flies inside the kitchen
- Several pans on the clean utensil rack are caked with dried food
- Cases of meat labeled “Keep Frozen” are setting on the floor and leaking
- Utensils are being washed in 3-compartment sink and chlorine sanitizer is available but not used
- There is no soap at the handwashing sink

What should I do now?

Scenario #4

- First, identify & rank violations according to risk level:
 - Priority Items
 - Mixing slaw with bare hands – 3-301.11(B)
 - No sanitizer used in 3-compartment sink – 4-701.11(C)(1)
 - Priority Foundation Items
 - No soap at handwashing sink – 6-301.11
 - Pans stored with dried food – 4-601.11(A)
 - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11(A)
 - Many flies, not using some method of fly control – 6-501.11(C)
 - Core Items
 - Cases of meat on floor – 3-305.11(A)(3)
 - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11
- Immediately correct P items, then Pf items, then C items
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

How to Use the Annexes

- **The Annexes are not requirements!**
- The Annexes are included to support you in your food safety mission:
 - To recognize common food safety hazards
 - To better communicate food safety messages
 - To promote correction and long term behavior change for poor food safety practices

How to Use the Annexes

- Each individual annex can be extracted and used as a separate training module for that purpose alone (food safety hazard recognition, communication, behavior)
- When a specific food safety problem persists, information in the Annexes may provide assistance in identifying antecedents (contributing factors) to the underlying cause of the problem
- The Annexes provide basic background information which regulators, operators and trainers can find useful for any food safety activity

Annex A

How can regulators, operators and trainers effectively change behavior?

Effective Behavior Change

- Correcting violations without behavior change will result in the same repeated violations
- **Training by itself does not always lead to improved behaviors**
- We must create a culture where everyone knows:
 - Food safety is a **priority**
 - Their personal **responsibility** for food safety
 - Which of their activities, if done incorrectly (Priority Item violations), can result in foodborne illness or injury

A Food Safety Culture

- PICs and Regulators need to have established policies, standards and procedures for food safety
 - the food safety message must be uniform and consistent
 - Priority Items listed in the Food Code can provide that uniformity
- PICs should explain these expectations to employees as it relates to their specific job duties
- PICs and Regulators must hold employees accountable
 - Managers must monitor for expected performance
 - Immediate correction must be done when not in compliance
 - Retraining should be done as necessary
 - Known consequences must be carried out

Regulatory Inspections

- Uniform, consistent inspections should be made based on P, Pf and C Items in the 2009 Food Code
- Knowledgeable and skilled inspectors can request immediate correction for P Items, explain, demonstrate or provide options to encourage behavior change
 - Developing risk control plans (who, what, when, where, why) for P Items encourages long term correction
- Focus on risk factors (P Items) for foodborne illness demonstrates their importance

A Food Safety Culture

- Managers should serve as good role models, especially for Priority code provisions
 - Otherwise: **“If you don’t do it, I don’t do it.”**
- Managers should provide education and training for all employees – now is the time to explain that food safety and protection of their customers is a high priority
- Managers should reinforce positive behaviors
 - Give positive feedback

Education and Training

- Certified food safety managers should be knowledgeable and do the following:
 - Provide initial orientation and on-going refresher training related to their job duties
 - Explain why a particular behavior is necessary
 - Explain the food safety reason for requirements – that people can become ill or injured if things go wrong
 - Make it personal – they/their family can get sick, customers can get sick, job/business loss
 - Include personal testimonials, stories, etc.

Education and Training

- The Instructor/Manager should demonstrate the correct way of doing the task from the beginning
- Hands on training works best (coaching)
- Try different approaches and allow individual to choose option they prefer (for better buy-in)

Education and Training

- Management should remove barriers to learning
 - Provide time (on the clock) for training
 - Provide training in appropriate language, using familiar words and examples
 - Provide necessary resources
 - Computer for on-line training
 - Trainer and training materials
 - Supplies, utensils, equipment to carry out the task

Education and Training

- Training should be reinforced
 - Use posters, signs, pamphlets, wallet cards, etc.
 - Provide on-line or face-to-face updates
 - Give reminders during work – “teaching moments”
 - Use novelty to create renewed interest

Incentives Provide Motivation

- Management should consider rewards and the use of positive motivation
 - Recognition – awards, win a contest, media mention, ceremonies
 - Things – tickets, free meal, branded items, etc.
 - Praise – “Good Job!”, certificates
 - Money – prizes, job promotion, cash awards

Incentives Provide Motivation

- Sometimes negative consequences follow poor food safety practices:
 - Re-training
 - Warnings
 - Time-off
 - Loss of job

Annex B

What are some communication techniques to help convey our messages of food safety?

Food Workers as Oral Culture Learners

- Effective communication is necessary to get your message across
- Inspectors and QA staff are usually print culture learners
 - They read for primary information
 - They have linear, analytical thoughts, are task oriented and able to strategize
- Food workers are often oral culture learners
 - Most workers like to give and receive information verbally
 - Workers are less likely to follow rules made by someone they do not know or trust

Oral Culture Learners

- Verbal information, repeated regularly and reinforced with signs, posters, handouts is an effective way to communicate
 - Fewer words and more pictures is better
- Storytelling is an important method of getting information for oral culture communicators
- Many owner/managers think employees should read food safety rules to learn
 - This thinking reveals a lack of understanding of how oral culture communicators learn and process information

Effective Communication

- Communication has to be 2-way to be effective
 - Explain/demonstrate the issue and have it explained/demonstrated back to you
 - Hands on training reinforces explanation
 - Feedback that they are “doing it right” is important
 - Oral culture communicators require interaction to internalize knowledge and change behavior
 - Active listening skills help pinpoint misunderstanding or lack of understanding
 - There is no other way to know if their communication was effective or even heard
 - This promotes joint problem solving

Communication by Behavior

- Effective communication shapes behavior
- We want to change unsafe food behavior and attitudes that disregard food safety processes
- 80-90% of what we communicate is by non-verbal behavior rather than by what we say
- Doing and correctly practicing the behavior internalizes the information communicated
- It is important for regulators, operators and trainers to consider different methods and their appropriateness to communicate risk and change poor behavior.

Communication by Behavior

- Correct behavior is often not modeled by management
 - **“Do as I say, not as I do”** doesn't work
 - Role models (managers, co-workers, inspectors) are important
- Correct behavior is often not a priority
 - **“If it's not important to you, it's not important to me”**

Use Plain Language

- Use “I,” “you” and “we” and avoid “it”
- Use short sentences, limit subjects to one per sentence
- Use vertical lists with parallel construction
- Avoid technical and legal jargon or “big words”
- Use terms listeners or employees are familiar with
- Make factual statements and avoid subjective statements that imply judgment

Communication

- Pertinence to job duties
 - People learn if they understand the importance of their job behavior
 - Communication is best understood when it is personal
 - Related to assigned job duties
 - Described with vivid, real-life examples
 - Connected to their own family, health and well being

Communication

- General statements may not be considered relevant to the job – be specific
 - Why is something important?
 - What is the right way to do it?
 - Can the right way be demonstrated?
- Provide options/examples that are specific to that job
 - Use easily available equipment, utensils or materials
 - Give employees a choice and ask which one they prefer
 - Ask employees to try it out

What doesn't work well?

- Presenting all training in written form such as signs, pamphlets, on-line computer training, handout materials
- Using examples that aren't related to their job duties
- Using negative reinforcement (by itself)
- Saying something only once
- Using unfamiliar language or terminology

Annex C

What are common food safety hazards?

Biological, Chemical & Physical Hazards in Food

- **Each provision in the Food Code is intended to prevent, eliminate, reduce to an acceptable level or control hazards that could directly or indirectly contribute to a foodborne illness or injury**
- A hazard is a biological, chemical or physical property or agent that may cause an unacceptable consumer health risk
- A hazard must be identified as the first step in conducting a risk assessment

Biological Hazards

- Biological hazards consist of microbiological pathogens, including:
 - Spore-forming bacteria
 - Vegetative bacteria
 - Viruses
 - Parasites
- Most yeast and molds are spoilage organisms and do not cause illness or injury

New Foodborne Pathogens Identified Since 1977

More than 70 foodborne pathogens are known with the following added to the list since 1977

Campylobacter jejuni

Cryptosporidium parvum

Shiga-toxin producing *E. coli*

Noroviruses

Vibrio vulnificus

Yersinia enterocolitica

Salmonella Typhimurium DT 104

Spongiform encephalopathy prions

Campylobacter fetus ssp. Fetus

Cyclospora cayentanensis

Listeria monocytogenes

Salmonella Enteritidis

Vibrio cholerae 0139

Vibrio parahaemolyticus

Controls for Biological Hazards

- Provisions in the Food Code control biological hazards by eliminating, preventing, and/or reducing to acceptable levels or holding numbers unchanged by:

Cooking, pasteurization

Retorting

pH/acidity

Water activity

Competing organisms

Bacteriocins, nisin

Preservatives

Hot holding

Cooling

Refrigeration

Sanitizers

Fermentation

Irradiation

High pressure

Nitrites, nitrates

Spore-Forming Bacteria

- *Clostridium botulinum*, *Clostridium perfringens*, *Bacillus cereus*
- Spores are able to survive cooking & other adverse conditions
- Spores do not multiply in this form so require no nutrients, water, etc. to survive
- Spores germinate & start to multiply when conditions are right – best control at this stage to prevent growth
- Retort processing (high temp & pressure) is necessary to destroy spores
- Toxins form after germination when the spore is actively growing

Vegetative Bacteria

- The growth phase of spore-forming and non spore-forming bacteria
- Nutrients, water and adequate environmental conditions (pH, a_w , temperature, etc.) are necessary for growth
- May form toxins in food or in the body
- Susceptible to cooking and many other environmental factors on a case-by-case basis
- Controlled by refrigeration although some vegetative bacteria can multiply slowly at refrigeration temperatures (e.g., *Listeria*, non-proteolytic *Clostridium botulinum*)

Viruses

- Viruses are pathogens which cannot multiply outside of a living cell
- Norovirus, hepatitis A and rotavirus are the most common foodborne viruses
- Infected human beings (not animals) are the usual source
- Preventing contamination (exclude infected workers, handwashing, no hand contact) and thorough cooking control viruses
- Viruses are very heat resistant

Typical Sources of Biological Hazards

- Field and farm crops – soil, birds, other infected animals, failed septic systems, sludge and bio-solids contaminate food products
- Animals – manure, slaughtering process (skin, intestinal tract), service animals, pets and petting zoos contaminate food
- Fish and seafood – marine bacteria, histamine producing bacteria and fish parasites contaminate food

Typical Sources of Biological Hazards

- Infected workers – fecal material, vomitus, nasal discharge, coughing, sneezing and pus from infected lesions
- Cross-contamination from other sources during transport and storage
- Contaminated equipment, utensils and surfaces
- Water – irrigation, contaminated well water or ice, water main break, backflow or back siphonage

Characteristics of Pathogens

- Infectivity – potential or ease of transfer, infectious dose
- Severity – virulence of the pathogen, length & severity of illness, hospitalization or death
- Spore formers/vegetative cells – ability to survive adverse conditions
- Acid resistance – susceptibility to pH
- Heat resistance – ability to survive cooking
- Biofilm formation – ability to form a protective polysaccharide covering resistant to cleaning & sanitizing
- Association with certain foods – SE with eggs, *E. coli* O157:H7 in meat, cider, etc.

Clostridium botulinum

Minimal growth requirement for *C. botulinum*

<u>Property</u>	<u>Group I</u>	<u>Group II</u>
	Proteolytic	Non-Proteolytic
	Type A, B, F	Type B, F, E
Inhibitory pH	4.6	5.0
Inhibitory NaCl	10%	5%
Minimum a_w	0.94	0.97
Temp. optimum	98°F	86°F
Temp. range	50 -118°F	38 -113°F
Toxin production	$\geq 50^\circ\text{F}$	$\geq 38^\circ\text{F}$

Clostridium botulinum

- *C. botulinum* is an obligate anaerobe, spore-former, common in soil & aquatic environments (salt and fresh water)
 - Proteolytic *C. bot* – more pH & salt resistant, more resistant to low a_w , only grows & produces toxin down to 50°F
 - Non-proteolytic *C. bot* – less pH & salt resistant, less able to grow at low a_w , can grow and produce toxin down to 38°F
- Preformed toxin is heat labile (boiling 10 min.)
- Improper canning, retorting and reduced oxygen packaging (ROP) are risks

Clostridium perfringens

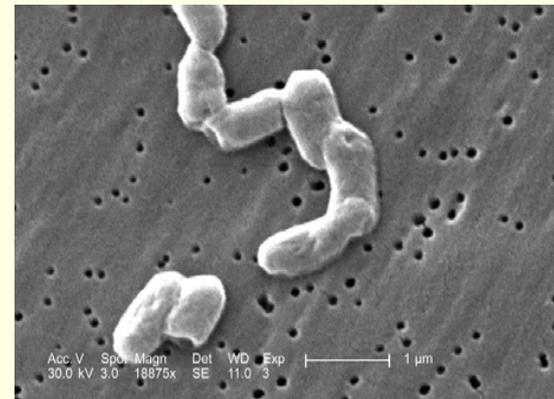
- *C. perfringens* is an anaerobic spore-former found in humans, animals, soil and vegetation
- Cooking heat shocks spores
- Generation time can be 8 minutes starting at 122 - 127°F
- Contributing factors for illness include:
 - Slow cooling (allows germination of spores)
 - Inadequate refrigeration (allows growth of cells)
 - Inadequate reheating (allows survival of cells)
- Vegetative cells sporulate (return to spore form) in gut and release toxin
- Large numbers of cells ($\geq 10^5$) are required to cause illness

Bacillus cereus

- *B. cereus* is an aerobic spore-former
- Spores are ubiquitous in the soil & environment
- 2 types of toxins can be formed:
 - Emetic is heat stable, formed in food
 - Diarrheal is heat labile, formed in intestine
- Slow cooling and inadequate refrigeration allow spore germination and growth to high numbers
- Toxin is not produced at temperatures < 50°F
- $10^5 - 10^6$ cells needed to produce toxin

Salmonella Spp.

- Commensal organism in the lower gut of mammals
- High survival rate in the environment (up to several months)
- More than 2000 species of *Salmonella* are known
- Relatively heat tolerant
- Infected food workers, poor handwashing, hand contact, and cross-contamination are contributing factors to illness
- *Salmonella* is invasive in the gut and causes systemic infections



Escherichia coli O157:H7

- Cattle and other animals are reservoirs
- Survives well in the environment
- Forms biofilms resistant to washing and sanitizing
- pH resistant
- Transmitted mainly through the ingestion of food contaminated with ruminant feces



Escherichia coli O157:H7

- Inadequate cooking and cross-contamination of RTE food are contributing factors
- Shiga-toxin produced in the gut is absorbed into the blood stream
- Damages small blood vessels
 - Leading to bloody diarrhea, kidney failure and death
 - Causes 90% of diarrhea and associated HUS



Staphylococcus aureus

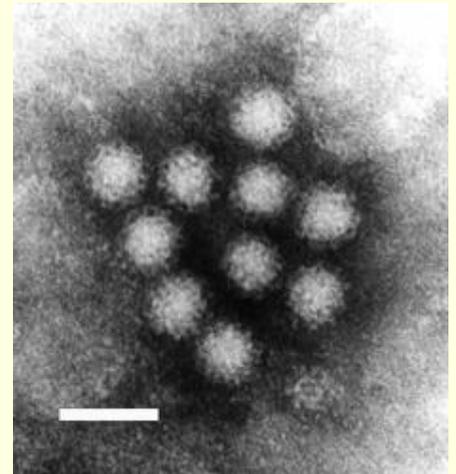
- People are carriers (skin, nasal passages, infected lesions) as well as dogs, fowl, cows with infected udders
- Non spore-former produces toxin at a_w too low for competing bacteria
 - Growth at $a_w = 0.83$,
 - Toxin production requires $10^6 - 10^7$ CFU/g
 - Toxin produced at $a_w = 0.88$
 - Pre-formed toxin produced in food
- Reheating destroys cells but toxin is heat stable
- Food likely to be contaminated by hand contact with RTE food and infected lesions

Listeria monocytogenes (Lm)

- *Listeria* is ubiquitous in the environment
- Lm forms biofilms resistant to washing & sanitizing in high moisture niches
- Lm multiplies slowly at refrigeration temperatures down to 32°F
- Controls include addition of listeriocides to food, short shelf life (datemarking), preventing contamination from the environment, refrigeration, cooking, adequate cleaning & sanitizing
- Fetuses (miscarriages), babies, pregnant women and the elderly are particularly susceptible – high case fatality rate

Norovirus (NOV)

- Human beings are the reservoir for NOV
- Norovirus is reported as the single most common cause of gastroenteritis in the western world
- NOV is transmitted by:
 - Fecal-oral route (through food)
 - Inhalation (breathing vomitus droplets)
 - Person-to-person (touching someone contaminated)
 - Environment to person (touching contaminated surfaces)

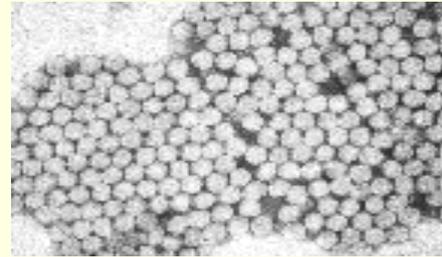


Norovirus

- NOV infectious dose is 1 particle (a cluster of 200-300 viruses), highly infectious
- $10^9 - 10^{10}$ particles/g feces (the size of the tip of a fingernail)
- NOV is highly resistant to disinfectants
- Projectile vomiting or diarrhea episode
 - Needs to be contained (covered)
 - Then double wash and disinfect surfaces
 - Discard protective clothing and cleaning materials
- Virus survives in environment hours to days

Hepatitis A (HAV)

- HAV is spread from human beings through:
 - Contaminated sewage in wells, seafood harvest areas, recreational waters
 - Fecal-oral route (contaminated food)
 - Person to person
- HAV is shed at 10^8 viral particles /g feces
- Shed in feces midway through incubation period before symptoms appear
- Symptoms can last 6-9 months
- Controls are handwashing, no bare hand contact with RTE foods, exclusion with jaundice, shellfish certification & tag retention for 90 days



Parasites

- *Anisakis*

- The motile larval stage burrows into the stomach walls
- Infection caused by eating raw or undertreated marine fish

- *Cryptosporidium parvum*

- Infects 45 different species besides man
- Oocysts (infective stage) often associated with contaminated drinking & recreational water
- Oocysts are highly resistant to disinfection

Parasites

- ***Cyclospora cayentanensis***

- Oocysts are infective
- Often found in contaminated water

- ***Giardia lamblia***

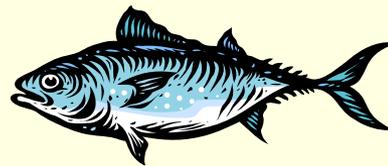
- Reservoir is human beings & wild animals
- Protozoan cysts & trophozoites shed in feces
- Often associated with contaminated water or person-to-person transfer in day cares

Chemical Hazards

- A chemical hazard may be naturally occurring or may be added during processing or preparation
- Normal cleaners, sanitizers and other chemicals used in a facility may be a food hazard
- Scombrototoxin (histamine poisoning)
 - Formed by bacteria that convert histidine to histamine
 - Found in tuna, mackerel, skipjack, bonito, mahi mahi, blue fish and certain cheeses
 - Temperature abuse allows bacterial growth and histamine formation

Chemical Hazards

- Ciguatoxin
 - Found in tropical reef fish (i.e., barracuda, a predator fish)
 - Dinoflagellates and algae that produce the toxin are consumed by fish
 - Causes temperature reversal (hot ↔ cold) and other neurological symptoms, often for years



Chemical Hazards

- Tetrodotoxin
 - Certain fish (e.g., puffer fish, fugu, blow fish) produce toxin in their skin and viscera
 - Tetrodotoxin is heat stable – cooking will not destroy
- Aflatoxin
 - Mycotoxin produced in corn, nuts and other grains
- Patulin
 - Mycotoxin produced in rotten apples
 - Not destroyed by pasteurization or cooking

Chemical Hazards

- Monitoring shellfish harvest areas for certain phytoplankton prevents shellfish poisoning
- Common shellfish poisoning includes:
 - Paralytic shellfish poisoning (PSP)
 - Molluscan shellfish, lobster and crab concentrate saxitoxin from certain dinoflagellates (“red tide”)
 - From a heat stable toxin
 - Flushed from animal within weeks

Chemical Hazards

- Common shellfish poisoning includes:
 - Diarrhetic shellfish poisoning (DSP)
 - Molluscan shellfish concentrate toxins from certain dinoflagellates
 - Heat stable toxin
 - Neurotoxin shellfish poisoning (NSP)
 - Molluscan shellfish concentrate brinetoxins from algal blooms
 - Toxic to fish, birds and sea mammals too

Chemical Hazards

- Common shellfish poisoning includes:
 - Amnesic shellfish poisoning (ASP)
 - Shellfish, Dungeness crabs and anchovies concentrate domoic acid produced by a diatom
 - Produces short term memory loss
- Toxic mushroom species – False morels, Little Brown Mushrooms, Jack-O’-Lantern, Green-Spored Lepiota, Deathcap, Death Angel
- Toxic plant species – Belladonna, bloodroot, buckeyes, castor bean, foxglove, hemlock, holly berries, Lily of the Valley, mandrake, May apple, mistletoe, rhubarb leaves, snakeroot

Physical Hazards

- Illness and injury can result from foreign objects in food including:
 - Glass – from lights, bottles and jars, utensils, gauge covers
 - Wood – from fields, pallets, boxes, buildings
 - Stones, metal fragments – from fields, buildings, machinery, wire
 - Bone – from improper plant processing
 - Plastic – from packaging materials, pallets
 - Personal effects – jewelry, buttons, bandaids, etc.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 024
Issue: 2010 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:

Criticality Implementation&Education Committee- Criticality Training Slides

Issue you would like the Conference to consider:

The Criticality Implementation and Education Committee requests that the Conference for Food Protection (Conference) accept the PowerPoint presentation 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. Further, the committee recommends that the Conference send a letter to FDA requesting the same presentation be made available on the FDA web site.

Public Health Significance:

The Criticality Implementation and Education Committee acknowledges that extensive training will be necessary for successful implementation of the re-designation of the 2009 Food Code provisions from two to three risk-based priority designations. Therefore, a PowerPoint training tool, complete with speaker's notes, has been prepared by the committee. Providing workable and readily available training tools is a value for all public health stakeholders and should be shared in many venues. It is advantageous for trainers of any organization to be able to fully utilize training materials for a varied audience.

Recommended Solution: The Conference recommends...:

1. 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.
2. That a letter be sent to FDA requesting the same PowerPoint presentation and speaker notes be made available through its web site.

Submitter Information:

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Attachments:

- ""Re-designation of Food Code Provisions" PowerPoint Slides and Speaker Note"

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.

Re-designation of Food Code Provisions

By the 2008-2010 CFP Criticality
Implementation and Education Committee

Objectives of Criticality Implementation Training

- #1 – Explain the **three new definitions** and the **risk assessment process** used to define the level of risk of Food Code provisions and their relationship to preventing foodborne illness.
- #2 – Provide clear and concise **training** for regulators, operators and trainers in restaurants, retail food stores, institutions and vending with examples and how to communicate this information in an effort to reduce the incidence of foodborne illness and injury

Objectives of Criticality Implementation Training

- #3 – **Increase awareness and understanding of the changes** in compliance and enforcement sections of the Food Code related to the re-designated provisions
- #4 – Give different examples of where and how to **apply the new designations** of Food Code provisions in routine activities to achieve long term behavior change, including in training, active managerial control and inspections

Introduction to Re-Designated Food Code Provisions - History

- The usual inspection/enforcement system in a food establishment emphasizes reactive, rather than preventive measures for food safety
- Additional measures must be taken by operators and regulators to better prevent, eliminate or reduce the occurrence of foodborne illness and injury **before it occurs**
- The re-designated provisions focus attention on the level of risk for foodborne illness or injury for any violation in the Food Code

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The new system of designating the provisions of the Food Code according to the level of risk of causing foodborne illness or injury will help focus attention so operators, regulators and trainers prevent rather than react to a foodborne illness or injury.

History of Changes

- Issues were submitted to CFP since 2000 to remove “critical” and “non-critical” designations of Food Code provisions and replace them
 - “Critical item” was defined as a provision of this Code, that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard.
 - There was misunderstanding about critical items being connected to HACCP
- 11 issues, 3 committees and 1 work group were established to work on the charges
 - In 2004, CFP charged FDA to develop alternative terms

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Members of the Conference for Food Protection have tried since 2000 to remove the terms “critical” and “non-critical” as code provision descriptors. The main reason appeared to be a misunderstanding that “critical” was related to HACCP (as in critical control point or critical limit). The definition of “critical item” was also considered to be a little unclear. More information about the issues that were submitted and the results of the Committees and work groups that considered the issues can be found at CFP’s website, <http://www.foodprotect.org> under Previous Biennial Meetings.

History of Changes

- In 2008, FDA submitted a 3-tiered set of definitions to CFP to rank Food Code provisions by risk
- The definitions were used with a qualitative risk assessment process to rank the Food Code provisions by their risk (high, medium or low risk) of causing foodborne illness or injury
- The re-designated terms were incorporated into the 2009 Food Code

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In 2008, FDA submitted a new 3-tiered set of definitions along with a qualitative risk assessment in response to a charge from CFP in 2004 and 2006. The new designation system for the provisions in the Food Code were based on risk of foodborne illness or injury.

This was a 4 year process where FDA's work group collaborated with the CFP Critical Items Committee, as CFP stakeholders, to develop the process and re-designations.

While there was some disagreement over the name of the designated terms used in the risk assessment, there was good agreement on the process itself. Neither the present committee nor the CFP Executive board were able to come to a full consensus on new terms. Therefore, FDA used the original terms as submitted to the Conference in 2008 to amend the 2009 Food Code.

New Definition of Priority Item

- **“Priority Item”**
 - **“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.
 - **“Priority item”** includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
 - **“Priority item”** is an item that is denoted in this Code with a superscript – ^P.

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Note in the “Priority Item” definition:

- These provisions contribute directly to the elimination, prevention or reduction to an acceptable level, hazards (or agents) associated with foodborne illness or injury.
- A test to determine if this is a Priority Item or not is to ask if there is another provision that more directly controls the identified hazards).
- Priority items always have a quantifiable measure (or critical limit) that will indicate control of the hazards.
 - Examples are time/temperature parameters, chemical concentrations, presence/absence, etc.

Priority Item^P

- When a Priority Item in the Food Code is out of compliance, it has the highest risk of causing foodborne illness or injury
- Compliance with a Priority Item eliminates, prevents or reduces to an acceptable level, biological, chemical or physical hazards that **directly** cause foodborne illness or injury (see Annex C – What are common food safety hazards?)
- No other provision more directly controls the hazard
- There is a **quantifiable measure or critical limit** for each Priority Item
- The term Priority Item implies an importance and need for immediate correction.



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Note that a Priority Item directly controls a hazard

•It is designated by a superscript P in the Code.

•Annex C, “What are common food safety hazards?” provides introductory information about hazards that the Food Code provisions are designed to control, either directly or indirectly.

New Definition of Priority Foundation Item

- **“Priority Foundation Item”**
 - **“Priority foundation item”** means a provision in this Code whose application supports, facilitates or enables one or more Priority Items.
 - **“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
 - **Priority foundation Item”** is an item that is denoted in this Code with a superscript Pf – ^{Pf}.

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The second defined term is a “Priority Foundation Item”

- A Priority Foundation Item when applied, supports, facilitates or enables a Priority Item
- These provisions are usually actions, equipment or procedures that help or support the control of a hazard by a Priority Item
- A provision is designated by a Pf in the Code.

Priority Foundation Item^{Pf}

- A Priority Foundation Item is usually linked to a Priority Item and supports, enables or helps achieve it
- Active managerial control/industry control systems support the compliance of Priority Items, such as:
 - Conducting personnel training (See Annex A&B)
 - Monitoring and enforcing Priority activities
 - Providing necessary equipment, facilities, etc. to carry out Priority activities
 - Developing & carrying out HACCP plans when necessary
 - Maintaining documents or records as necessary
 - Labeling food for employees or consumers
- The term Priority Foundation links the provision to a Priority Item

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•There is usually a clear link between a Pf and P Item so the Pf Item supports or enables the P Item.

•Using Pf items, industry control systems or active managerial control can support the compliance of P Items.

•Annex A, “How can regulators, operators, and trainers effectively change behavior?” and Annex B, “What are some communication techniques to help convey our messages of food safety?” can assist us achieve more effective training.

•Policies, procedures, documentation, HACCP plans (if required), labeling, equipment, infrastructure, etc. provide a foundation for achieving a Priority Item.

New Definition of Core Item

- **“Core Item”**
 - **“Core item”** means a provision in this Code that is not designated as a Priority Item or a Priority Foundation Item.
 - **“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.

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A Core Item is usually a general provision that is not directly related to a specific Priority Item but rather to the entire facility.

General sanitation, SSOPs, facility or equipment design and construction, and general maintenance are examples of Core Items.

A Core Item has no specific superscript designation in the Code.

Core Item

- A Core Items is a good retail practice (GRP) which is not intended to control a particular hazard but hazards in general
- A Core Item has no superscript in the Food Code
- Core Items include:
 - General sanitation requirements
 - Sanitation Standard Operating Procedures (SSOPs)
 - Equipment design
 - Design & construction of facilities and structures
 - General maintenance & repair
 - Operational controls

Relationship between Priority Items and Imminent Health Hazards

- **Imminent health hazard:**
 - A significant threat in an entire establishment that may endanger the public health which requires the operation to cease operation if immediate correction is not possible and to notify the RA
 - Priority Items such as smoke or fire damage, flood, extended electrical or water outage, extended lack of hot water, sewage back-up, foodborne outbreaks, misuse of toxic substances, gross insanitary condition, etc.
- **Not all Priority Item violations are imminent health hazards**, only those that affect the operation of the entire establishment or a large part of that operation

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- The Food Code in Section 8-404.11 calls for an Operator to cease operation and report to the Regulatory Authority in case of an imminent health hazard because of an emergency situation.
- An imminent health hazard is a significant threat to public health in the entire establishment and requires the facility to cease operation if immediate correction is not possible.
- The emergency is usually directly related to Priority Items such as”
 - floods,
 - Extensive smoke or fire damage
 - Extended electrical or water outage
 - Extended lack of hot water
 - Sewage backup
 - Foodborne outbreak
 - Misuse of toxic substances (i.e., pesticides)
 - Gross insanitary conditions
- Note that not all Priority Item violations are imminent health hazards, only those that affect the entire establishment operation.
- Note also that often corrective actions can be taken in a short time, i.e., a few hours, to resolve the situation. The situation should be reported to the Regulatory Authority to work out what would be acceptable to continue operating. For example, bottled water could be used for a short time before repairs when a water main breaks or heating water for washing hands and using single-service items could be done when the hot water heater breaks down but can be replaced soon.

Qualitative Risk Assessment Process

- A qualitative risk assessment is used to rank risk of foodborne illness or injury in very complex situations such as a food service/food store or provisions in the Food Code
- A qualitative risk assessment process considers:
 - The likelihood of causing foodborne illness or injury
 - The characteristics of the hazard (virulence and severity)
 - The size and/or number of outbreaks (infectivity or potential for illness or injury)
 - Any contributing factors (contamination, proliferation or survival) identified in previous foodborne outbreaks reported to CDC

What does this change to a risk assessment process mean to me?

- Food Code provisions are prioritized according to their risk of causing foodborne illness or injury (P, Pf or C)
- Using science-based reasoning for the new terms promotes:
 - Internal consistency in the Food Code
 - Objective, not subjective designations
- For further explanation of the ranking process, see:
 - Risk assessment decision making process
 - Public Health Reasons, Annex 3 of the Food Code
 - Published references in the Excel spreadsheet and Annex 2 of the Food Code, available at:
 - <http://fda.gov/Food/FoodSafety/RetailFoodProtection.default.htm>

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- This is a change from critical and non-critical, often difficult to categorize, to a risk-based system that prioritizes enforceable Food Code provisions.
- This is done by ranking the provisions as Priority (P), Priority Foundation (Pf), or Core (C) according to the risk of causing foodborne illness if the provisions are uncontrolled (Out of Compliance)
- The risk assessment process with definitions provides a scientific decision making process for ranking the provisions.
- Annex 2 and 3 of the 2009 Food Code provide additional information about the ranking process.

What does this change to a risk assessment process mean to me?

- It is possible to prioritize operational and regulatory food safety activities according to the level of risk provided by that violation
 - Priority Item – highest risk, direct connection to foodborne illness or injury
 - Priority Foundation Item – supports one or more Priority Items
 - Core Item – lowest risk, general good practices
- There is a recognized critical limit (quantifiable measure) to show compliance with the highest risk priority items

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•Because the provisions have already been ranked according to their level of risk, operators and regulators can use the ranking (P, Pf, or C) to prioritize their food safety activities.

•When a Food Code provision contains a quantifiable measure or critical limit, that usually means it is a P item.

Risk Assessment Process

- The risk assessment process starts by identifying the food safety hazard(s) each provision in the Code will control
- Biological Hazards* include, for example:



- Vegetative bacteria



- Spore-forming bacteria



- Viruses



- Parasites

*** See Annex C for more examples and explanations of hazards in foods**

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- The decision-making process in assigning a risk level to a provision first starts with identifying a food safety hazard(s) that is typically controlled by that provision.
- Biological hazards that may be controlled by a provision include some or all of the following:
 - Vegetative and spore-forming bacteria, viruses and parasites
 - Annex C, “What are common food safety hazards?” contains additional information about the hazards that may be controlled by that provision. The slides can also be used as a stand-alone training course.

Risk Assessment Process

- Chemical hazards* include, for example:



- General chemical contamination (cleaning compounds, sanitizers, allergens, additives)



- Scombroid toxin (*B. proteus* breaks histadine down to histamine in certain temperature-abused fish)
- Ciguatera toxin (natural toxin in reef-fish)

*** See Annex C for more examples and explanations of hazards in foods**

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- Chemical hazards that are controlled by particular Food Code provisions include:
 - Common chemicals used in a food establishment (cleaners, sanitizers, allergens, additives, etc.)
 - Scombrototoxin (histamine) poisoning from certain temperature abused fish.
 - Ciguatera and other phytotoxins that are contained in dinoflagellates and other microscopic plants that are consumed by fish.

Risk Assessment Process

- Physical hazards* include, for example:



Bone



Metal fragments

Bandage

Jewelry



Hair



* See Annex C for more examples and explanations of hazards in foods

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•Physical hazards in food which must be controlled include:

•Non-food items such as bone, metal, glass, bandages, hair and more.

Risk Assessment Process

Initial Evaluation

- After identifying the hazard associated with that provision, determine which of the 3 defined terms (P, Pf or C) most clearly describes this provision, e.g.,
 - Cook poultry to 165°F for 15 sec. (CL) destroys vegetative pathogens (Priority Item)
 - No date marking system used on RTE potentially hazardous/TCS food to limit shelf life and control *Listeria* (Priority foundation Item)
 - Floor in grill area dirty – general sanitation (Core Item)

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- Make an initial determination of the provision designation by considering the hazard, which of the 3 definitions most likely applies and whether there is a quantifiable measure (something measurable).
- If the initial choice is P, ask whether there is another provision that more directly controls the hazard. If so, the provision may not be a P but will probably be a Pf.

Risk Assessment Process

Other Characteristics

- Determine if other characteristics of the hazard increase the risk:
 - Virulence where hazard has severe consequences - HIGH
 - high potential by ill food worker to spread hazard to food or patrons
 - more than one mode of transmissions (ingestion, inhalation, person-to-person)
 - shed at high levels (i.e., norovirus)
 - extremely virulent
 - low infectious dose (i.e., *Listeria monocytogenes*)
 - potential for secondary infection (e.g., Norovirus, *Shigella* spp., *E. coli* O157:H7)
 - extremely toxic chemical or natural toxin (i.e., *Clostridium botulinum*)
 - high incidence of hospitalization and death, (e.g., *Clostridium botulinum*, *Listeria monocytogenes*)
 - chronic sequelae possible (*E. coli* O157:H7, *Salmonella* spp., parasites)

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•Once the initial determination has been made, the consideration of other factors in conjunction with the definitions confirm or change the designation.

•Virulence or severity of the hazard's effect is controlled by the provision under consideration.

•For example, a highly virulent hazard controlled directly by a provision confirmed the provision as a Priority Item.

•The virulence of the controlled hazard can also indicate the priority of attention that provision should receive, that is, the more virulent a pathogen is that is being controlled, the greater attention it should receive.

Risk Assessment Process

Other Characteristics

- Assess characteristics of the hazard:
 - Virulence or severity of hazard - MEDIUM:
 - medium potential for ill food worker to spread hazard to food or patrons
 - medium infectious dose
 - unlikely secondary infection
 - high incidence of hospitalization but few deaths

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•A medium severity for a particular hazard may change the immediacy of corrective action compared to a highly virulent hazard but will not change the fact, for example, that a provision is a Priority Item and directly related to causing foodborne illness.

Risk Assessment Process (cont'd.)

- Assess characteristics of hazard:
 - Virulence or severity of hazard - LOW:
 - low potential for ill food worker to spread hazard to food or patrons
 - low infectious rate
 - unlikely secondary infection (e.g., *Clostridium perfringens*, *Bacillus cereus*)
 - high incidence of illness but low incidence of hospitalization or death
 - mild symptoms
 - short duration

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•A low severity of the hazard associated with that provision does not usually change the designation (P, Pf or C) but may affect the order of response when other violations of the same designation are present.

Risk Assessment Process

Other Characteristics

- Assess size & number of outbreaks based on infectivity of the hazard in the absence of control provided by the Code:
 - **High** – large outbreaks, large number of outbreaks
 - **Medium** – small outbreaks, small number of outbreaks
 - **Low** – individual cases, sporadic cases

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•Infectivity of the hazard does not change the designation, e.g., P, Pf or C. That is based on the definition.

•Infectivity of a biological hazards often has an impact on the number of people involved in an outbreak.

•Norovirus is a good example. This virus is highly infective and often causes large outbreaks, therefore infectivity will be high.

•C. botulinum does not cause large numbers of ill or large numbers of outbreaks but it is highly virulent (the symptoms of botulism are very severe).

Risk Assessment Process

- Identify relevant CDC contributing risk factors including contamination, proliferation or survival
- Revise the initial designation based on additional information
- Provide rationale for the decision and references that explain or support designation

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- The CDC contributing factors can help point out the activities related to contamination, proliferation or survival of particular hazards.
- The number or percentage of a particular contributing factor should not be used to designate or rank provisions because the collated data which CDC summarizes and publishes is incomplete. Nearly half of all outbreaks reported to CDC do not contain identified contributing factors.

What criticality changes were made in the Food Code?

- Three new definitions were added to Chapter 1:
 - Priority Item
 - Priority Foundation Item
 - Core Item
- Section 2-102.11(A) Demonstration (of Knowledge) was changed to say one of the ways the PIC could show compliance with the Code was by having no Priority Item (instead of critical item) violations during the current inspection
- A superscript (^P or ^{Pf}) is used to identify Priority or Priority Foundation Items in Chapters 2-8, Core Items have no superscript
- Five sections in Chapter 8 were amended to change Critical Item and/or Non-Critical Item to Priority Item, Priority Foundation Item and/or Core Item.

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•The 2009 Food Code was amended to remove the terms “critical,” “non-critical” and “swing” items and replace them with the terms “Priority,” “Priority Foundation” and “Core.”

•The new terms P, Pf and C were defined in Chapter 1 of the Code to show how closely linked an individual provisions was to preventing, eliminating or reducing to an acceptable level hazards that cause foodborne illness

•The terms Priority (designated by a superscript P), Priority foundation (designated by a superscript Pf) and Core (no superscript designation) are defined in Chapter 1 and used in Chapter 2 and 8.

•Section titles, statements that work in conjunction with the following provision and italicized language are not designated because they are not enforceable.

Chapter 2 Management and Personnel (2-102.11)

- Paragraph 2-102.11(A) Demonstration (of Knowledge)
 - One of the options open to operators of food establishments to show demonstration of food safety knowledge as it applies to their facility is to have no violations of Priority Items during the current inspection

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- An operator of a food establishment must be able to demonstrate to the regulatory inspector that he/she has knowledge of foodborne disease prevention, application of HACCP principles and requirements of the code in the jurisdiction where the facility is located.
- The operator can demonstrate this knowledge by having no violations of Priority Items during the current inspection according to paragraph (A) in 2-102.11
- The other two options available to the operator or person in charge are:
 - Being a certified food manager based on an accredited test
 - Responding correctly to questions from the inspector about specific areas of knowledge as they relate to that establishment.

Chapter 8 Compliance & Enforcement (8-401.20)

- **Section 8-401.20 Performance- and Risk-Based (inspection frequency)**
 - Prioritize and conduct more frequent inspections based on:
 - Food establishment's history of non-compliance with P & Pf items in the Code or HACCP Plan
 - Numerous or repeat violations of C items
 - This section of Chapter 8 is recommendation only and not enforceable

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- The system used to set the frequency of inspection for food establishments should include consideration of the history of non-compliance with P and Pf Items.
- When an establishment's management control system does not effectively control P and Pf items, the Regulatory Authority should require more frequent regulatory inspections.
- NOTE: this provision is not enforceable (Section 8-401.20 ends in .20 based on the Food Code writing convention).

Chapter 8 Compliance & Enforcement (8-403.10)

- **Section 8-403.10 Documenting Information and Observations (documentation on inspection forms)**
 - Document on an inspection report non-compliance with P and Pf Items and non-conformance with critical limits of a required HACCP Plan
 - This section of Chapter 8 is recommendation only and not enforceable

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•The subparagraphs ((B)(3) and (B)(6) in Section 8-403.10 recommends the inspector document violations on an inspection report observed during an inspection for all P and Pf violations as well as non-conformance with critical limits of any required HACCP Plan (e.g., variances, ROP with or without a variance, packaged juice).

•NOTE: This is a recommendation and not a requirement (Section number ends in .10).

Chapter 8 Compliance & Enforcement (8-405.11)

■ Section 8-405.11 Timely Correction

- Correct P or Pf Items at the time of inspection
- Implement corrective actions for a required HACCP plan provision that is not in compliance with its critical limit (CL)
- The Regulatory Authority may agree to a longer time for correction (usually for Pf Items), not to exceed 10 days, based on the potential hazard and complexity of the corrective action
 - The P Item it supports must be in compliance using some other procedure, method, equipment, etc. for an extended period for compliance

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•Section 8-405.11 requires correction of P and Pf Items at the time of an inspection because of their direct and supporting roles, respectively, in controlling hazards that cause foodborne illness and injury.

•It also requires correction of provisions of a required HACCP plan not in compliance with their critical limits (equivalent to a P Item).

•Paragraph (B) is an exception which allows a Regulatory Authority (inspector) to extend the time for correction of P, Pf or HACCP Plan provisions with a critical limit up to 10 days based on the severity or virulence of the hazard or on the complexity of the corrective action, i.e., extensive repairs are needed, something must be ordered from a supplier.

Chapter 8 Compliance & Enforcement (8-405.20)

- **Section 8-405.20 Verification and Documentation of Correction**
 - Record correction of P and Pf Items or corrected HACCP Plan deviations observed during an inspection on an inspection report
 - After receiving notification that a violation of a P or Pf Item or a HACCP Plan deviation has been corrected, the Regulatory Authority will verify and document correction of the violation
 - This Section of Chapter 8 is recommendation only and not enforceable

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•This section recommends that any P or Pf Item or HACCP Plan deviation that is corrected during the inspection (COS or corrected on-site) should be noted on the inspection report.

•NOTE: This is a recommendation and not required.

Chapter 8 Compliance & Enforcement (8-406.11)

- **Section 8-406.11 Time Frame for Correction**
 - Correct C Items by a date and time agreed to by the Regulatory Authority but no later than 90 days after the inspection
 - The Regulatory Authority may approve a longer compliance schedule:
 - If it is provided in writing
 - If no health hazard exists or will result from the extended compliance schedule

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•Time for correction of Core Items may be extended up to 90 days or longer if the operator or permit holder submits a written plan of correction, i.e., when the facility intends to make the correction when the facility is next remodeled.

Who can use the new terms?

- The new terms allow focusing and prioritizing of tasks, training* and corrective actions for the
 - Inspector
 - Person-in-charge
 - Trainer



* See Annex A – Effective Behavior Change and Annex B – Communication Techniques for training assistance

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- The inspector has a responsibility to conduct food safety inspections to prevent foodborne illness.
- The Person in Charge (PIC) has a responsibility and duty (see Sec. 2-103.11) to explain, train and then monitor employees in certain food safety activities.
- The trainer helps both the inspector and PIC train employees in food safety practices to protect consumers against foodborne illness.
- The new designation terms (P, Pf and C) allow the PIC, inspector and trainer to prioritize and focus on activities that are most directly related to causing and preventing foodborne illness and injury.
- NOTE: Annex A on effective behavior change and Annex B on communication techniques provide additional information to help accomplish these objectives. These annexes are not mandatory.

How can the new terms be used?

- New terms P, Pf and C:
 - Designations help identify issues for “Active Managerial Control”
 - They guide regulatory inspections and enforcement.
 - They aid trainers focus their courses on the most important food safety information for their students



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- These terms give a credible, science-based way to identify the most significant activities requiring incorporation into the:
 - Management’s food safety systems
 - Inspector’s risk-based inspections
 - Trainer’s food safety training

How can regulators, QA & 3rd party inspectors use the new terms?

- Increase frequency of inspections for establishments with history of non-compliance with P Items
- Do risk-based inspections that focus on P Items
- Require immediate correction or initiate correction of all P or Pf violations during inspections
- Use “teachable moments” to explain why P Items are most important
- Develop various options for correction of P Items
 - E.g., different methods for cooling, accomplishing no bare hand contact with RTE food, reheating
- Present inspection findings at exit interview based on level of risk (P Items first, then Pf Items and finally C Items if time permits)
- Assure that P and Pf Items are addressed during plan reviews.

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• Inspections, whether done by a regulatory authority, 3rd part auditor or the manager as he/she does a walk-through, should focus on issues that have the most impact on preventing, eliminating or reducing to an acceptable level, factors that cause foodborne illness or injury.

• The new designation of terms allows them to do that.

Potential Uses - Compliance & Enforcement

- Develop intervention strategies for long term compliance for “P” items identified in inspection summaries, baseline surveys, foodborne outbreaks, etc.
- Amend state or local Food Code to reflect use of new terms
- Provide longer time for correction of Priority Foundation Items (if the P item it supports is controlled) and Core Items because of lower risk level
- Provide stakeholders with an explanation of the definitions and risk assessment process and their link to preventing foodborne illness and injury

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•Regulatory agencies (or companies) can develop specific long term strategies to change behaviors that contribute to foodborne illness, especially those related to P items.

- Use summary data to identify where attention is needed
- Change codes, policies and procedures to focus attention on new terms
- Require immediate correction of P Items that directly relate to foodborne illness or injury but allow longer periods for correction of Pf Items where there may be other ways to support the item.

How can the food industry use the new terms?



Shift attention to Priority Items in:

- Management systems
- Standard Operating Procedures
- Recipes
- Self inspections
- 3rd Party Audits

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•Operators and managers can review their policies and procedures to determine if all applicable P Items are addressed in:

- Management systems
- SOPs
- Recipes
- Self inspections, walk-throughs and 3rd party audits

How can the food industry use the new terms?



They will help prioritize...

- Corrective actions for “out of compliance” inspection findings
- monitoring, walk throughs
- Training content for employees within food establishments
- Limited resources of time and money

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•The retail food store and food service industries can use the new terms P, Pf and C to help prioritize:

- Corrective actions
- Activities for specific monitoring
- Training content for employees
- Use of limited time and money

How can the food industry use the new terms?



They can build in compliance for Priority Items....

- during Plan Review
- during construction
- during remodeling
- during training

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•Since prevention is always more effective than reacting after the fact, build in compliance for P and Pf Items before violations occur during:

- Plan reviews
- Construction
- Remodeling
- training

How can food safety trainers use the new terms?

- Trainers can explain:
 - The new definitions, 3-tiered re-designation system with examples of each
 - Immediate correction of Priority Items because of direct connection to foodborne illness
 - Priority Foundation Items provide options to correct, manage and control Priority Items
 - Core Items are general good practices
 - How to prepare for accredited Food Protection Manager Certification examinations

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•Trainers for both regulators and industry managers and employees can help their students better understand the new 3 tiered system to designate Food Code provisions by explaining:

- The definitions of P, Pf and C items and giving examples
- Why immediate correction of P Items decreases the risk of foodborne illness and injury the most
- Why C Items or good sanitation practices are general good support for food safety.
- How the new system relates to preparing for and using Food Protection Manager Certification.

What do you think about this? Scenario #1

- **One day, a retail establishment was inspected and several violations were noted.**

- Several holes in drywall of stockroom (pallets hit wall and made a hole)
- Excess fly activity at open trash containers in outside receiving area

When I arrived at the location the following day, I found store personnel repairing and painting the dry storage area. Painting requires ventilation, therefore all receiving doors were propped open. Guess what? The excess fly activity that was once outside was now inside the stockroom and kitchen.

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•This scenario and other that follow will help you understand how to prioritize your response to real life situations in food establishments, based on the three-tiered designation system for Food Code Provisions P, Pf and C.

What do you think about this? Scenario #1

- Do we consider implications and unintended consequences of our activities (opening door for ventilation allows flies to enter)?
- Were the holes in the drywall corrected before more serious violations were corrected (prioritizing risk, time for correction and cost of correction)?
- Were other priority violations (handwashing, time/temperature control, etc.) in compliance when maintenance repairs were made?

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•After identifying the violations and their designation (P, Pf or C), prioritize the corrective response so P Items are corrected first, then Pf Items and finally C Items. This gives the greatest reduction in risk of foodborne illness and injury in the shortest time and also will result in correction of P Items if only some violations are corrected.

- In addition, consider unintended consequences of your corrective actions,
 - Leaving the door open for ventilation allows flies into the establishment
 - Repairmen contaminating food products or making it difficult for employees to wash hands, etc.

What is a risk-based inspection process?

- A risk-based inspection process:
 - Prioritizes inspection activities, corrections and enforcement based on risk of foodborne illness or injury
 - Focuses on factors that contribute more directly to foodborne illness or injury
 - Bases frequency of inspection on establishment type and history of non-compliance
 - Requires more inspection time when more P & Pf Items are present and immediate correction of P and Pf Items
 - Monitors critical limits to determine compliance with P Items

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•A risk-based inspection process is another way to put more focus on factors that are more directly related to the causes of foodborne illness.

•Frequency of inspection and inspection time should be greater for establishments with more Out of Compliance P and Pf Items.

What is a risk-based inspection process?

- Corrective actions are confirmed for P & Pf violations at time of inspection (or later through a written confirmation)
- Explanations of the P & Pf link to foodborne illness or injury are offered to reinforce correct appropriate correction to operators
- Alternate options for correction are used to develop a risk control plan with the operator to achieve long term change (see Annex A for additional advice)

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•To reduce the risk of foodborne illness and injury most effectively, corrective actions are required for P and Pf Items at the time of inspection with explanations and options offered for long term correction.

•A Risk Control Plan in which the inspector and PIC mutually agree to a plan of action that will correct an Out of Compliance Priority Item helps change behavior. Record keeping will encourage employees to document the critical limits or quantifiable measures and continue to do so for a period of time that should result in long terms behavior change (4-6 weeks). The PIC has the responsibility of monitoring (verifying) the behavior and record keeping done by employees and reporting that to the inspector.

What is a risk-based inspection process?

- At the exit interview, an inspector can:
 - Discuss inspection findings with the operator based on the P & Pf risk
 - Confirm understanding of risk and correction with operator
 - Confirm timeline for correction of P & Pf violations

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•Time with the PIC during an exit interview after an inspection can be most effective at decreasing the risk of foodborne illness and injury when the focus of attention is P and Pf Items. This will ensure that everyone's valuable time is spent discussing correction of violations that have the greatest impact on food safety.

Examples of P, Pf and C Violations

- The following examples will provide the:
 - Violation of a P, Pf or C Item
 - Provision in the Food Code that, if Out of Compliance, will result in potential hazards in food that will cause foodborne illness or injury
 - Rationale or explanation of why/how violation of that provision is a P, Pf or C Item.

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•The following examples of P, Pf and C Items on slides #47 – 93 will help explain the new re-designation terms.

Priority Item Examples

Example of Priority Item^P Violation

- **Employee working with symptoms of vomiting**
 - Provision in Food Code: 2-201.11(A)(1)(a) Responsibility of Permit Holder, PIC & Conditional Employees
 - Correction – Employee reports symptoms to PIC and stops working, and
 - Provision in Food Code: 2-201.12(A)(1)
 - Correction – PIC excludes employee from work
 - Rationale – High numbers of pathogens, especially norovirus, contaminate food, clothing, surfaces, air (through aerosols) and cause illness when ingested

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- Vomiting is a typical symptom of foodborne illness.
- Employees should have been informed that they should stop work and report their symptoms to the PIC.
- The PIC should exclude from work the employee exhibiting symptoms of vomiting unless they have a physician's note to say the vomiting is from a non-infectious cause such as pregnancy, etc.
- This is a P Item (as are the other symptoms of foodborne illness – diarrhea, jaundice, sore throat with fever and unprotected lesions with pus on hands and arms because food employees can contaminate food and food contact surfaces. This often results in foodborne illness unless controls such as reporting and exclusion are in place.

Example of Priority Item^P Violation

- **Employee working with uncovered, infected cut on finger**
 - Provision in Food Code: 2-201.11(A) Responsibility of Permit Holder, PIC & Conditional Employees
 - Correction: Employee reports to PIC or covers infected lesion with double, impermeable barriers (i.e., waterproof bandage or finger cot plus a single-use glove worn on top of that)
 - Rationale: Infected lesions with pus, typically contaminated with *Staphylococcus aureus*, can contaminate RTE food unless covered with double, waterproof barrier

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•The rationale for reporting an uncovered, infected lesion on hands or arms is similar to that for vomiting while working (see previous slide) except that the correction is less severe (covering with two layers of impermeable bandages) because the resulting illness from an infected lesion (usually from *Staphylococcus*) is less severe.

Example of Priority Item^P Violation

- **No vigorous hand rubbing during handwashing**
 - Provision of Food Code: 2-301.12(B)(3) Cleaning Procedure
 - Correction: Rub vigorously with soap and water for 10-15 seconds
 - Rationale: Friction from rubbing hands together vigorously helps loosen soil on hands and reduces pathogen levels as they are rinsed off

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•Each part of the handwashing procedure, including vigorous rubbing of hands contributes to the reduction in pathogen load.

Example of Priority Item^P Violation

■ **Home-canned green beans served in a restaurant**

- Provision in Food Code: 3-201.11(B) Compliance with Food Law
- Correction: Discard and do not use home canned foods in a food establishment
- Rationale: Home-canned green beans, a low acid food, are often inadequately processed which allows germination of *C. botulinum* spores and toxin formation

51

•Processing of low acid canned foods (LACF) such as green beans requires stringent controls to prevent hazards such as *Clostridium botulinum* from growth and toxin production.

•Most foodborne outbreaks now from *C. botulinum* are related to home-canned foods.

•Note: Many provisions in Chapter 3 Food apply specifically to PHF/TCS food. Before applying a provision to a food or process, first consider whether the food meets the definition of PHF/TCS food.

•Factors that will help you make this determination include:

- Whether the food is raw/heat treated animal food
- Whether the food is heat treated plant food
- Whether the food is raw seed sprouts
- Whether the food is cut melons, cut tomatoes or cut leafy greens
- Whether the food is unmodified (not acidified) garlic-in-oil.

•pH and/or water activity can also show whether the food is or is not PHF/TCS food

•Past epidemiologic history of the food can also give an indication whether it supports the growth of foodborne pathogens.

Example of Priority Item^P Violation

■ **Employee using bare hands to make sandwiches**

- Provision in Food Code: 3-301.11(B) Preventing Contamination from Hands
- Correction: Use utensils or gloves to touch ready-to-eat food, not bare hands
- Rationale: Ill or infected but asymptomatic employees can transfer pathogens from inadequately or unwashed hands to RTE foods such as sandwiches

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- Even if employees report symptoms of foodborne illness and the PIC restricts or excludes as necessary AND handwashing takes place:
 - Asymptomatic employees (infected but not showing symptoms yet, recovering from illness but still shedding pathogens in stool, or in the carrier state where they are infected but not showing any symptoms at all (i.e., Typhoid Mary) may still contaminate food.
 - Employees may not always wash hands thoroughly enough to remove all pathogens present or all supplies such as warm water, soap and towels may not be present to ensure good handwashing
- The last barrier to prevent infected employees from contaminating food is to prohibit bare hand contact with RTE food.

Example of Priority Item^P Violation

- **Chef cooking chicken to 155°F for 15 sec.**
 - Provision in Food Code: 3-401.11(A)(3) Raw Animal Foods
 - Correction: Cook chicken to 165°F for 15 seconds
 - Rationale: Undercooking chicken which may be contaminated with bacteria will allow survival of pathogens

53

•Since chicken has a higher pathogen load than other meats, a higher cooking temperature is needed to destroy pathogens present.

Example of Priority Item^P Violation

- **Cooking egg rolls that received a non-continuous (partial) cook to 145°F for 15 sec.**
 - Provision in Food Code: 3-401.14(D) Non-Continuous Cooking of Raw Animal Foods
 - Correction: If cooking process was interrupted and product cooled, it must have a final cook temperature of 165°F for 15 seconds
 - Rationale: The final heating process of 165°F for 15 seconds must overcome any pathogen growth resulting from normal contamination, cooling and cold holding.

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•When a non-continuous cooking process is used (interrupting the cooking process before it reaches the required time/temperature, then cooling the product to 41°F, storing it for a period of time under refrigeration and then completing the final cooking process to 165°F), a higher final cooking temperature is required no matter what the food is to overcome any additional pathogen growth from germinating spores or cross-contamination during cooling and cold holding.

Example of Priority Item^P Violation

- **5 gallons of chili made yesterday afternoon according to the cook now at 57°F in cooler at 9:30 am**
 - Provision in Food Code: 3-501.14(A) Cooling
 - Correction: Discard chili. In future, cool from 135°F to 70°F within 2 hrs., then to 41°F in a total of 6 hrs.
 - Rationale: Spore formers (*C. perfringens*, *B. cereus*) have had sufficient time in optimum temperature range to germinate and form toxins, or produce high levels of bacteria that may not be destroyed by reheating

55

While you are unable to observe the entire cooling process, the cook confirmed that the chili was made in the afternoon of the previous day and at 57°F at 9:30 am the next morning, still hasn't reached the required 41°F within 6 hours total. Even allowing for cooling starting in the late afternoon, the chili has been cooling for more than 15 hours and didn't reach 41°F in less than 6 hrs. This is a P Item violation according to 3-501.14(A)(2).

While cooling large volumes of food in large, deep containers will generally not meet cooling parameters without the assistance of other procedures, (ice bath, stirring, ice paddle, adding ice to food, etc.), this could be considered a "double mark" by some and is discouraged. Corrective methods including experimenting to find the method or combination of methods that are able to meet the requirements with logging times and temperatures for a time to verify that (A Risk Control Plan), should be part of the discussion with the PIC.

Example of Priority Item^P Violation

- **RTE, PHF/TCS food (not exempted) was not date marked or, if date marked, was held for more than 7 days**
 - Provision in Food Code: 3-501.18(A)(1), (A)(2) & (A)(3)
RTE, PHF (TCS Food), Disposition
 - Correction: Discard food, begin using a date marking system and monitor for expiration
 - Rationale: *Listeria monocytogenes* can multiply at refrigeration temperatures, therefore time is the only control. If time is not used, food must be discarded.

56

•Developing and using a date marking system (3-501.17) is a Pf Item because it enables the operator to determine a safe shelf life for refrigerated foods that support the growth of *Listeria monocytogenes*.

•Disposal of foods that support growth of *Listeria monocytogenes* (when no date marking system was used or because the storage time exceeded 7 days at 41°F or less) is the actual Priority Item that the date marking system supports or enables.

Example of Priority Item^P Violation

- **Cooked chicken placed in bags, sealed (cook chill/ROP) and held for 30 days at 41°F**
 - Provision in Food Code: 3-502.12(D)(2)(e)(i) Reduced Oxygen Packaging without a Variance, Criteria
 - Correction: Discard food. In future, cook chill processed food must be stored at 34°F, if held for 30 days or submit a validated process (inoculation study) plus variance application and HACCP Plan
 - Rationale: If cooked chicken was re-contaminated or if spore formers were present before ROP packaging, the longer shelf life could allow growth and/or toxin formation

57

•The provisions in 3-502.12 are processes that allow certain foods to be processed and packaged using ROP technology without a variance because a validated process was submitted to FDA for approval and inclusion in the FDA Food Code.

•Without any secondary barriers in place besides refrigeration at 41°F (such as $\text{pH} \leq 4.6$, $a_w \leq 0.91$, high levels of competing organisms, curing with nitrite and salt or intrinsic factors in certain cheeses).

•The storage temperature must be decreased to prevent growth of non-proteolytic *C. botulinum* and *Listeria monocytogenes*.

•Since cooked chicken has no secondary barriers, it must be held at 34°F for a shelf life of 30 days or at 38°F for 72 hrs. or a validated process (inoculation study) must be provided according to Section 3-502.11(D).

Example of Priority Item^P Violation

- **Using galvanized metal can to mix and store fruit juice punch**
 - Provision in Food Code: 4-101.15 Galvanized Metal, Use Limitation
 - Correction: Discard. Use glass, plastic or other safe metal (aluminum, stainless steel, etc.)
 - Rationale: Acid fruit punch will leach toxic tin from the galvanized can

58

•The hazard in using galvanized metal in contact with acid fruit juices is that the acid product will leach tin from the container, producing toxic metal poisoning when consumed.

Example of Priority Item^P Violation

- **Hot water dish machine does not achieve 160°F surface temperature on utensils (using temperature sensitive tape or maximum registering thermometer)**
 - Provision in Food Code: 4-703.11(B) Hot Water and Chemical
 - Correction: Re-sanitize if temperature not achieved. Check wash and final rinse water temperatures, method of racking dishes (no masking), clear spray nozzles, etc. and correct as necessary
 - Rationale: Pathogens could survive on the surface of utensils and dishes

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•A surface temperature of 160°F is the control for sanitization that reduces the pathogen load to an acceptable level.

•The requirement for 180°F final rinse water in 4-501.112 (see slide #73) along with other factors such as wash temperature, method of racking dishes, clear spray nozzles, etc. is a Pf Item because it enables the 160°F surface temperature.

Example of Priority Item^P Violation

- **No backflow prevention device on a faucet with hose attached and end in bucket of mop water**
 - Provision of Food Code: 5-203.14(B) Backflow Prevention Device, When Required
 - Correction: Attach a backflow preventer such as an atmospheric vacuum breaker when hose is attached to faucet and no control valve is present
 - Rationale: Mechanical atmospheric vacuum breaker prevents backflow of waste water into water supply

60

•A backflow prevention device directly prevents contamination of the drinking water supply in case of a drop in water pressure.

Example of Priority Item^P Violation

- **Direct connection between building sewer line and drain line of ice machine storage bin and 3-compartment sink**
 - Provision of Food Code: 5-402.11 Backflow Prevention
 - Correction: Provide an air gap on the drain line between the drain/waste line and the ice machine and 3-compartment sink
 - Rationale: Air gap prevents possible backflow of waste water into ice machine and 3-compartment sink

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•An indirect connection on the ice machine drain line will prevent backflow of waste water into ice in the ice machine storage bin.

Example of Priority Item^P Violation

- **Cans of bug spray stored on shelf with bags of chocolate chips**
 - Provision of Food Code: 7-201.11(A) Separation
 - Correction: Separate toxic chemicals from food products
 - Rationale: Dripping of toxic insecticide could cross-contaminate food or food contact surfaces to cause illness, injury or death

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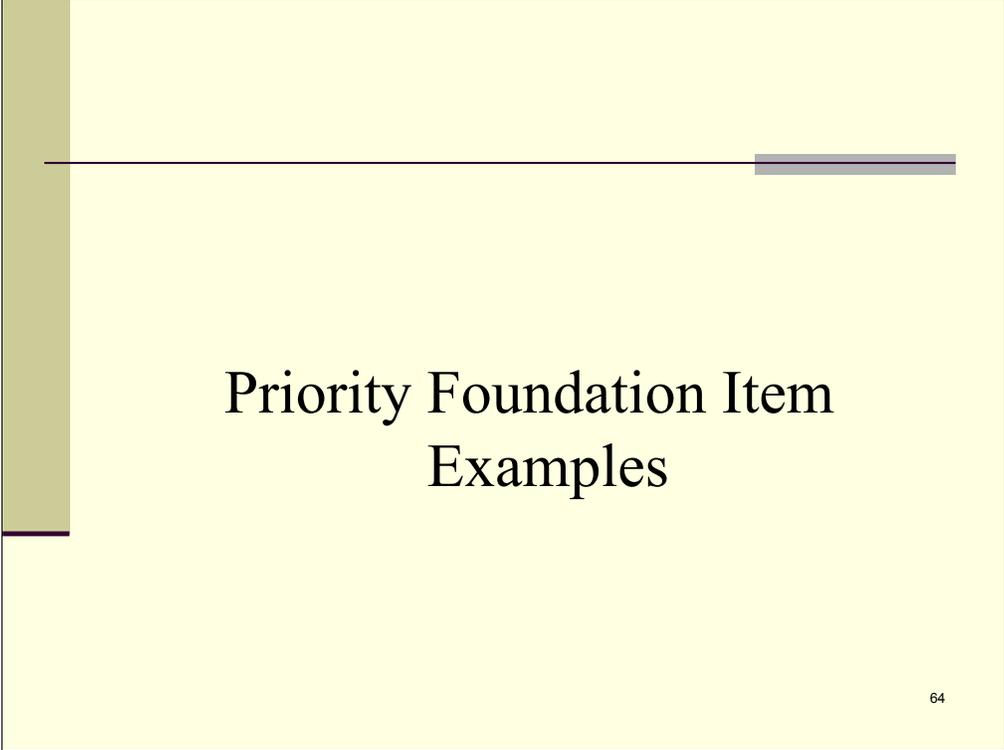
• Improper storage (no separation) of toxic pesticides with food could result in cross-contamination.

Example of Priority Item^P Violation

- **The active chemical ingredient used in a commercially manufactured hard surface sanitizer is not listed in EPA's 40 CFR 180.940.**
 - Provision of Food Code: 7-204.11 Sanitizers, Criteria
 - Correction: Use only EPA registered chemical sanitizers with an EPA Registration number and instructions for use on the sanitizer container's label.
 - Rationale: EPA has not evaluated and approved the sanitizer as safe and effective for use

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•If the manufacturer of the chemical sanitizer has not petitioned and received approval from EPA for safety and efficacy of the chemical sanitizer, it may not effectively sanitize food contact surfaces as advertised.



Priority Foundation Item Examples

Example of Priority Foundation Item^{Pf} Violation

- **No designated person in charge (PIC)**
 - Provision of Food Code: 2-101.11(A) Assignment
 - Correction: Identify a PIC during all hours of operation
 - Rationale: A PIC facilitates management control systems (monitoring, verification, training, etc.) that ensure Priority Items are in compliance

65

•If no one has been specifically identified as the person in charge, times when the regular manager (PIC) is absent from illness or other duties, no one person has the responsibility to make decisions and verify that corrective actions are done and conduct other activities related to active managerial control.

Example of Priority Foundation Item^{Pf} Violation

- **PIC does not monitor employees for necessary handwashing**
 - Provision of Food Code: 2-103.11(D) Person in Charge (Duties)
 - Correction: It is the PIC's duty to monitor employees for handwashing at appropriate times
 - Rationale: There is no management procedure to control (monitor and verify) employee handwashing to prevent fecal contamination of food

66

•If the PIC does not monitor handwashing for appropriate time and method used, he/she will not be able to enable this important control for contamination of food and food contact surfaces and will not be able to take corrective action such as explaining and retraining.

Example of Priority Foundation Item^{Pf} Violation

- **Employees are not trained in food safety practices related to their job duties**
 - Provision of Food Code: 2-103.11(L) Person in Charge (Duties)
 - Correction: Communicate and educate employees about food safety in their jobs
 - Rationale: Training facilitates employees' understanding and application of Priority Items as they perform their duties

67

•Initial orientation training, refresher training and corrective training at the time inappropriate activities occur enable the PIC to support and enable employees to correctly carry out controls required by Priority Items.

Example of Priority Foundation Item^{Pf} Violation

- **Paper towel dispenser empty at kitchen hand sink**
 - Provision in Food Code: 6-301.12(A) Hand Drying Provision
 - Correction: Monitor and refill as necessary
 - Rationale: Sanitary paper towels enable employees to properly dry their hands after washing and prevent using clothing to dry them

68

- Maintaining and refilling supplies for proper handwashing enables employees to wash and dry their hands when necessary.
- Lack of paper towels at one hand sink is not a P Item because an employee who needs to wash and dry their hands could get paper towels from the store room or go to another hand sink for handwashing.
- If they wash hands without using a sanitary hand towel for drying (e.g., they use their clothes or a dirty cloth or don't dry them at all, then this is a P violation (2-301.12)/
- The friction of drying hands with a towel can add another log reduction of pathogens to the handwashing procedure.

Example of Priority Foundation Item^{Pf} Violation

- **Food for self-service sale packaged or re-packaged in-house not labeled with ingredients**
 - Provision in Food Code: 3-602.11(A) Food Labels
 - Correction: Label package with common name of product, ingredient statement, any major food allergens, quantity, place of business and other information as necessary (claims, etc.)
 - Rationale: Proper labeling of ingredients enables consumers to make informed decisions about consumptions of that food

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•Proper ingredient labeling enables consumers to make decisions about consumption because of allergens or other health reasons.

Example of Priority Foundation Item^{Pf} Violation

- **Last date that molluscan shellfish were sold/served was not written on the tag**
 - Provision of Food Code: 3-203.12(B) Shellstock, Maintaining Identification
 - Correction: Train employees of responsibility to put that date on the tag
 - Rationale: Writing this date on the tag facilitates a traceback investigation in case of a shellfish outbreak to prevent other shellfish from that harvest area being consumed

70

•Writing the date shellfish were last sold on the tag enables the foodborne illness investigator to bracket the time the shellfish could have been consumed, facilitating tracebacks and stopping shipment for shellfish that may be responsible for an outbreak.

Example of Priority Foundation Item^{Pf} Violation

- **5 gallons of chicken stock in stock pot at 110°F cooling in walk-in cooler for 1 ½ hrs. (put in cooler at 135°F)**
 - Provision of Food Code: 3-501.15(A)(1) to (A)(7) Cooling Methods
 - Correction: Use an appropriate cooling method or combination of methods to cool PHF/TCS food within required criteria (including shallow pans, smaller portions, blast chiller, stirring, ice stick, ice bath, etc.)
 - Rationale: Specific cooling methods that enable rapid cooling would allow product to safely meet cooling parameters

71

•Although the chicken stock still has ½ hour to cool to 70°F to meet the first part of the cooling parameters (that is, to cool from 135°F to 70°F within 2 hrs. so this is not a cooling violation yet), your experience and ample research tells you that this method of cooling will not achieve 70°F for this large volume of product within the required time. You should make every effort to take a temperature later before you leave the facility to confirm the violation.

•A Pf Item requires use of specific actions or procedures by industry management to attain control of certain risk factors (P Items). The procedure or method of cooling 5 gallons of PHF in large containers does not adequately meet cooling parameters. The hazard, *Clostridium perfringens*, has a rapid generation time once any spores present have germinated.

•Always check with the PIC or specific individual responsible for moving the containers to be cooled into the walk-in cooler for the times and procedures they normally use so you can understand the process. Work with the PIC to identify methods to meet the cooling parameters.

Example of Priority Foundation Item^{Pf} Violation

- **No date marking system used on RTE, PHF/TCS food (leftovers, opened containers of commercially processed foods) in the facility**
 - Provision of Food Code: 3-501.17(A) RTE, PHF (TCS Food), Date Marking
 - Correction: Date mark RTE, PHF/TCS food (not exempted) held more than 24 hrs. to show when 7 day shelf life has expired
 - Rationale: Use of a date marking system enables PIC to discard or use RTE, PHF/TCS product before high levels of *Listeria* are present

72

In this slide, the operator has not developed and implemented a date marking system for RTE, PHF/TCS food held for more than 24 hrs. This system or procedure, 3-501.17, a Pf Item, enables the PIC to identify and discard food that is not served or sold within 7 days. The actual P Item, to prevent a hazard (infective doses of Lm) that could cause foodborne illness, is discarding RTE, PHF/TCS food that has been stored longer than 7 days.

Example of Priority Foundation Item^{Pf} Violation

- **Acidifying sushi rice (to pH 4.1) to hold at room temperature without a variance**
 - Provision of Food Code: 3-502.11(C)(2) Variance Requirement
 - Correction: Variance application with HACCP plan required to show food is non-PHF/non-TCS food
 - Rationale: A variance with HACCP plan and appropriate record keeping enables PIC to verify that acidification and any necessary corrective actions have occurred with rice held at room temperature

73

•A variance showing a validated procedure is used and a HACCP Plan that documents and verifies the use of this procedure to acidify rice to pH 4.1 or less enables the PIC to safely hold this product, previously PHF/TCS food, at room temperature.

Example of Priority Foundation Item^{Pf} Violation

- **Hot water temperature gauge shows sanitizing rinse at manifold in the warewashing machine is 170°F**
 - Provision of Food Code: 4-501.112(A)(2) Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures
 - Correction: Check booster heater and water heater are operating at high enough temperature that that the temperature gauge is accurate
 - Rationale: Monitoring temperature at the manifold facilitates trouble-shooting to verify effective sanitization is occurring at the utensil surface

74

The temperature gauge for the final rinse in a hot water sanitizing warewashing machine, measuring sanitizing water temperature at the manifold as it sprays out, gives an indication (enables the operator to judge) whether the sanitization process will be effective. Therefore this is a Pf Item. If the gauge shows a temperature less than required (i.e., 160°F instead of 180°F), this is an indication that something is wrong and sanitization at the surface of the utensil will likely not occur. The booster heater may not be operating properly. The water heater may be set too low. (A booster heater can only raise the temperature of water from the hot water heater about 40°F) The temperature gauge may also be inaccurate.

A surface temperature of 160°F or more on the utensil to achieve sanitization is the P Item that this provision supports. Other problems that can contribute to ineffective sanitization include racking dishes so some surfaces are masked from the sanitizing final rinse, clogged spray nozzles, altered spray pattern (nozzles bent), etc.

Example of Priority Foundation Item^{Pf} Violation

- **No thin probe thermometer, thermistor or thermocouple available to check hamburger patty cook temperatures**
 - Provision of Food Code: 4-302.12(B) Food Temperature Measuring Devices
 - Correction: Provide thin probe temperature measuring device
 - Rationale: A thin probe allows verification of the final cook temperature that destroys pathogens

75

•Without the appropriate equipment (thin probe temperature measuring device), it is not possible to accurately measure final cook temperatures of PHF/TCS food. Cooking temperatures is the P Item.

Example of Priority Foundation Item^{Pf} Violation

- **Drinking water from a restaurant's private well is tested every two years**
 - Provision of Food Code: 5-102.13 Sampling
 - Correction: Well water must be tested annually according to state water quality regulations
 - Rationale: Testing well water at a sufficient frequency according to EPA or state standards enables PIC to verify its potability

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•Sampling and testing well water enables the PIC to determine if the water source provides safe drinking water free of pathogens and chemicals. If testing shows that it does not meet the standards, the PIC can treat the water to remove the impurities or use an alternate source of water.

Example of Priority Foundation Item^{Pf} Violation

- **Hot water at handwashing sink is 70°F**
 - Provision in Food Code: 5-202.12(A)
Handwashing Sink, Installation
 - Correction: Adjust water heater, sink mixing valve, etc. to provide 100°F water for handwashing
 - Rationale: Maintaining 100°F water for proper handwashing facilitates optimum temperature for use of soap and more effective removal of food soils and pathogens from hands

77

• Many food greases tend to solidify at lower temperatures, making them more difficult to remove.

• In addition, employees may be less likely to wash hands in cold water because of comfort levels.

Example of Priority Foundation Item^{Pf} Violation

- **No handwashing sink in food preparation and dispensing areas**
 - Provision of Food Code: 5-204.11 Handwashing Sinks
 - Correction: Install convenient handwashing sink in the areas
 - Rationale: Nearby handwashing sinks facilitate handwashing when necessary to remove pathogens and soil from hands

78

•Because of the fast-paced environment in food establishments, employees may not leave the immediate area of their work station if there is no nearby hand sink for handwashing.

Example of Priority Foundation Item^{Pf} Violation

- **Evidence of mice with no pest control plan in place**
 - Provision of Food Code: 6-501.111(C) Controlling Pests
 - Correction: Implement a pest control plan such as seal entry holes, place traps, remove harborage, and routinely inspect for water and food sources, as well as presence of pests
 - Rationale: A pest control plan enables PIC to systematically rid establishment of pests which may carry disease –causing organisms to the facility

79

•A pest control plan which includes prevention, monitoring and eradication measures enables the PIC to keep the establishment free of pests which can contaminate food and food contact surfaces.

Example of Priority Foundation Item^{Pf} Violation

- **Unlabeled spray container of green liquid**
 - Provision of Food Code: 7-102.11 Common Name
 - Correction: Label working containers of poisonous or toxic chemicals such as cleaners
 - Rationale: Labeling working containers of cleaners prevents mix-ups with food products or the wrong chemical and accidental ingestion of chemicals that can cause illness, injury or death

80

•Labeling on containers allows employees to distinguish between foods and chemicals and also between different chemicals which may have different uses and different toxicities.

Example of Priority Foundation Item^{Pf} Violation

- **Safe handling statement not placed on label of fresh meat or poultry packaged in a meat market**
 - Provision of Food Code: 3-201.11(F) Compliance with Food Law
 - Correction: Add the safe handling statement to each consumer sized package of raw meat or poultry
 - Rationale: Information on the Safe Handling Statement enables consumers to safely handle and prepare meat and poultry and avoid foodborne illness

81

•This labeling provides information to improve food safety handling of fresh meat and poultry in the home.

Core Item Examples

Example of Core Item Violation

- **Cook not wearing an effective hair restraint**
 - Provision of Food Code: 2-402.11(A)
Effectiveness
 - Correction: Food employees should wear hat, cap, net or other effective hair restraint
 - Rationale: Hair restraints prevent hair from falling into food and keep employees from touching hair and scalp to reduce hands as a vehicle of cross-contamination

83

•A hair restraint prevents loose hair, a direct and indirect vehicle of contamination, from falling into food and may deter employees from touching their hair.

Example of Core Item Violation

- **Cartons of food stored on the floor**
 - Provision of Food Code: 3-305.11(A)(3) Food Storage
 - Correction: Store food on shelves, pallets, etc. six inches off the floor
 - Rationale: Storing food off the floor allows good sanitation practices such as sweeping, mopping, inspection for pests and protecting food containers from splash.

84

• Storing food on the floor prevents employees from carrying out good sanitation practices such as cleaning, pest control inspections, etc.

Example of Core Item Violation

- **No drain board on 3-compartment sink for dirty dishes/utensils and air drying dishes & utensils**
 - Provision of Food Code: 4-301.13 Drainboards
 - Correction: Add drain boards or use nearby tables, counters or carts for soiled and clean items
 - Rationale: Proper design with drain boards promotes proper dishwashing procedures and sanitization

85

- Drainboards allow separation of dirty and clean dishes and utensils and control the runoff of draining water.
- Lack of a drainboard could promote storage of wet utensils (wet nesting)

Example of Core Item Violation

- **Heavy grease build-up on sides of fryers and grill**
 - Provision of Food Code: 4-601.11(C) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils
 - Correction: Set up a cleaning schedule to prevent build-up of grease
 - Rationale: Good sanitation practices prevent conditions that contribute to pest problems

86

•Heavy grease build up on equipment allows microorganisms to reach high levels in the environment, a potential source for cross-contamination, and also provides an attractant and food source for pests (roaches, mice, etc.)

Example of Core Item Violation

- **Cold water faucet in mop sink leaks**
 - Provision of Food Code: 5-205.15 System Maintained in Good Repair
 - Correction: Repair or replace faucet to prevent leaking
 - Rationale: Leaking faucet provides a water source for pests and erodes fixtures which prevents easy cleaning

87

•In addition to attracting pests and eroding fixtures, dripping faucets increase costs and waste water. If the faucet is turned off at the shut off valve, it also discourages employees from washing hands.

Example of Core Item Violation

- **Garbage dumpster lids open outside**
 - Provision of Food Code: 5-501.113(B) Covering Receptacles
 - Correction: Close lids of dumpsters, grease barrels and garbage cans after each use
 - Rationale: Leaving waste containers uncovered allows flies, rodents and birds access to garbage and creates a nuisance

88

•Uncovered garbage is an attractant which provides food and breeding grounds for pests. They can then easily enter the food establishment to contaminate food and food contact surfaces.

Example of Core Item Violation

- **Broken and missing floor tiles in prep area and toilet room**

- Provision of Food Code: 6-201.11 Floors, Walls, and Ceilings
- Correction: Replace broken and missing floor tiles
- Rationale: Floors in good repair allow easy cleaning and good sanitation practices

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•Broken and missing floor tiles can allow spills and cleaning water to deteriorate subfloors and also prevent easy cleaning and good sanitation practices.

Example of Core Item Violation

- **Missing grease filter in ventilation hood above grill**
 - Provision of Food Code: 6-202.12 Heating, Ventilating, Air Conditioning System Vents
 - Correction: Replace missing grease filter or close open space with a metal spacer
 - Rationale: Closing all openings in hood with grease filters or spacers prevents grease build-up in ductwork, a fire hazard and food source for pests

90

- Designing ventilation food systems above cooking appliances so the grease filters close off the entire space ensures that greasy air is filtered before being exhausted decreases the buildup in ductwork
- The PIC should ensure that a full set of grease filters is replaced when they are removed for cleaning.

Example of Core Item Violation

- **Open space (1/3 inch) under back delivery door.**
 - Provision of Food Code: 6-202.15(A)(3) Outer Openings, Protected
 - Correction: Close off space with weather stripping, threshold sill repair, etc.
 - Rationale: Tight fitting doors prevent entry of pests

91

•Protecting outer openings (around doors, windows, utility lines that pass through the building walls, etc.) prevents the entry of pests from the environment around the facility.

Example of Core Item Violation

- **No area designated for employees' personal belongings**
 - Provision of Food Code: 6-403.11 Designated Areas
 - Correction: Identify lockers, specific area or room where employees can safely store their coats, shoes, street clothes, purses, etc.
 - Rationale: Street clothes can potentially contaminate food, utensils, single-service articles, etc. if not properly stored

92

•If employees do not have a safe and separate area designated for the personal belongings, they will likely keep them nearby their work stations which could potentially contaminate food and food contact surfaces.

Example of Core Item Violation

- **Food employee wearing a watch and decorative ring**
 - Provision of Food Code: 2-303.11 Prohibition
 - Correction: Jewelry, except a plain wedding band, should be removed
 - Rationale: Food debris can accumulate around and under jewelry without notice and is not easily cleaned

93

- Jewelry, if not easily cleanable, can act as a reservoir for pathogenic organisms and cross-contaminate food.
- Stones and metal work from decorative jewelry can also fall off and become a physical hazard.

What should you do now? Scenario #2

You (manager or inspector) open the door of a walk-in cooler. You look around and notice:

- Dirty fan guards and dirty shelves
- Broken light covers
- Dirty floors
- Raw chicken (dripping) stored above an uncovered container of salad dressing
- Many leftovers including two 3-gallon stock pots full of refried beans at 40°F on lower shelf – not date marked and not covered

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- This is another scenario to help you identify out of compliance provisions and prioritize or rank them according to their risk of causing foodborne illness.
- Once the priority items in violation are identified, they should be corrected immediately.

What should you do now?

Scenario #2

- First, identify & rank the violations according to risk level (P, Pf or C):
 - Priority Items
 - Raw chicken dripping over salad dressing - 3-302.11(A)(1)(b)
 - Disposition of undate marked RTE, PHF/TCS food not date marked - 3-501.18)
 - Priority Foundation Items
 - Refried beans cooled in 3 gallon stock pots - 3-501.15(A)(1-7) (DISCUSS)
 - No date marking system used – 3-501.17(A)
 - Core
 - Dirty fan guards & shelves – 4-601.11(C)
 - Broken light shield – 6-202.11(A)
 - Uncovered food – 3-302.11(A)(4)
- Next, immediately correct P items, then Pf items, then C items as able
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

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The two P Items are RTE salad dressing cross-contaminated with drippings from raw chicken and disposition of many containers of leftover RTE, PHF/TCS food with no date marking.

Immediate correction of the cross-contaminated salad dressing (discard) but disposition of RTE PHF/TCS food with no date marking is more complicated. Section 3-501.18 says undate marked RTE PHF/TCS food must be discarded but there are a number of criteria and exemptions.

- The food must be held more than 24 hrs for required date marking.
- A management system where no food prepared on-site or opened, commercially prepared food is held overnight requires no date marking.
- Some RTE, PHF/TCS foods have natural or added intrinsic factors that inhibit Listeria, the pathogen of concern, so no date marking is required. Examples include:
 - Commercially processed deli salads (generally with a listeriocide added)
 - Hard, semi-soft, or pasteurized process cheese made under a standard of identity.
 - Cultured dairy products (yogurt, sour cream or buttermilk) with live cultures and lowered pH
 - Preserved (pickled or salted) fish products
 - Shelf stable (no refrigeration required), dry fermented sausages (pepperoni or Genoa salami)
 - Shelf stable, salt-cured products (prosciutto or Parma ham)
- When it is confirmed with the PIC that the foods with no date marking are not exempted and should have been date marked, the foods should be discarded if a reasonable way to identify how old they are (daily work orders, etc.) is not available.
- Double marking both 3-501.17 (no date marking system) and 3-501.18 (disposition) is not recommended but inspection remarks written as observations should explain the situation with recommended corrections if that is your policy and the discussion with the PIC should address both development of a system for date marking and disposition.

What should you do now?

Scenario #3

It is 10:30 am. You are inspecting a nursing home kitchen and the first lunch will be served at 11:15.

- You notice the cook taking a tightly covered pan (product 6" deep) out of the reach-in cooler. She goes straight to the steam table and places the pan in it. She reaches down and turns on the steam table. You discover the pan is Spanish rice that was made five days ago according to the tag.
- The cook has no thermometer and the thermostat dial on the steam table is broken.
- You also hear her say to another cook that she started running a fever this morning and her throat was sore.

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•Some of the things you observe are part of a process so you must follow up with questions to verify whether your deductions based on observations are in fact correct. Examples include:

•Whether the cooling method for the Spanish rice was cooling it in 6" deep pans or was it spread in sheet pans for example and then transferred to the deep pan.

•Also check whether the steam table is capable of reheating the Spanish rice to 165°F within 2 hrs when it is not pre-heated and the thermostat is broken.

•Once the Priority Item violations are identified (cooking with a sore throat and fever in a nursing home facility that serves highly susceptible populations and reheating using a method that will not reach the required temperature within the required time period – THIS MUST BE VERIFIED BEFORE IT IS MARKED AS A VIOLATION)

What should you do now?

Scenario #3

- First, identify & rank violations according to risk level (P, Pf or C):
 - Priority Item
 - Cook has not reported fever & sore throat to PIC (exclude for HSP in nursing home, restrict for others) – 2-201.11(A)(1)(d)
 - Reheating Spanish rice (verify final reheated temp. reached 165°F in 2 hrs. or before service) – 3-403.11(A)
 - Priority Foundation Item
 - No thermometer to measure food temps – 4-302.12(A)
 - Spanish rice in 6” pans – 3-501.15(A)(1) (method unlikely to meet cooling parameters, need to verify procedure for cooling)
 - Core Item
 - Broken thermostat in steam table – 4-502.11(C)
- Immediately correct P items, then Pf items, then C items
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

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•The two Priority Items include

- excluding the cook with a sore throat and fever (she/he should report these symptoms to the PIC and the PIC should then in turn exclude the cook from work in a facility that serves HSP or only restrict in a facility that serves a normal population)
- Verifying that the Spanish rice is reheated to 165°F before serving. Since there are only 45 minutes before serving and the steam table was just turned on and may not be in good repair (broken thermostat), reheating criteria may not be met. Make a note to check before serving or point out that the reheating method being used may not meet reheating parameters so another method (microwave oven, steamer, etc.) might be more effective.

•The two Priority Foundation Items are:

- No thermometer to check product temperatures such as refrigeration and reheating
- Apparent method of cooling the Spanish rice (6” deep in containers put into the cooler) is unlikely to meet the cooling parameters. Verify with the PIC or the individual who prepared the rice and put it in the cooler the exact time and method that the rice was cooled. It is possible the rice was prepared and spread in thin layers on sheet pans, put into the cooler and then transferred to a deep container and covered to save storage space in the cooler. You did not observe a P Item violation (cooling) but there may be a Pf cooling methods violation based on their answer.
- If you are unable to stay long enough to verify the effectiveness of either the cooling method or reheating method, you can still make the observation but no mark on the inspection report that methods used were unlikely to comply with Code requirements. Recommendations for meeting the criteria should be discussed with the PIC.

What should you do now? Scenario #4

You walk into a kitchen. This is what you see.

- The cook is mixing the slaw and dressing with his bare hands
- The back door is propped open so it will not close and there are a lot of flies inside the kitchen
- Several pans on the clean utensil rack are caked with dried food
- Cases of meat labeled “Keep Frozen” are setting on the floor and leaking
- Utensils are being washed in 3-compartment sink and chlorine sanitizer is available but not used
- There is no soap at the handwashing sink

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- The same process of identifying and ranking the violations must be done in this scenario.
- First, identify the Priority Item violations which are most likely to directly result in foodborne illness or injury because they need immediate correction.

What should I do now?

Scenario #4

- First, identify & rank violations according to risk level:
 - Priority Items
 - Mixing slaw with bare hands – 3-301.11(B)
 - No sanitizer used in 3-compartment sink – 4-701.11(C)(1)
 - Priority Foundation Items
 - No soap at handwashing sink – 6-301.11
 - Pans stored with dried food – 4-601.11(A)
 - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11(A)
 - Many flies, not using some method of fly control – 6-501.111(C)
 - Core Items
 - Cases of meat on floor – 3-305.11(A)(3)
 - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11
- Immediately correct P items, then Pf items, then C items
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

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•The two P Item violations that have the highest risk of causing foodborne illness are mixing slaw with bare hands (bare hand contact with RTE food) and not using a final sanitizing rinse (hot water or chemical) in the 3 compartment sink utensil washing procedure.

•The Pf Item violations are:

•No soap at hand sink (6-301.11) to assist the handwashing procedure be more effective. They still have the opportunity to go to another hand sink with soap or get soap from supplies for handwashing when it is necessary. If the observation was actually washing hands with no soap, then it would be a P Item violation, 2-301.12(B)(2).

•The procedure for receiving frozen food (“Keep Frozen”) should be to verify it is frozen upon receipt (mark 3-202.11(E), if not, and to place it immediately in the freezer for storage (not leave it out on the floor to thaw after delivery 3-501.11(A)). It is unlikely that the product is intentionally being thawed at room temperature on the floor, therefore 3-501.13(A) is not the correct mark. Ask the PIC what time the delivery was made to the facility.

•No procedure or control measures were being used (pesticide application, fly bait, fly “zapper”, etc.) to control excess flies numbers of flies in the establishment. The corrective action is to not prop the door open (a self-closer is implied in the scenario, check for it) or install a screen door for ventilation (both are design/construction – Core Items). Then they must apply control measures to get rid of the flies. Flies indirectly contribute to spread of foodborne pathogens by walking or vomiting on food or food contact surfaces and transferring pathogens from their bodies.

How to Use the Annexes

- **The Annexes are not requirements!**
- The Annexes are included to support you in your food safety mission:
 - To recognize common food safety hazards
 - To better communicate food safety messages
 - To promote correction and long term behavior change for poor food safety practices

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- The three Annexes attached to these training slides are not requirements of the Food Code.
- Rather, they are provided to help you as you carry out your food safety activities, whether you are a regulator, industry representative or trainer
- One Annex helps you identify common food safety hazards that must be controlled to prevent foodborne illness or injury.
- Another Annex provides some hints to help you communicate better.
- The third Annex helps you make your education and training more effective at changing behavior that results in poor food safety practices.

How to Use the Annexes

- Each individual annex can be extracted and used as a separate training module for that purpose alone (food safety hazard recognition, communication, behavior)
- When a specific food safety problem persists, information in the Annexes may provide assistance in identifying antecedents (contributing factors) to the underlying cause of the problem
- The Annexes provide basic background information which regulators, operators and trainers can find useful for any food safety activity

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Annex A

How can regulators, operators and
trainers effectively change
behavior?

Effective Behavior Change

- Correcting violations without behavior change will result in the same repeated violations
- **Training by itself does not always lead to improved behaviors**
- We must create a culture where everyone knows:
 - Food safety is a **priority**
 - Their personal **responsibility** for food safety
 - Which of their activities, if done incorrectly (Priority Item violations), can result in foodborne illness or injury

A Food Safety Culture

- PICs and Regulators need to have established policies, standards and procedures for food safety
 - the food safety message must be uniform and consistent
 - Priority Items listed in the Food Code can provide that uniformity
- PICs should explain these expectations to employees as it relates to their specific job duties
- PICs and Regulators must hold employees accountable
 - Managers must monitor for expected performance
 - Immediate correction must be done when not in compliance
 - Retraining should be done as necessary
 - Known consequences must be carried out

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Regulatory Inspections

- Uniform, consistent inspections should be made based on P, Pf and C Items in the 2009 Food Code
- Knowledgeable and skilled inspectors can request immediate correction for P Items, explain, demonstrate or provide options to encourage behavior change
 - Developing risk control plans (who, what, when, where, why) for P Items encourages long term correction
- Focus on risk factors (P Items) for foodborne illness demonstrates their importance

A Food Safety Culture

- Managers should serve as good role models, especially for Priority code provisions
 - Otherwise: **“If you don’t do it, I don’t do it.”**
- Managers should provide education and training for all employees – now is the time to explain that food safety and protection of their customers is a high priority
- Managers should reinforce positive behaviors
 - Give positive feedback

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Education and Training

- Certified food safety managers should be knowledgeable and do the following:
 - Provide initial orientation and on-going refresher training related to their job duties
 - Explain why a particular behavior is necessary
 - Explain the food safety reason for requirements – that people can become ill or injured if things go wrong
 - Make it personal – they/their family can get sick, customers can get sick, job/business loss
 - Include personal testimonials, stories, etc.

Education and Training

- The Instructor/Manager should demonstrate the correct way of doing the task from the beginning
- Hands on training works best (coaching)
- Try different approaches and allow individual to choose option they prefer (for better buy-in)

Education and Training

- Management should remove barriers to learning
 - Provide time (on the clock) for training
 - Provide training in appropriate language, using familiar words and examples
 - Provide necessary resources
 - Computer for on-line training
 - Trainer and training materials
 - Supplies, utensils, equipment to carry out the task

Education and Training

- Training should be reinforced
 - Use posters, signs, pamphlets, wallet cards, etc.
 - Provide on-line or face-to-face updates
 - Give reminders during work – “teaching moments”
 - Use novelty to create renewed interest

Incentives Provide Motivation

- Management should consider rewards and the use of positive motivation
 - Recognition – awards, win a contest, media mention, ceremonies
 - Things – tickets, free meal, branded items, etc.
 - Praise – “Good Job!”, certificates
 - Money – prizes, job promotion, cash awards

Incentives Provide Motivation

- Sometimes negative consequences follow poor food safety practices:
 - Re-training
 - Warnings
 - Time-off
 - Loss of job

Annex B

What are some communication techniques to help convey our messages of food safety?

Food Workers as Oral Culture Learners

- Effective communication is necessary to get your message across
- Inspectors and QA staff are usually print culture learners
 - They read for primary information
 - They have linear, analytical thoughts, are task oriented and able to strategize
- Food workers are often oral culture learners
 - Most workers like to give and receive information verbally
 - Workers are less likely to follow rules made by someone they do not know or trust

Oral Culture Learners

- Verbal information, repeated regularly and reinforced with signs, posters, handouts is an effective way to communicate
 - Fewer words and more pictures is better
- Storytelling is an important method of getting information for oral culture communicators
- Many owner/managers think employees should read food safety rules to learn
 - This thinking reveals a lack of understanding of how oral culture communicators learn and process information

Effective Communication

- Communication has to be 2-way to be effective
 - Explain/demonstrate the issue and have it explained/demonstrated back to you
 - Hands on training reinforces explanation
 - Feedback that they are “doing it right” is important
 - Oral culture communicators require interaction to internalize knowledge and change behavior
 - Active listening skills help pinpoint misunderstanding or lack of understanding
 - There is no other way to know if their communication was effective or even heard
 - This promotes joint problem solving

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Communication by Behavior

- Effective communication shapes behavior
- We want to change unsafe food behavior and attitudes that disregard food safety processes
- 80-90% of what we communicate is by non-verbal behavior rather than by what we say
- Doing and correctly practicing the behavior internalizes the information communicated
- It is important for regulators, operators and trainers to consider different methods and their appropriateness to communicate risk and change poor behavior.

Communication by Behavior

- Correct behavior is often not modeled by management
 - **“Do as I say, not as I do”** doesn't work
 - Role models (managers, co-workers, inspectors) are important
- Correct behavior is often not a priority
 - **“If it's not important to you, it's not important to me”**

Use Plain Language

- Use “I,” “you” and “we” and avoid “it”
- Use short sentences, limit subjects to one per sentence
- Use vertical lists with parallel construction
- Avoid technical and legal jargon or “big words”
- Use terms listeners or employees are familiar with
- Make factual statements and avoid subjective statements that imply judgment

Communication

- Pertinence to job duties
 - People learn if they understand the importance of their job behavior
 - Communication is best understood when it is personal
 - Related to assigned job duties
 - Described with vivid, real-life examples
 - Connected to their own family, health and well being

Communication

- General statements may not be considered relevant to the job – be specific
 - Why is something important?
 - What is the right way to do it?
 - Can the right way be demonstrated?
- Provide options/examples that are specific to that job
 - Use easily available equipment, utensils or materials
 - Give employees a choice and ask which one they prefer
 - Ask employees to try it out

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What doesn't work well?

- Presenting all training in written form such as signs, pamphlets, on-line computer training, handout materials
- Using examples that aren't related to their job duties
- Using negative reinforcement (by itself)
- Saying something only once
- Using unfamiliar language or terminology

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Annex C

What are common food safety hazards?

Biological, Chemical & Physical Hazards in Food

- **Each provision in the Food Code is intended to prevent, eliminate, reduce to an acceptable level or control hazards that could directly or indirectly contribute to a foodborne illness or injury**
- A hazard is a biological, chemical or physical property or agent that may cause an unacceptable consumer health risk
- A hazard must be identified as the first step in conducting a risk assessment

Biological Hazards

- Biological hazards consist of microbiological pathogens, including:
 - Spore-forming bacteria
 - Vegetative bacteria
 - Viruses
 - Parasites
- Most yeast and molds are spoilage organisms and do not cause illness or injury

New Foodborne Pathogens Identified Since 1977

More than 70 foodborne pathogens are known with the following added to the list since 1977

Campylobacter jejuni

Cryptosporidium parvum

Shiga-toxin producing *E. coli*

Noroviruses

Vibrio vulnificus

Yersinia enterocolitica

Salmonella Typhimurium DT 104

Spongiform encephalopathy prions

Campylobacter fetus ssp. Fetus

Cyclospora cayentanensis

Listeria monocytogenes

Salmonella Enteritidis

Vibrio cholerae 0139

Vibrio parahaemolyticus

Controls for Biological Hazards

- Provisions in the Food Code control biological hazards by eliminating, preventing, and/or reducing to acceptable levels or holding numbers unchanged by:

Cooking, pasteurization	Cooling
Retorting	Refrigeration
pH/acidity	Sanitizers
Water activity	Fermentation
Competing organisms	Irradiation
Bacteriocins, nicin	High pressure
Preservatives	Nitrites, nitrates
Hot holding	

Spore-Forming Bacteria

- *Clostridium botulinum, Clostridium perfringens, Bacillus cereus*
- Spores are able to survive cooking & other adverse conditions
- Spores do not multiply in this form so require no nutrients, water, etc. to survive
- Spores germinate & start to multiply when conditions are right – best control at this stage to prevent growth
- Retort processing (high temp & pressure) is necessary to destroy spores
- Toxins form after germination when the spore is actively growing

Vegetative Bacteria

- The growth phase of spore-forming and non spore-forming bacteria
- Nutrients, water and adequate environmental conditions (pH, a_w , temperature, etc.) are necessary for growth
- May form toxins in food or in the body
- Susceptible to cooking and many other environmental factors on a case-by-case basis
- Controlled by refrigeration although some vegetative bacteria can multiply slowly at refrigeration temperatures (e.g., *Listeria*, non-proteolytic *Clostridium botulinum*)

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Viruses

- Viruses are pathogens which cannot multiply outside of a living cell
- Norovirus, hepatitis A and rotavirus are the most common foodborne viruses
- Infected human beings (not animals) are the usual source
- Preventing contamination (exclude infected workers, handwashing, no hand contact) and thorough cooking control viruses
- Viruses are very heat resistant

Typical Sources of Biological Hazards

- Field and farm crops – soil, birds, other infected animals, failed septic systems, sludge and bio-solids contaminate food products
- Animals – manure, slaughtering process (skin, intestinal tract), service animals, pets and petting zoos contaminate food
- Fish and seafood – marine bacteria, histamine producing bacteria and fish parasites contaminate food

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Some sources of hazards are introduced to the food product while it is being grown, raised, harvested or processed, that is, outside the food establishment and only control or destruction by cooking, for example, is possible, not always prevention.

Typical Sources of Biological Hazards

- Infected workers – fecal material, vomitus, nasal discharge, coughing, sneezing and pus from infected lesions
- Cross-contamination from other sources during transport and storage
- Contaminated equipment, utensils and surfaces
- Water – irrigation, contaminated well water or ice, water main break, backflow or back siphonage

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Some sources of hazards are introduced to the food at the food establishment by food employees or dirty food contact or environmental surfaces. Some provision of the Food Code can prevent, eliminate or reduce to an acceptable level hazards that cause foodborne illness or injury. The degree of risk is dependent on many things:

on the pathogen itself (virulence, severity, etc.)

the level of contamination (pathogen load)

the consuming individual (, immuno-compromised, HSP or not)

Characteristics of Pathogens

- Infectivity – potential or ease of transfer, infectious dose
- Severity – virulence of the pathogen, length & severity of illness, hospitalization or death
- Spore formers/vegetative cells – ability to survive adverse conditions
- Acid resistance – susceptibility to pH
- Heat resistance – ability to survive cooking
- Biofilm formation – ability to form a protective polysaccharide covering resistant to cleaning & sanitizing
- Association with certain foods – SE with eggs, *E. coli* O157:H7 in meat, cider, etc.

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- The characteristics of a pathogen can help determine the risks of causing a foodborne illness and therefore was used to assign risk levels to provisions that are intended to control those pathogens.
- The levels of infectivity, how easily the organism/hazard infects an individual vary according to:
 - Highly infective norovirus can infect through 3 different pathways (ingestion of water or food, contact with mucus membranes such as eyes, or by aerosolization/inhalation)
 - Listeria monocytogenes* has a very low infective dose, tens to hundreds of organisms, and is therefore highly infective.
- Severity describes the effect the hazard has on the individual:
 - Virulence means the hazard/agent is extremely harmful
 - The length, symptoms and severity of the foodborne illness often results in hospitalization and/or death.
 - Less severe illnesses or injuries are shorter, have fewer or less harmful symptoms
- The ability to form spores means the pathogens can survive adverse conditions for long periods of time including normal cooking, dry conditions, lack of oxygen/ROP, etc.
- Acid (low pH) resistance means the pathogens can survive in naturally acid food (fruit and fruit juices) or in acidified foods.
- Heat resistance – some pathogens can adapt to higher temperatures, especially when protected by fats in the food.
- Some organisms including *E. coli* O157:H7, *Salmonella* and *Listeria monocytogenes* can form protective biofilms, a polysaccharide matrix, that protects them in adverse conditions.

Clostridium botulinum

Minimal growth requirement for *C. botulinum*

<u>Property</u>	<u>Group I</u>	<u>Group II</u>
	Proteolytic	Non-Proteolytic
	Type A, B, F	Type B, F, E
Inhibitory pH	4.6	5.0
Inhibitory NaCl	10%	5%
Minimum a _w	0.94	0.97
Temp. optimum	98°F	86°F
Temp. range	50 -118°F	38 -113°F
Toxin production	≥ 50°F	≥ 38°F

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- The minimum growth parameters for *Clostridium botulinum* show why this spore former has to have such stringent controls.
 - There are 6 human strains and several different ways to classify *C. botulinum*: by Group, whether it is proteolytic (lyses blood cells) or non-proteolytic and by name of Type.
- The characteristics and sources (part of the world, soil, aquatic, etc.) of the pathogen are used to classify them
 - pH or resistance to acid – Group I/Proteolytics are much more resistant to acid environments as they can germinate and produce toxin down to pH 4.6. This is the reason why pH 4.6 was previously considered the lower range of PHF food. Non-proteolytic *C. botulinum* is more sensitive to pH, it can only grow and produce toxin down to pH 5.0.
 - Salt concentration – Group I/Proteolytic *C. botulinum* strains are able to grow and produce toxin in a 10% salt solution (very salty) versus 5% for non-proteolytics.
 - Water activity – Group I/Proteolytic strains are able to grow and produce toxin at a relatively low water activity of 0.94. Group II/Non-Proteolytic strains' lower limit is 0.97.
 - Temperature – Temperature is the parameter most easily controlled with foods and the growth factor for *C. botulinum* that separates the two most easily. Group I/Proteolytic strains have an optimum growth temperature of 98°F and a lower range of 50°F (well controlled by normal refrigeration temperatures.) Group II/Non-Proteolytic strains (generally found in seafood) can multiply and produce toxin at 38°F, below normal refrigeration temperatures, therefore more difficult to control with temperature alone.

Clostridium botulinum

- *C. botulinum* is an obligate anaerobe, spore-former, common in soil & aquatic environments (salt and fresh water)
 - Proteolytic *C. bot* – more pH & salt resistant, more resistant to low a_w , only grows & produces toxin down to 50°F
 - Non-proteolytic *C. bot* – less pH & salt resistant, less able to grow at low a_w , can grow and produce toxin down to 38°F
- Preformed toxin is heat labile (boiling 10 min.)
- Improper canning, retorting and reduced oxygen packaging (ROP) are risks

Clostridium perfringens

- *C. perfringens* is an anaerobic spore-former found in humans, animals, soil and vegetation
- Cooking heat shocks spores
- Generation time can be 8 minutes starting at 122 - 127°F
- Contributing factors for illness include:
 - Slow cooling (allows germination of spores)
 - Inadequate refrigeration (allows growth of cells)
 - Inadequate reheating (allows survival of cells)
- Vegetative cells sporulate (return to spore form) in gut and release toxin
- Large numbers of cells ($\geq 10^5$) are required to cause illness

Bacillus cereus

- *B. cereus* is an aerobic spore-former
- Spores are ubiquitous in the soil & environment
- 2 types of toxins can be formed:
 - Emetic is heat stable, formed in food
 - Diarrheal is heat labile, formed in intestine
- Slow cooling and inadequate refrigeration allow spore germination and growth to high numbers
- Toxin is not produced at temperatures < 50°F
- $10^5 - 10^6$ cells needed to produce toxin

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Escherichia coli O157:H7

- Cattle and other animals are reservoirs
- Survives well in the environment
- Forms biofilms resistant to washing and sanitizing
- pH resistant
- Transmitted mainly through the ingestion of food contaminated with ruminant feces



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• *E. Coli* is also a commensal organism in the lower gut of mammals. All of us in fact, carry *E. coli*. But as with *Salmonella*, some of them exchanged a little genetic material with their bacterial friends and we have Enterotoxigenic *E.coli*, Enterohemorrhagic *E.coli*, or Enteroinvasive *E.coli*.

• Cattle are the primary reservoirs but other animals and humans may be as well.

• It survives well in the environment for weeks or even months under the cool, wet conditions.

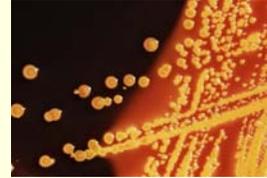
• It forms biofilms for protection as does *Salmonella* and *Listeria*.

• It is very pH resistant, surviving in apple cider at pH's as low as 3.3. Many people think that fresh produce, especially fruits are protected by their low pH but this may not always be the case.

• You often see generic *E. coli* used as an indicator organism for fecal contamination. Since an indicator should have a survival rate equal to or slightly higher than the bacteria of interest. *E.coli* may not be a good indicator for *Salmonella*.

Escherichia coli O157:H7

- Inadequate cooking and cross-contamination of RTE food are contributing factors
- Shiga-toxin produced in the gut is absorbed into the blood stream
- Damages small blood vessels
 - Leading to bloody diarrhea, kidney failure and death
 - Causes 90% of diarrhea and associated HUS



Staphylococcus aureus

- People are carriers (skin, nasal passages, infected lesions) as well as dogs, fowl, cows with infected udders
- Non spore-former produces toxin at a_w too low for competing bacteria
 - Growth at $a_w = 0.83$,
 - Toxin production requires $10^6 - 10^7$ CFU/g
 - Toxin produced at $a_w = 0.88$
 - Pre-formed toxin produced in food
- Reheating destroys cells but toxin is heat stable
- Food likely to be contaminated by hand contact with RTE food and infected lesions

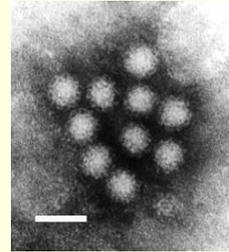
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Listeria monocytogenes (Lm)

- *Listeria* is ubiquitous in the environment
- Lm forms biofilms resistant to washing & sanitizing in high moisture niches
- Lm multiplies slowly at refrigeration temperatures down to 32°F
- Controls include addition of listeriocides to food, short shelf life (datemarking), preventing contamination from the environment, refrigeration, cooking, adequate cleaning & sanitizing
- Fetuses (miscarriages), babies, pregnant women and the elderly are particularly susceptible – high case fatality rate

Norovirus (NOV)

- Human beings are the reservoir for NOV
- Norovirus is reported as the single most common cause of gastroenteritis in the western world
- NOV is transmitted by:
 - Fecal-oral route (through food)
 - Inhalation (breathing vomitus droplets)
 - Person-to-person (touching someone contaminated)
 - Environment to person (touching contaminated surfaces)



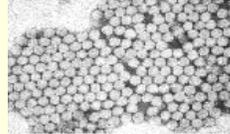
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Norovirus

- NOV infectious dose is 1 particle (a cluster of 200-300 viruses), highly infectious
- $10^9 - 10^{10}$ particles/g feces (the size of the tip of a fingernail)
- NOV is highly resistant to disinfectants
- Projectile vomiting or diarrhea episode
 - Needs to be contained (covered)
 - Then double wash and disinfect surfaces
 - Discard protective clothing and cleaning materials
- Virus survives in environment hours to days

Hepatitis A (HAV)

- HAV is spread from human beings through:
 - Contaminated sewage in wells, seafood harvest areas, recreational waters
 - Fecal-oral route (contaminated food)
 - Person to person
- HAV is shed at 10^8 viral particles /g feces
- Shed in feces midway through incubation period before symptoms appear
- Symptoms can last 6-9 months
- Controls are handwashing, no bare hand contact with RTE foods, exclusion with jaundice, shellfish certification & tag retention for 90 days



Parasites

- ***Anisakis***

- The motile larval stage burrows into the stomach walls
- Infection caused by eating raw or undertreated marine fish

- ***Cryptosporidium parvum***

- Infects 45 different species besides man
- Oocysts (infective stage) often associated with contaminated drinking & recreational water
- Oocysts are highly resistant to disinfection

Parasites

- ***Cyclospora cayentanensis***

- Oocysts are infective
- Often found in contaminated water

- ***Giardia lamblia***

- Reservoir is human beings & wild animals
- Protozoan cysts & trophozoites shed in feces
- Often associated with contaminated water or person-to-person transfer in day cares

Chemical Hazards

- A chemical hazard may be naturally occurring or may be added during processing or preparation
- Normal cleaners, sanitizers and other chemicals used in a facility may be a food hazard
- Scombrototoxin (histamine poisoning)
 - Formed by bacteria that convert histidine to histamine
 - Found in tuna, mackerel, skipjack, bonito, mahi mahi, blue fish and certain cheeses
 - Temperature abuse allows bacterial growth and histamine formation

Chemical Hazards

- Ciguatoxin
 - Found in tropical reef fish (i.e., barracuda, a predator fish)
 - Dinoflagellates and algae that produce the toxin are consumed by fish
 - Causes temperature reversal (hot ↔ cold) and other neurological symptoms, often for years



Chemical Hazards

- Tetrodotoxin
 - Certain fish (e.g., puffer fish, fugu, blow fish) produce toxin in their skin and viscera
 - Tetrodotoxin is heat stable – cooking will not destroy
- Aflatoxin
 - Mycotoxin produced in corn, nuts and other grains
- Patulin
 - Mycotoxin produced in rotten apples
 - Not destroyed by pasteurization or cooking

Chemical Hazards

- Monitoring shellfish harvest areas for certain phytoplankton prevents shellfish poisoning
- Common shellfish poisoning includes:
 - Paralytic shellfish poisoning (PSP)
 - Molluscan shellfish, lobster and crab concentrate saxitoxin from certain dinoflagellates (“red tide”)
 - From a heat stable toxin
 - Flushed from animal within weeks

Chemical Hazards

- Common shellfish poisoning includes:
 - Diarrhetic shellfish poisoning (DSP)
 - Molluscan shellfish concentrate toxins from certain dinoflagellates
 - Heat stable toxin
 - Neurotoxin shellfish poisoning (NSP)
 - Molluscan shellfish concentrate brinetoxins from algal blooms
 - Toxic to fish, birds and sea mammals too

Chemical Hazards

- Common shellfish poisoning includes:
 - Amnesic shellfish poisoning (ASP)
 - Shellfish, Dungeness crabs and anchovies concentrate domoic acid produced by a diatom
 - Produces short term memory loss
 - Toxic mushroom species – False morels, Little Brown Mushrooms, Jack-O'-Lantern, Green-Spored Lepiota, Deathcap, Death Angel
 - Toxic plant species – Belladonna, bloodroot, buckeyes, castor bean, foxglove, hemlock, holly berries, Lily of the Valley, mandrake, May apple, mistletoe, rhubarb leaves, snakeroot

Physical Hazards

- Illness and injury can result from foreign objects in food including:
 - Glass – from lights, bottles and jars, utensils, gauge covers
 - Wood – from fields, pallets, boxes, buildings
 - Stones, metal fragments – from fields, buildings, machinery, wire
 - Bone – from improper plant processing
 - Plastic – from packaging materials, pallets
 - Personal effects – jewelry, buttons, bandaids, etc.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 025
Issue: 2010 I-020**

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

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Title:

American National Standards for Food Equipment - Clarification of Food Code

Issue you would like the Conference to consider:

Section 4-205.10 of the Food Code, titled *Food Equipment, Certification and Classification* currently references ANSI accredited certifications or classifications of food equipment, but the Food Code language is not clear or specific as to what the certification or classification programs should be based on. In the U.S., state and local regulatory agencies routinely require retail foodservice equipment to comply with the specific requirements of American National Standards, which in turn comply with the requirements of the Food Code. Expanding the Food Code to reflect the wide range and complexity of retail foodservice equipment technical requirements is not practical. This considerable level of technical detail has traditionally, and effectively, been dealt with by reference to American National Standards. As such, it is requested that the Conference for Food Protection clarify this section of the Food Code to reflect the original intent and current practice. This is efficiently accomplished by adding "...to the corresponding American National Standard listed in Annex 8," to *Section 4-205.10*.

Public Health Significance:

The rapid increase of imported foods and food equipment, and the many public health related issues associated with imported products, makes it vitally important to have products comply with American National Standards, where specific requirements for compliance are clearly spelled out. Manufacturers, exporters, importers, wholesalers, retailers, consultants and regulators at all levels understand the role and importance of American National Standards, and participate in their development and maintenance. Specification of the appropriate national standards in the Model Food Code clarifies the original intent, increases consistency of certifications, and results in increased public health protection. Having clearly defined equipment requirements is essential to increasing regulatory compliance.

Background

Equipment sanitation is a critical component of state and local regulatory food safety programs, and is an integral part of the Model Food Code. Food equipment materials, performance, design and cleanability are all critical components of the Model Food Code and are detailed in the American National Standards for Food Equipment. The purpose of

the current Section 4-205.10 of the Food Code is to reference ANSI-accredited third party certifications or classifications of Food Equipment. It is implied that the certifications or classifications are to the requirements of specific American National Standards. Given the widespread adoption of the Model Food Code at the State and Local levels, it is very important that the intent of the FDA and the CFP is without question.

The 2009 Model Food Code currently references "Acceptability" of foodservice equipment in Section 4-205.10, titled Food Equipment, Certification and Classification. This section of the Food Code currently reads:

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 certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.*

Section 4 of the 2009 Model FDA Food Code addresses foodservice equipment sanitation requirements for only limited types of commercial food equipment, whereas today, the scope of food equipment used in the foodservice industry is much broader. This wider scope of equipment is collectively covered by the combined American National Standards established for commercial foodservice equipment listed in the attached Annex 8.

Referencing the ANSI standards simply reflects what manufacturers and regulators use today. Listing the ANSI Standards does not preclude other standards from being accepted by the state or local regulatory authorities.

Adoption of the proposed language recognizes that the technical requirements established in American National Standards for foodservice equipment meet the same minimum technical requirements of the 2009 Food Code, and more importantly, clarify that the American National Standards are the basis of ANSI-accredited certification programs, as currently cited in Section 4-205.10 of the Food Code.

Recommended Solution: The Conference recommends...:

sending a letter to the FDA requesting the addition of the language specified below to the Food Code, as well as Annex 8 that lists the relevant American National Standards.

Acceptability 4-205.10 Food Equipment, Certification and Classification.

- *FOOD EQUIPMENT that is certified or classified for sanitation to the corresponding American National Standard listed in Annex 8. by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.*

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Attachments:

- "Proposed ANNEX 8 of Food Code"
- "NEHA Letter of Support"

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Proposed ANNEX 8 of Food Code

List of ANSI Food Equipment Standards

The following standards were established and adopted by the ANSI process as minimum voluntary consensus standards and are also used internationally:

NSF/ANSI 2	Food equipment
NSF/ANSI 3	Commercial warewashing equipment
NSF/ANSI 4	Commercial cooking, rethermalization, and powered hot food holding and transport equipment
NSF/ANSI 5	Water heaters, hot water supply boilers, and heat recovery equipment
NSF/ANSI 6	Dispensing freezers
NSF/ANSI 7	Commercial refrigerators and freezers
NSF/ANSI 8	Commercial powered food preparation equipment
NSF/ANSI 12	Automatic ice making equipment
NSF/ANSI 13	Refuse processors and processing systems
NSF/ANSI 18	Manual food and beverage dispensing equipment
NSF/ANSI 20	Commercial bulk milk dispensing equipment
NSF/ANSI 21	Thermoplastic refuse containers
NSF/ANSI 25	Vending machines for food and beverages
NSF/ANSI 29	Detergent and chemical feeders for commercial spray-type dishwashing machines
NSF/ANSI 35	High pressure decorative laminates (HPDL) for surfacing food service equipment
NSF/ANSI 36	Dinnerware
NSF/ANSI 37	Air curtains for entranceways in food and food service establishments
NSF/ANSI 51	Food equipment materials
NSF/ANSI 52	Supplemental flooring
NSF/ANSI 59	Mobile food carts
NSF/ANSI 169	Special purpose food equipment and devices
ANSI/UL 2333	Infrared Thermometers



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December 21, 2009

Conference for Food Protection
2792 Miramar Lane
Lincoln, CA. 95648

To Whom It May Concern:

The National Environmental Health Association (NEHA) is pleased to provide this letter of support for the 2010 CFP issue titled: *American National Standards for Food Equipment – Clarification of Food Code Intent*, which was drafted by NSF International and Underwriters Laboratories Inc.

While Section 4-205.10 of the Model Food Code identifies the need for food service equipment to be certified by an ANSI-Accredited organization, it is lacking with respect to identifying a specific standard(s) for the equipment certification. The language proposed in this issue submission identifies the appropriate national standard(s) for product certification. Addition of this language completes both the need for certification as well as the means of certification.

NEHA urges the Conference for Food Protection to accept this issue and incorporate the suggested language into the Model Food Code.

Sincerely,

Welford C. Roberts, M.S., Ph.D., R.S. / R.E.H.S., D.A.A.S.
NEHA President

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 026
Issue: 2010 I-016**

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Title:

Criticality Implementation&Education Committee - Frequently Asked Questions

Issue you would like the Conference to consider:

The Criticality Implementation and Education Committee requests that FDA provide answers to a list of Frequently Asked Questions (FAQs) developed by the committee and have the FAQs and answers available for stakeholders on or before June 30, 2010.

Public Health Significance:

The re-designation of the Food Code provisions from two to three criticality ratings was accepted by the 2008 Biennial Meeting of the Conference Food Protection. The Criticality Implementation and Education Committee was charged with providing a variety of educational tools to explain the changes and the rationale of the new three risk-based priority designations. A list of Frequently Asked Questions (FAQs) was developed by the committee in anticipation of many of the questions that will be asked by stakeholders as they incorporate the use of the new designations into action plans, intervention strategies, and effectiveness measures. The FAQs will help stakeholders understand the use of the new designations in prioritizing violations and corrections in regards to risk factors.

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA requesting that they:

1. provide answers to the list of FAQs included in the attached document.
2. have the FAQs and answers available for stakeholders on or before June 30, 2010 by posting on the FDA website.

Submitter Information:

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Attachments:

- ""Frequently Asked Questions" Document"

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Criticality Implementation and Education Committee
2008-2010

FREQUENTLY ASKED QUESTIONS

THE RE-DESIGNATION OF FOOD CODE PROVISIONS



Introductory

1. Why have the terms “critical and “non-critical” been replaced with other terms in the Food Code?
2. What is the rationale for utilizing three designations in the Food Code, rather than two designations?
3. What are the names of the three designations and what are the definitions?
4. Who was involved in the process to change from critical/non-critical to priority, priority foundation, and core?
5. Why was the FDA Criticality Work Group formed and who was on the work group?
6. Are there any plans for a focus group study to be conducted by the Conference for Food Protection’s (CFP) Criticality Implementation and Education Committee or by FDA as was charged by the CFP?
7. What is the level of risk for each designation?
8. What are some examples of each designation?
 - a. Priority Item Examples:
 - b. Priority Foundation Item Examples:
 - c. Core Item Examples:
9. Why is each subparagraph of the Food Code now designated?
10. Will all regulatory jurisdictions be required to adopt the new designations?

11. When will the regulatory jurisdictions be required to adopt the 2009 Food Code with these new designations in order to meet Program Standard #1?

12. Will regulatory jurisdictions be required to adopt the designations Priority, Priority Foundation and Core in order to meet Program Standard #1?

Food Safety Issues

1. How will the change to three designations (or categories) of importance improve food safety and reduce illness?

2. Are the priority foundation items a direct cause of foodborne illness?

3. Are the three designations based on scientific data and will they change if the science changes?

4. How can the three designations be used by Industry to minimize risk factors within their operation?

Regulatory Issues

1. Will the methods used to conduct inspections change because of the new designations?

2. How can regulatory inspectors use the three designation system to maximize their time during inspections?

3. How will the three designation system help prioritize the time of regulators and industry?

4. My jurisdiction is using the CFP inspection form. Will the three designation system result in a modification of the provisions listed in the risk factor and intervention code reference table? Will the Good Retail Practices code reference table be modified due the change to the three designation system?

5. Will the inspection form change due to the change to the three designation system?

6. How much time must a regulator allow a food establishment to correct violations in the following designations?

a. Priority Item violations:

b. Priority Foundation Item violations:

c. Core Item violations:

7. What are some specific examples of the enforcement actions of the priority or priority foundation item violations?
 - a. If using a risk based assessment of a food establishment in a jurisdiction that enforces 41F, would TCS food held at 45F be considered a priority foundation item or priority item violation?
 - b. If using a risk based assessment of a food establishment in a jurisdiction that enforces 140F, would TCS food held at 135F be considered a priority foundation item or priority item violation?
 - c. If using a risk based assessment of a food establishment and the sanitizer sink solution in a refrigerated prep room falls below 75F, is this a priority item, priority foundation item, or core item violation or no violation?
8. Is there a recommended scoring mechanism or matrix relating violations of the three designations to points?
9. Will the new designations impact risk factor and intervention baseline activities that we are following as part of our enrollment in the FDA Program Standards?

Training / Industry Issues

1. When will the new three designation system be in effect?
2. Will there be a “transition time” from the old system to the three designation system?
3. Where can I find more information about the new three designation system?
4. When will the ANSI-CFP licensed examination providers integrate the new designations into their job analysis and examinations?
5. Will FDA revise the Standardization Procedures Manual to reflect the new three designation system? Will the new designations require any changes in the standardization process?
6. Are guidelines/tools being developed to assist local and state health jurisdictions in the process of evaluating their current risk-based inspection system based on the new designations?
7. Since uniform training is a priority to assure the knowledge and implementation of the new designations, will training workshops, materials or a PowerPoint be developed for industry and regulators?
8. Will the health department provide classes so we can understand the new designations?

9. How can industry use the new designations in training front line workers?
10. Will my health department inspection look different?
11. Is the new designation system more subjective?
12. Will a list of primary changes be provided?
13. What will cause a health code violation with the new designations?
14. How long will I have to correct violations in the following designations?
 - a. Priority Item violations:
 - b. Priority Foundation Item violations:
 - c. Core Item violations:
15. What happens if my restaurant gets multiple violations?
16. What is an example of a Priority violation that was a critical violation?
17. A display of window glass cleaner over paper towels is now listed as a critical violation by my regulatory agency. Would this practice now be designated as a Priority Item violation or a Priority Foundation Item violation? Why?

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 027
Issue: 2010 I-021**

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

All information above the line is for conference use only.

Title:

3-304.14 Wiping Cloths, Use Limitation

Issue you would like the Conference to consider:

Some state/county regulatory jurisdictions only allow the use of reusable wet wiping cloths to wipe counters/equipment and require they be stored in a chemical sanitizing solution. Many retail establishments across the United States use dry disposable towels with pre-mixed sanitizer supplied in spray bottles in lieu of the wet cloth and bucket method. Some health authorities require that a variance must be applied for to use dry disposable towels with a spray bottle of sanitizer instead of the wet wiping cloths. The Food Code needs to recognize the use of dry disposable towels and a spray bottle of chemical sanitizer solution in lieu of wet wiping cloths stored in a sanitizing solution is an acceptable and equivalent method for wiping down counters and equipment.

Public Health Significance:

As long as the disposable towels are disposed of after each use, and the chemical sanitizer solution in the spray bottle meets the concentration specified under 4-501.114, there are no adverse Public Health consequences. This process has been in use extensively throughout the retail food industry without consequence for years. In fact, it can further minimize risks by avoiding the potential build up of organic material associated with the re-usable cloth and bucket method for wipe downs. It also maintains the correct concentration of sanitizer since it is not exposed to dilution and organic buildup. Annex 3, 3-304.14 essentially supports this issue in that it states that dry wiping cloths do not require being stored in a sanitizer solution at all times and disposable wiping cloths avoid the issue of buildup of soil from organic material.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that section 3-304.14, section (B), be amended to add subsection 3 as follows:

3-304.14 Wiping Cloths, Use Limitation.

1. (A) Cloths in-use for wiping food spills from tableware and carry-out containers that occur as food is being served shall be:
 - (1) Maintained dry; and
 - (2) Used for no other purpose.

(B) Cloths in-use for wiping counters and other equipment surfaces shall be:

(1) Held between uses in a chemical sanitizer solution at a concentration specified under § 4-501.114; and

(2) Laundered daily as specified under ¶ 4-802.11(D); or

(3) Dry disposable towels used in conjunction with a spray bottle of chemical sanitizer solution at a concentration specified under § 4-501.114 are excluded from being maintained in a chemical sanitizer solution as long as the towels are disposed of after each use.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 028
Issue: 2010 I-024**

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

All information above the line is for conference use only.

Title:

Management Responsibility Code Section 2-101.11

Issue you would like the Conference to consider:

Food Code Chapter 2, Management and Personnel, Part 2-1 Supervision, Section 2-101.11 Responsibility: The current language fails to clearly define permit holder responsibility for implementation and maintenance of operating procedures to control and prevent the occurrence of risk factors known to cause foodborne illness after a food establishment is permitted.

Clearly the intent of the Food Code is that applicants for a permit to operate a food establishment develop operating procedures as required by Section 8-201.12 to ensure compliance with requirements of the Code. The duties of the Person-In-Charge and other management requirements specified in Chapter 2 would presumably be addressed in these operating procedures; however, this is not stated.

Public Health Significance:

Current Food Code language fails to assign specific management responsibility for the implementation and continued maintenance of operational procedures after a food establishment is permitted. Operating procedures are an important management tool for the control of risk factors inherent in a food establishment. The absence of procedures for performing specific task, training employees and management verification may compromise consumer safety. Operating procedures should be implemented and sustained to control risk factors and prevent "behavior creep." For example, a cooling procedure is designed to use a specific-size shallow pan for cooling. However, one day, the designated pan is not readily available, so an employee uses a deeper pan. New employees are hired and they adopt the new practice and it becomes routine for employees to use a deeper pan out of convenience, although it results in much longer cooling times. Because of behavioral creep, the procedure is no longer safe and the risk factor is no longer under control. Operating procedures provide a constant against which day to day operations may be evaluated by management to prevent behavior creep and ensure day to day control of risk factors.

Also, because there is no specific requirement in Chapter 2 that operating procedures be maintained and updated after a permit is issued, regulatory inspectors do not consistently verify that operating procedures are current or even exist. This often results in a discussion

of operating procedures after code violations are noted during a regulatory inspection and corrective action is necessary. A more desirable approach would be for regulator inspections to review and reinforce the food establishment's operating procedures during routine inspections to prevent future code violations.

The development and implementation of operating procedures which address polices and procedures, employee training, and management oversight are proven management principles. Operating procedures designed to control the risk inherent to a specific food operation provide the management structure for a safe and successful food operation.

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 replaced 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*

The PERMIT HOLDER through the certified food manager or person in charge (PIC) is responsible for ensuring:

- That standard procedures that ensure compliance with the requirements of this Code are developed & implemented as specified under 8-201.12 (E) & (F);
- Procedures for the operation of the FOOD ESTABLISHMENT are kept current and address all risk factors which are inherent to the food operation.
- Employees are trained to ensure tasks are performed in accordance with the operating procedures and that there is at least one trained individual present at all times;
- Food preparation activities are directed & action taken, as needed, to protect the health of the consumer; and
- In-house self-inspections of operations are conducted on at least a daily basis to ensure that food safety policies & procedures for the control of risk factors inherent to the operation are followed.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 030
Issue: 2010 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:

Consumer Advisory for pinned/injected/tenderized meats: Food Code 3-603.11

Issue you would like the Conference to consider:

The current consumer advisory requirement in Section 3-603.11 do not clearly communicate to the consumer that consumption of raw or undercooked meats which have been tenderized may increase there risk of foodborne illness. This is particularly relevant for beef steaks. Consumers are not generally aware that mechanical tenderization steak should be cooked to a higher temperature than whole-muscle intact beef steak to achieve the same degree of safety.

Public Health Significance:

The increased use of mechanically tenderized meats by food establishments is a growing food safety concern. Undercooked meats and beef steak in particularly must be cooked to higher temperatures to achieve the same degree of safety as whole-muscle intact cuts of meat. Consumers who consume tenderized steaks cooked rare or medium rare are not generally aware of this increased risk. A recent foodborne illness has been traced to the consumption of tenderized steaks which were cooked rare or medium rare.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that additional language be added to 3-603.11 (B) [1] and 3-603.11 (C) [3] to read as follows:

- 3-603.11 (B) [1] A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)" " raw-EGG Caesar salad," "hamburger (can be cooked to order)" and "mechanically tenderized meats (pinned or injected);" or
- 3-603.11 (C) [2] Consuming raw or undercooked Meats, Poultry, seafood, shellfish, eggs or tenderized meats (pinned or injected) may increase your risk of foodborne illness; or

Submitter Information:

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Attachments:

- "Recall Notice Update"

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Update #1 to National Steak and Poultry E. coli O157:H7 outbreak in blade tenderized steaks - CDC is collaborating with public health officials in several states and USDA FSIS to investigate a multistate outbreak of human infections due to E. coli O157:H7, in which as of January 4, 2010, 21 persons infected with the outbreak strain of E. coli O157:H7 have been reported from 16 states.

Organization: Centers for Disease Control and Prevention (CDC)

Source: CDC update from January 6, 2010

Date Released: 01/06/2010

Web site: The Jan. 6, 2010 CDC update is at <http://www.cdc.gov/ecoli/2010/index.html>

A Dec. 24, 2009 USDA FSIS press release is at

[The>http://www.fsis.usda.gov/News_ & Events/Recall_067_2009_Release/index.asp](http://www.fsis.usda.gov/News_&_Events/Recall_067_2009_Release/index.asp)

[The](http://www.nationalsteak.com) National Steak and Poultry web site is at <http://www.nationalsteak.com> but as of this writing contained no information on the recall.

A FIEN message on this topic from Dec. 25, 2009 is at <http://www.fien.com/articleDisplay.php?id=11852>

Contact: None provided.

Summary: From the Jan. 6, 2010 CDC update:

As of Monday, January 4, 2010, 21 persons infected with the outbreak strain of E. coli O157:H7 had been reported from 16 states. The number of ill persons who were identified resides in each state as follows: CA (1), CO (1), FL (1), HI (1), IA (1), IN (1), KS (1), MI (1), MN (3), NV (1), OH (2), OK (1), SD (2), TN (1), UT (2), and WA (1).

Known illness onset dates range from October 3, 2009 through December 14, 2009. Most patients became ill between mid-October and late November. Patients range in age from 14 to 87 years and the median age of patients is 34 years, which means half are younger than 34 years. Forty-three percent of patients are females. There have been 9 reported hospitalizations, 1 case of hemolytic uremic syndrome (HUS), and no deaths.

In early December 2009, CDC's PulseNet staff identified a multistate cluster of 14 E. coli O157:H7 isolates with a particular DNA fingerprint or pulsed-field gel electrophoresis (PFGE) pattern reported from 13 states. CDC's OutbreakNet team began working with state and local partners to gather epidemiologic information about persons in the cluster to determine if any of the ill individuals had been exposed to the same food source(s). Health officials in several states who were investigating reports of E. coli O157:H7 illnesses in this cluster found that most ill persons had consumed beef, many in restaurants. CDC is continuing to collaborate with state and local health departments in an attempt to gather additional epidemiologic information and share this information with FSIS. At this time, at least some of the illnesses appear to be associated with products subject to a recent FSIS recall.

On December 24, 2009, FSIS issued a notice about a recall of 248,000 pounds of beef products from National Steak and Poultry that may be contaminated with E. coli O157:H7. The recall was issued after FSIS determined there was an association between non-intact steaks (blade tenderized prior to further processing) and illnesses in Colorado, Iowa, Kansas, Michigan, South Dakota and Washington.

Prepared by: This message was distributed by Cindy Roberts, who may be reached at e-mail: emailE=('car@' + 'fien.com') document.write(" + emailE + ") car@fien.com or 202-669-6951

This article (#11964) was distributed by e-mail on January 7, 2010 to those whose names are on the FIEN, LLC Subject Matter Distribution Lists for Food Safety; Meat, Poultry and Eggs

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 034
Issue: 2010 I-002**

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

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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 committee report and requests that the committee be reinstated to continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2012 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...:

1. Acknowledgement of the CFP Plan Review Committee Report;
2. Re-creation of the committee to continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2012 CFP Biennial Meeting; and,
3. Thanking the Committee members.

Submitter Information:

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Organization: 2008-2010 Plan Review Committee
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Attachments:

- "Plan Review Committee Final Report"

- "2008-2010 Plan Review Committee Member Roster"

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**Conference for Food Protection
Committee FINAL Report**

COMMITTEE NAME: Plan Review Committee

COUNCIL (I, II, OR III): I

DATE OF REPORT: December 4, 2009

SUBMITTED BY: Liza Frias, Chair

COMMITTEE CHARGE(s):

The Conference recommends that the Plan Review Committee continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2010 CFP Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Due to the resignation of the prior committee chair and lack of prior history, no committee work was completed until the first conference call which was held on August 18, 2009.

During the initial conference the following was discussed:

Review the progress of the past Plan Review Committee and to determine next steps.

- The final document as approved at the 2008 CFP Biennial Meeting was not formatted. The committee will complete formatting and send to the FDA Plan Review Working Group for final review. No additional charge is needed since the document was approved pending the final formatting.

Discuss how to approach the CFP charge with limited time.

- The committee decided to work on changes to the Pre-Operational Temporary Food Establishment document.

The committee has held monthly conference calls since August 2009 and has initiated discussions and recommended changes to the Pre-Operational Temporary Food Establishment document. Unfortunately, there is not a final draft that can be presented at the 2010 CFP Biennial Meeting.

Recommendations for future charge:

The committee recommends that the following charges be made to a re-created Plan Review committee following the CFP 2010 Biennial Meeting:

- Continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2012 CFP Biennial Meeting.

REQUESTED ACTION:

The Plan Review committee will submit one issue at the 2010 Biennial Meeting based on the recommendations of the committee.

Acknowledgement of Plan Review Committee's report with continuation charges.

COMMITTEE MEMBER ROSTER: See attached

Committee Name: Plan Review Committee

Last Name		Position (Chair/Member)		Constituency	Employer	Address	City	State	Zip	Telephone	Email
Brown	Vakesha	Member	Regulatory - State	FL Department of Health	4052 Bald Cypress Way, Bin A-08	Tallahassee	FL	32399	(850) 245-4277	Vakesha_Brown@doh.state.fl.us	
Brown	Robert	Member	Industry - Retail Food Stores	Whole Foods Market	550 Bowie St	Austin	TX	78703	512-542-3043	robert.brown@wholefoods.com	
Bullock	Teresa	Member	Regulatory - State	Arkansas Department of Health	4815 West Markham, Slot H-46	Little Rock	AR	72205	(501) 661-2171	teresa.bullock@arkansas.gov	
Coleman	Gary	Member	Other - Standards and Compliance	Underwriters Laboratories, Inc.	12 Laboratory Drive	Research Triangle Park	NC	27709-3995	(919) 549-1732	gary.coleman@us.ul.com	
Daye	Judy	Member	Regulatory - State	Environment and Natural Resources	PO Box 1908	Salisbury	NC	28145-1908	(704) 645-0590	judy.daye@ncmail.net	
Frias	Liza	Chair	Industry - Retail Food Stores	Supervalu	1421 S. Manhattan Avenue	Fullerton	CA	92831-5221	(714) 300-6813	liza.frias@supervalu.com	
Grenawitzke	Harry E.	Member	Other - Standards and Compliance	NSF International	50 Sheridan Drive	Monroe	MI	48162-2941	(734) 241-7434	harryeg@comcast.net	
Grzywinski	Kristie	Member	Industry - Food Service	National Restaurant Association Solutions	175 W. Jackson Blvd., Suite 1500	Chicago	IL	60404	(312) 715-6784	kgrzywinski@restaurant.org	
Hirsch	Brian W.	Member	Regulatory - Local	Summit County General Health District	1100 Graham Road Circle	Stow	OH	44224	(330) 926-5653	bhirsch@sched.org	
Jue	Robert	Member	Regulatory - Local	Central District Health Department	707 N. Armstrong Place	Boise	ID	83704-2628	(208) 327-8523	rjue@cdhd.idaho.gov	
Madden	Tressa	Member	Regulatory - State	Oklahoma State Department of Health	1000 NE 10th	Oklahoma City	OK	73117-1299	(405) 271-5243	tressam@health.ok.gov	
Menikheim	Jody	Member	Regulatory - State	State of Maryland - Food Protection/Consumer Health	6 St Paul Street, Suite 1301	Baltimore	MD	21202	(410) 767-8454	jodym@dnhm.state.md.us	
Mitchell-Baker	Cassandra	Member	Regulatory - Local	Fairfax County Health Department	10777 Main Steet, Suite 111	Fairfax	VA	22030	(703) 246-8438	cassandra.mitchell@fairfaxcounty.gov	
Mygind	Claus	Member	Vending Industry	National Automatic Merchandising Association	508 Braemar Ave.	Naperville	IL	60563-1373	(630) 355-2423	cmygind@yahoo.com	
Odom	Alan	Member	Industry - Food Service	Compass Group	310 West Church St.	Benton	IL	62812	(618) 439-9753	alan.odom@compass-usa.com	
O'Sullivan	Frank	Member	Other - Consulting Services	Frank O'Sullivan Consulting	22542 Indian Springs Road	Salinas	CA	93908-9602	(408) 832-5844	frankos@ix.netcom.com	
Steinbach	Pamela	Member	Regulatory - State	Minnesota Department of Health	1645 Energy Park Drive, Suite 300	St. Paul	MN	55108	(651) 632-5147	pam.steinbach@health.state.mn.us	
Wagner	Jim	Member	Other-Laboratory Services	The Steritech Group, Inc.	7621 Little Avenue	Charlotte	NC	28227	(508) 207-5769	jim.wagner@steritech.com	
Watts	Debbie	Member	Regulatory - Local	Tulsa Health Department	4616 E. 15th Street	Tulsa	OK	74112	(918) 595-4305	dwatts@tulsa-health.org	
Williams	Debra	Member	Regulatory - State	Florida Division of Hotels and Restaurants	1940 North Monroe Street	Tallahassee	FL	32399-0760	(850) 488-1133	deborah.williams@dbpr.state.fl.us	
Wise	Kendra	Member	Regulatory - Local	Tulsa Health Department	4615 East 15th	Tulsa	OK	74112	(918) 595-4322	kwise@tulsa-health.org	
Wyckoff	Steven L.	Member	Industry - Food Service	Wal-Mart Stores Inc.	702 Southwest 8th Street	Bentonville	AR	72716-0275	(479) 277-9202	steve.wyckoff@wal-mart.com	
George	Shaji	Member	Industry - Food Service	Walt Disney World Company	P.O. Box 10,000	Lake Buena Vista	FL	32819	(407) 397-6605	shaji.george@disney.com	
Moore	Veronica	FDA Advisor	Regulatory - Federal	US Food & Drug Administration	CPK1 Room 3B035 HF320 5100 Paintbranch	College Park	M	20740	(301) 436-1409	veronica.moore@fda.hhs.gov	
Redditt	Dan	FDA Advisor	Regulatory-Federal	US Food & Drug Administration	60 8th St. N.E.	Atlanta	GA	30309	(404) 253-1265	joseph.redditt@fda.hhs.gov	

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 038
Issue: 2010 I-018**

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

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Title:

Effective Risk Communication for Process HACCP

Issue you would like the Conference to consider:

The current FDA Food Code form of using "Priority, Priority foundation and Critical item" designations needs better clarification, categorization and communication within the code Annex.

Public Health Significance:

Use of the same terms but from different perspectives has led to confusion among food handlers, inspectors and the public relative to "critical limits" for critical control points.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that the following language be placed in the Food Code Annex 3 section 1-201.10, after "Accredited Program" section and before "egg" section:

There are up to *three different critical limit concepts* or points of refence for every *pathogen* related critical control point:

1. The science based critical limit. Lets call is the "SCL". It is the same in Saigon as in St. Paul. If we identify all of the environmental and food characteristics that give rise to the given microbial hazard, then we can agree upon peer reviewed published data and given statistical analysis and the consensus standards process establish a single fixed "SCL". With that, we'd likely say that 127.5F is the SCL for hot food holding based upon peer reviewed, published scientific research (*F. Busta, et al*).
2. The compliance critical limit. Lets call it the "CCL". In Minnesota, since their administrative rule (MR4626) is based on the 1995 FDA Food Code, that minimum hot safe food holding temp is 140F. In Maryland where they modeled code after the 2008 FDA Food code and their Title 10, subtitle 15 Chapt 03.06 states: "(7) Except as provided in §B(8)-(14) of this regulation, the internal temperature of a potentially hazardous food is kept at 41°F or less or 135°F or greater". The downward revision to 135F was hotly debated for several CFPs with data presented in council 3 to support the scientific critical limit was at least 12 degress below 140. The revision finally passed at the '08 conference. (comment: some will say that the point at which the critical limit should be measured is a core temp. *This is not true*. Surface temps

are most likely to be abused when you are hot or cold holding....not core temps.)
Note that the CCL's change based upon the local licensing authority, and the
method and means for measuring the critical limit may vary by interpretation and
inspector. Further confusion abounds do to differences in equipment performance
test standards critical limits and the food codes criteria. For example, the NSF/ANSI
standard 7 critical limit measurement point for cold holding is 1" below the surface of
the food. The food code requires all of the food to be at the stated CL or better
without exempting the top 1" layer of food. Then, where is the point of measurement
for hot holding critical limit relative to the code vs. NSF/ANSI Std 4? These "gaps"
reduce the effectiveness of the codes risk message.

3. The quality critical limit. Lets call this the "QCL". One of my global QSR clients sets
a QCL for hot food holding at 160F. One of their franchisees sets a QCL for his
stores at 165. QCL's change with each operator. In some cases it varies by
franchisor. But in others it may vary from one franchisee to another. Multiunit
operators food safety plans must have the flexibility to accommodate these
differences without confusing its food handlers and risk managers at corporate and
franchise levels.

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Attachments:

- "The Three Tiers for Microbial Critical Limits"

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or a commercial proprietary process.*

The Three Tiers for Critical limits

By Tom Johnson, JDP, Inc. tomi@jdpinc.com

Effective risk communication is crucial to reducing risk and it is a core principle of risk management.

The FDA Food Code has embraced the principles of HACCP from a process perspective, whereby throughout the code critical control points are denoted as **Priority items** (^P), control points, or the control procedures needed to ensure compliance of the Priority item are referred to as **Priority foundation** (^{Pf}), and standard sanitary operating procedures (SOP's, which have also been called *prerequisite programs*) are referred to as **Core items**.

The above recent addition/revisions to the code were implemented in part to enhance the risk communication relative to common food product/processes. It is well known that effective risk communication requires that those in the communication loop share the same perspective and frame of reference. Because the FDA Food code is constantly evolving, the specific critical limits in today's code are often different than those found in food rules published in older editions. This presents a moving target due to the different dates of rule adoption by the many dozens of States and the thousands of boards of health and other licensing authorities.

This jurisdiction-to-jurisdiction variability confuses food handlers, risk managers and the public yielding ineffective risk communication. When people do not understand the basis for the variability of critical limits, the integrity of the whole code suffers with a corresponding increase in risk.

Here is but one example of the above referenced critical limit confusion: *what is the critical limit for hot food holding?*

The answer: it depends where you are and what you are talking about.

Effective risk communication mandates that we cut through this fog and clearly articulate facts.

To keep our process HACCP risk communication effective, we must have a tight correlation of each stated critical limit to our intended point of reference.

There are up to *three different critical limit concepts* or points of reference for every *pathogen* related critical control point:

1. **The science based critical limit.** Lets call it the "SCL". It is the same in Saigon as in St. Paul. If we identify all of the environmental and food characteristics that give rise to the given microbial hazard, then we can agree upon peer reviewed published data and given statistical analysis and the consensus standards process establish a single **fixed "SCL"**. With that, we'd likely say that 127.5F is the SCL for hot food holding based upon peer reviewed, published scientific research (*F. Busta, et al*).
2. **The compliance critical limit.** Lets call it the "CCL". In Minnesota, since their administrative rule (MR4626) is based on the 1995 FDA Food Code, that minimum hot

safe food holding temp is 140F. In Maryland where they modeled code after the 2008 FDA Food code and their Title 10, subtitle 15 Chapt 03.06 states: “(7) Except as provided in §B(8)—(14) of this regulation, the internal temperature of a potentially hazardous food is kept at 41°F or less or 135°F or greater”. The downward revision to 135F was hotly debated for several CFPs with data presented in council 3 to support the scientific critical limit was at least 12 degrees below 140. The revision finally passed at the '08 conference. (comment: some will say that the point at which the critical limit should be measured is a core temp. *This is not true.* Surface temps are most likely to be abused when you are hot or cold holding....not core temps.) Note that the **CCL's change based upon the local licensing authority,** and the method and means for measuring the critical limit may vary by interpretation and inspector. Further confusion abounds do to differences in equipment performance test standards critical limits and the food codes criteria. For example, the NSF/ANSI standard 7 critical limit measurement point for cold holding is 1” below the surface of the food. The food code requires all of the food to be at the stated CL or better without exempting the top 1” layer of food. Then, where is the point of measurement for hot holding critical limit relative to the code vs. NSF/ANSI Std 4? These “gaps” reduce the effectiveness of the codes risk message.

3. **The quality critical limit.** Lets call this the “QCL”. One of my global QSR clients sets a QCL for hot food holding at 160F. One of their franchisees sets a QCL for his stores at 165. **QCL's change with each operator.** In some cases it varies by franchisor. But in others it may vary from one franchisee to another. Multiunit operators food safety plans must have the flexibility to accommodate these differences without confusing its food handlers and risk managers at corporate and franchise levels.

HACCP is about RISK, not quality. That said many if not most companies integrate quality criteria into their HACCP plans, largely for convenience. Nonetheless, it is not logical to have your QCL as your CCP. You may use the local CCL for your CCP, but the SCL must be also stated so food handlers and risk manager can better understand the required interventions for the stated hazard given its scientific underpinnings.

If everyone that got certified as a food manager by one scheme or another had this fundamental differentiation as a part of their training, then they would have the foundation to understand the science based limit and the public health rationale for the compliance critical limit being different specific values.

Further, by accommodating a quality critical limit, retailers and food service operators can create a single HACCP plan (or food plan if you prefer) with dramatic improvement in the effectiveness of their plans risk communication.

Effective risk communication is fundamental to risk analysis and management. HACCP is mush without it.

Tom Johnson CFP 2010

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 039
Issue: 2010 I-009**

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 Model Food Code, Section 3-603.12.

Issue you would like the Conference to consider:

The Model 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. Grocery stores and vendors selling packaged food should 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 play an important role in removing recalled foods from the shelves, this does not address the products that have already been sold. The amendment proposes two approaches to better inform consumers about recalled products.

Posting of recall information in a prominent manner in grocery stores is an important part of protecting the public health from contaminated product. Consumers may purchase product that is later implicated in a recall, and grocery stores can play an integral role in warning consumers not to consume the product. Unfortunately, current warning systems are inadequate to reach consumers. Providing notice in grocery stores would remind consumers of ongoing recalls, so that they may better check their home kitchens for recalled products.

Further, where retailers routinely collect consumer purchase data, that information can be used to assist consumers in the event of a Class I recall. Retailers should be using purchase information and the coordinating consumer contact information to alert consumers to their previous purchases of products that are currently subject to 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 FDA recommending the addition of the following Section 3-603.12 of the Model Food Code, *Recall Notification*.

3-603.12 Recall Notification.

(A) Every FOOD ESTABLISHMENT that offers PACKAGED FOOD for purchase by consumers shall, in the event of a Class I Recall of any FDA or USDA product sold by the FOOD ESTABLISHMENT, inform consumers of the recall by way of a DISCLOSURE and REMINDER as specified in sections (1) and (2) of this section.

(1) DISCLOSURE shall include:

1. A sign indicating that a Class I Recall is in effect for the relevant product, which shall be:
 - 1.1. at the location within the FOOD ESTABLISHMENT where a consumer would ordinarily find the product, such as a shelf, freezer case, or produce cart, and
 - 1.2. Within 3 feet of the cash register or point of purchase, and
 - 1.3. Within 3 feet of the entrance to the FOOD ESTABLISHMENT.

(2) REMINDER shall include contacting consumers for whom the store has purchasing information (through use of a consumer loyalty card or other data-collection methods) indicating the purchase of the recalled product within the previous 60 days, and for whom the FOOD ESTABLISHMENT has contact information.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 041
Issue: 2010 I-004**

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

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Title:

Inclusion of Inspection Result Posting in the Model Food Code

Issue you would like the Conference to consider:

Rigorous health inspections are a critical component of an effective food safety system. The Model 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. For more information, visit

<http://www.cspinet.org/dirtydining/index.html>.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending addition of the following language to Section 8-4 *Inspection and Correction of Violations*:

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 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
2010 Issue Form**

**Internal Number: 042
Issue: 2010 I-003**

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 Model 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 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 recommending the addition of the following language to Section 8-4 *Inspection and Correction of Violations*:

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
2010 Issue Form**

**Internal Number: 043
Issue: 2010 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:

Key Drop

Issue you would like the Conference to consider:

"Key drop" delivery is a common practice in the food industry, including the retail and restaurant segments. The practice allows for the safe delivery of food and other products during hours when the establishment is closed, usually between midnight and 6 am. Delivery personnel store items appropriately as refrigerated, frozen or dry goods and establishment personnel inspect and officially confirm receipt of the goods upon their arrival the day of the delivery.

Public Health Significance:

The current FDA Food Code (§ 2.103.11 (E)) identifies the importance of having a Person in Charge or "employee" duty include the receipt and inspection of foods and other goods delivered to an establishment. Food Code § 1.201.10 (B) defines an employee to mean "the permit holder, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in the food service establishment." This definition allows for the lawful delivery of goods by a distribution company provided that the distribution personnel are performing their duties under contract with the food establishment.

It is important to clarify this role in § 2-103.11 (E) to include distribution personnel and affirm that the key drop practice, already in accordance with FDA Food Code, is specifically identified for all to understand. It is with this further clarity that all States may confidently adopt this segment of the FDA Food Code and consistently enable the key drop practice.

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 drop deliveries by including the following language:

(F) Distribution EMPLOYEES for key drop deliveries are delivering goods at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the delivered goods at time of delivery Pf;

Further, that ¶ 1-201.10 (B) be amended to define key drop as follows:

"Key Drop" means a delivery of food and goods to an establishment that occurs when it is closed. Distributors deliver and place products in coolers, freezers and dry goods storage areas for LATER confirmation of receipt and inspection by representatives of the establishment.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 044
Issue: 2010 I-017**

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

All information above the line is for conference use only.

Title:

Criticality Implementation&Education Comm. -Timely Correction of Violations

Issue you would like the Conference to consider:

The FDA Criticality Work Group re-designated each Food Code provision into one of three terms. The three terms were used to rank the provisions in the Food Code according to how direct their relationship was to preventing, eliminating or reducing to an acceptable level, hazards that cause foodborne illness or injury. Out of compliance risk factors and Food Code interventions have a direct relationship and good retail practices have an indirect relationship. The timely correction sections in Chapter 8 that specify how long an operator has to correct a violation still has only two categories and does not adequately reflect the three separate terms now being used.

Sequentially, a need exists to combine existing Code sections 8-405.11 (Timely Corrections of Priority or Priority Foundation items) with 8-406.11 (Time Frame for Correction for Core Item violation), and add a third section to correspond with the new three tier structure in the Food Code. The new sections will be numbered 8-405.11, 8-405.12, and 8-405.13.

Public Health Significance:

The three terms defining criticality will enable both regulators and industry to prioritize their time and efforts. These three terms are distinct with Priority Items directly controlling hazards associated with food borne illness or injury. Priority Foundation Items support, facilitate or enable other Priority Items; and Core Items are general sanitation, maintenance, operations control, and facility and equipment design.

These three categories are based on risk ranking, with Priority violations being the highest risk and Core the lowest risk. There are currently only two categories defining the timely corrections of these violations, based on the previous critical and non-critical terms. Priority and Priority Foundation are currently lumped together even though the risk ranking for the two is not the same. For the purpose of training and compliance, the time for correction should also be a new three- tier system to be consistent with the level of risk clearly identified.

There can be punitive penalties associated with the highest risk category. These penalties can include fines, re-inspections, and suspended or revoked license with what used to be critical violations. Placing all Priority and Priority Foundation violations together in Chapter

8 will result in confusion with both regulatory and industry thinking all of the violations carry the same risk and legal weight.

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 Food Code: 8-405.11, 8-405.12 and 8-405.13 (new language is in underline format; deleted language in strike through).

Violation of Priority Item ~~or Priority Foundation Item~~ 8-405.11 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a permit holder shall at the time of inspection immediately initiate and correct a violation of a priority item ~~violations or priority foundation item~~ of this Code and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit. ^{Pf}

(B) *Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame for corrective actions that have been initiated but not yet completed, not to exceed 72 hours ~~10 calendar days~~ after the inspection, for the permit holder to correct violations of a priority item ~~or priority foundation item or HACCP plan deviations~~ violations.*

Violation of Priority Foundation Item 8-405.12 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a permit holder shall at the time of inspection immediately initiate and correct priority item violations of this Code.

(B) *Considering the nature of the violation involved or the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame, not to exceed 10 calendar days after the inspection, for the permit holder to correct violations of a priority item violations.*

Core Item Violation ~~8-406.11~~ 8.405.13 Time Frame for Correction.

(A) Except as specified in ¶ (B) of this section, the permit holder shall correct core items-violations by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 050
Issue: 2010 I-019**

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

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Title:

4-501.114-Manual and Mechanical Warewashing Equipment Chemical Sanitation

Issue you would like the Conference to consider:

Every sub-section (A-E) in Section 4-501.114 currently has an individual criticality rating although complying with the first part automatically covers all subsequent items. Having the sub-sections individually rated may result in the food establishment incurring multiple Priority ^P violations when in fact they should only have one.

Public Health Significance:

Section 4-501.114 begins with a requirement that a chemical sanitizer used in a sanitizing solution for manual or mechanical warewashing at contact times specified elsewhere in the FDA Food Code meet additional criteria specified in 7-204.11, be used in accordance with EPA registered label use instructions and be used as set forth in sub-paragraphs (A) through (E). This entire paragraph is classified as a Priority ^P item as is each individual sub-section (A) - (E). The result is that instead of one Priority ^P item assessed for 4-501.114, the food establishments are now subject to 9 additional Priority ^P items that all essentially are covered in the first paragraph of this section. If anyone of the variables listed under (A) through (E) was not in compliance, the food establishment would not be in compliance with the first section of 4.501.114. Having the extra 9 Priority ^P items only adds to the Food Establishment being subjected to additional violations for the same reason. Removing the Priority ^P item classifications from the sub-sections in (A) through (E) would not affect Public Health since any one not in compliance would be assessed a violation under the first paragraph.

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA requesting that Section 4-501-114(A) through (E) have a single Priority ^P item classification for the entire section, and that the subsequent 9 Priority ^P item classifications contained within sections (A) through (E) be removed. The initial paragraph and Priority ^P item classifications (as indicated below in italics) would cover any and all of the requirements under Section 4-501.114.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows ^P:

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 052
Issue: 2010 I-013**

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

Delegate Action: Accepted _____ Rejected _____

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Title:

Jewelry Prohibition

Issue you would like the Conference to consider:

Add earrings and facial jewelry to the types of jewelry that are prohibited from being worn by Food Service Employees during food preparation (Section 2-303.11 of the Food Code).

Public Health Significance:

Eliminating facial/ear jewelry while performing food service would prevent Physical Contamination of food and prevent medical problems for consumers such as chipped and/or broken teeth and internal cuts and lesions. The same hazards associated with rings, bracelets and watches also apply to earrings and facial jewelry.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA advising that changes be made to Food Code section 2-303.11 to state:

Except for a plain ring such as a wedding band, while preparing FOOD, FOOD EMPLOYEES may not wear jewelry including medical information jewelry on their arms and, hands, ears and face.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 070
Issue: 2010 I-007**

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

All information above the line is for conference use only.

Title:

Addition to Section 3-603.11 of the Model Food Code, Consumer Advisory.

Issue you would like the Conference to consider:

The Model 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 model 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.

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. Although it is mainly associated with mild gastroenteritis in persons with healthy immune systems, cases, while rare, also exist that document life threatening infections in persons without known pre-existing medical conditions. Each year 30 or more people are diagnosed with *V. vulnificus* induced septicemia from raw oysters sourced to Gulf 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 would be a ban on Gulf oysters unless they have been 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 FDA recommending the addition of the following language to Section 3-603.11 of the Model Food Code, *Consumer Advisory*.

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.

Submitter Information:

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Attachments:

- "Journal Article re Gulf Coast oysters"
- "Vibrio Vulnificus Infection: Diagnosis and Treatment"

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The Demand for Eastern Oysters, *Crassostrea virginica*, from the Gulf of Mexico in the Presence of *Vibrio vulnificus*

WALTER R. KEITHLY, Jr., and HAMADY DIOP

Introduction

The bacteria *Vibrio vulnificus* is a naturally occurring organism in estuarine waters and is found in an unknown proportion of eastern oysters, *Crassostrea virginica*, harvested from the Gulf of Mexico (hereafter, the Gulf). The presence of *Vibrio vulnificus* is highly correlated with water temperature, and virtually all Gulf-harvested oysters contain some concentration of it in the warmer summer months (McQuaid, 1997). As noted by Corcoran (1998) in the Nutri-

tion Action Healthletter: “[e]very year, more than 50 people become ill and at least 10 die after eating uncooked Gulf Coast oysters that are contaminated with *Vibrio vulnificus* bacteria.” Most of these illnesses and deaths occur between May and October.

California, in response to this health concern, initiated a program on 1 March 1991 which required anyone selling Gulf oysters to notify potential consumers that the “consumption of raw oysters can cause illness and death among people with liver disease, chronic illnesses, or weakened immune systems” (Liddle, 1991). California’s mandatory warning received extensive coverage in newspapers (and the trade literature) both there and across the country and particularly in the Gulf region.¹

In a further step to promote public safety, the U.S. Food and Drug Administration (FDA) in 1994 proposed banning consumption of raw oysters from the Gulf from April through October when *Vibrio vulnificus* was most prevalent. After “heavy pressure from the Gulf oyster industry and members of Congress from Louisiana and other Gulf states,” the FDA backed away from its initial proposal and instead opted for a “public awareness campaign” to notify and educate those people at risk (McQuaid, 1997).

The primary goal of this paper is to examine the extent to which the demand for Gulf oysters has been reduced as a result of the mandatory warning labels and associated media attention and to examine the impact on consumer wel-

fare associated with further regulation of the harvesting sector. A secondary goal of the paper is to analyze the impacts of other factors, such as the quantity harvested and income, on the demand for Gulf oysters. To accomplish these goals, an overview of the oyster industry is presented here, followed by a review of relevant literature. Then, the model used for the analysis is specified, and the data and estimation issues are briefly examined. The empirical results are then presented, and the paper concludes with a discussion of the implications of the findings.

Industry Overview

The U.S. oyster industry operates on both the U.S. east and west coasts. The primary oyster species harvested on the east coast (i.e. Atlantic and Gulf), the eastern oyster, produced average annual landings of about 31 million pounds during 1981–97 with an associated \$77 million dockside value (NMFS²). Annual landings of Pacific oysters, *Crassostrea gigas*, the primary west coast species, averaged about 9 million pounds valued at \$18 million (dockside) during 1981–97.

Gulf oyster production averaged 20 million pounds annually during 1981–97, or about 60% of the total eastern oyster production. Louisiana, the primary producer there, accounted for almost 60% of the Gulf output, while Texas accounted for an additional 20%.

Chesapeake Bay, once the nation’s largest oyster source, has seen production fall sharply since the early 1980’s

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ABSTRACT—California, in response to health concerns, initiated a program on 1 March 1991 which required anyone selling eastern oysters, *Crassostrea virginica*, from the Gulf of Mexico area to notify potential consumers that there was a risk in consuming them raw. This mandatory warning, followed shortly thereafter by a similar warning in other states, including Louisiana and Florida, received extensive press coverage throughout the country and particularly in the Gulf area. This paper examines the extent to which the demand for Gulf-area oysters has been reduced as a result of mandatory warning labels and negative publicity. In general, the results suggest that since 1991 the “summer” dockside price has been reduced by about 50% as a result of warning labels and associated negative publicity, while the “winter” dockside price has been reduced by about 30%.

¹ Subsequently, other states—most notably Louisiana and Florida—have enacted mandatory warning label programs similar to that of California.

² NMFS Commercial Fisheries Landings data compiled by the Fisheries Statistics and Economics Division, Office of Science and Technology available at <http://www.st.nmfs.gov/commercial>.

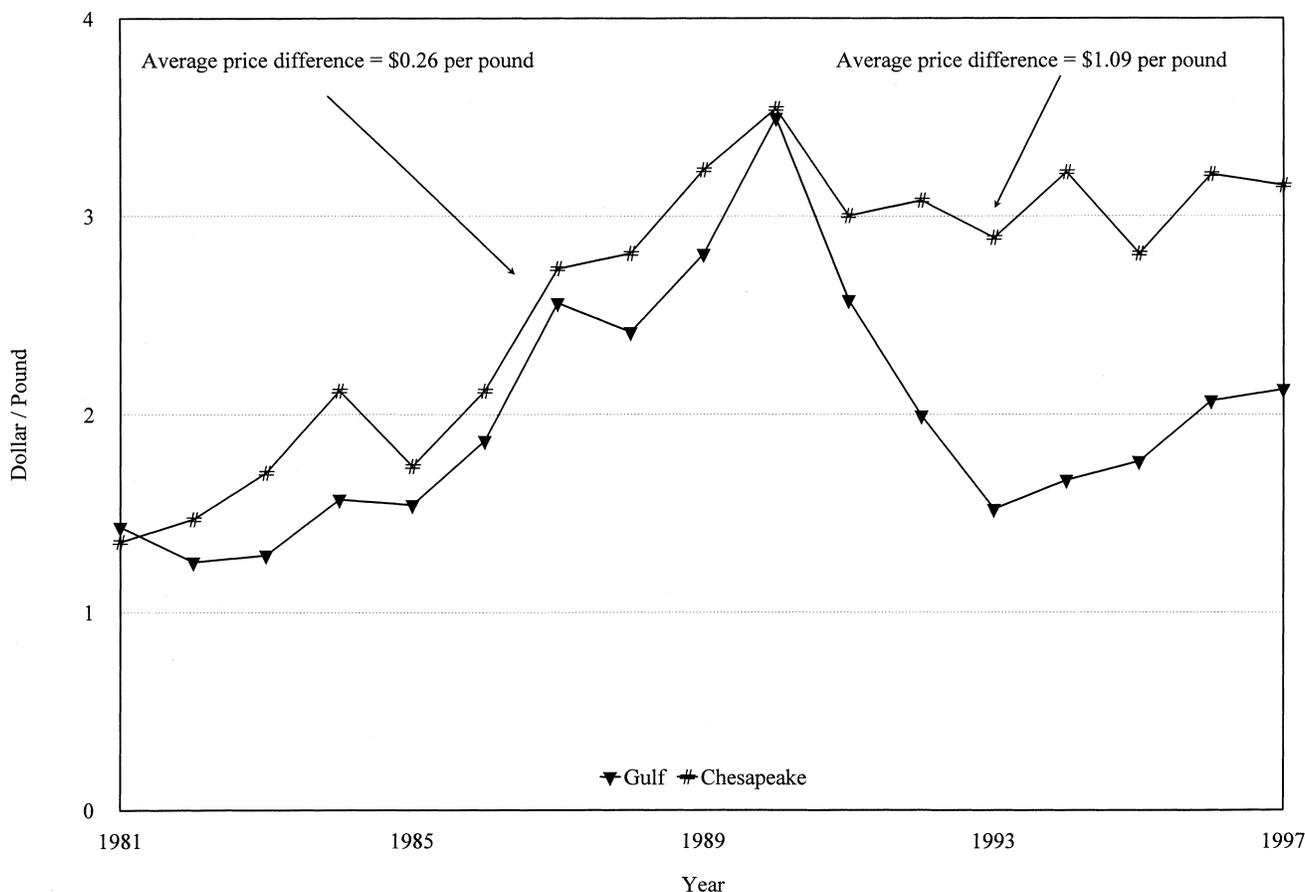


Figure 1.—Annual dockside oyster prices (current) in the Gulf and Chesapeake regions, 1981–97 (NMFS text footnote 2).

due to habitat degradation, overfishing, and disease (Rothschild et al., 1994). Then averaging close to 17 million pounds annually, the Chesapeake's output fell more than 90% to about 1.5 million pounds annually during 1995–97 (NMFS²).

Prior to 1991, annual dockside Gulf and Chesapeake oyster prices tended to “mirror” one another, with annual price differentials rarely exceeding \$0.40 per pound (NMFS²) and an average price differential equal to only \$0.26 per pound (Fig. 1). Since 1991, however, the prices in those regions have become decidedly more distinct, with the average annual price differential exceeding \$1.00 per pound. The large price differential since 1991 provides some preliminary evidence that the mandatory warning labels and media attention may have impacted demand and, hence, price of the Gulf product.

Theoretical Basis and Literature Review

Strand (1999) reviewed the literature pertaining to consumer behavior with respect to food-borne contamination events, concluding that the information related to an event, which is subjectively evaluated by consumers, is critical to perception formation. He further suggested that uncertainty contained in the information can also be critical in perception formation. Finally, Strand suggested that the credibility of the information depends on its source.

Perceptions, of course, can alter consumer choice. Strand (1999) further concluded that consumers react to negative news by reducing demand for the product and/or by taking defensive actions to lower the level of health risk. Furthermore, as a result of uncertainty (e.g. uncertainty of the marketing channels through which they obtain their

consumables), consumers may reduce demand even though there is no scientifically supported risk to them from normal consumption. Finally, Strand (1999) suggested that changes in demand owing to reports of persistent toxic compounds (like DDT) appear to be a reaction to cumulative news reports, and while the effects associated with news will decay over time, the decay is slow.

Strand's synthesis of the literature provides several insights that are relevant to this study. First, one might hypothesize that consumers have reacted to the negative publicity concerning the consumption of raw Gulf oysters by reducing demand for the raw product and/or taking defensive actions to lower the level of health risk. Such actions may include increasing demand for the processed product vis-a-vis the raw product or by reducing consumption only in the

“summer” months when health risks (in terms of mortality) from the consumption of raw oysters are greatest.

Second, uncertainty is likely to be a major factor in determining the change in demand for Gulf oysters. The uncertainty is inherent in both the information presented to the consumer as well as uncertainty presented to the consumer as to whether he/she possesses the health characteristics (i.e. liver disease, chronic illness, or a weakened immune system) that would make the consumption of raw oysters “risky.”

Third, one could argue that the change in demand for Gulf oysters is analogous to Strand’s (1999) discussion regarding changes in demand for food products resulting from reports of persistent toxic compounds. Specifically, while *Vibrio vulnificus* is not a toxic compound, like some such compounds, it is persistent in nature and continues to receive adverse publicity several years after the initiation of warning labels.

Model Specification

For purposes of analysis, the demand for Gulf oysters is specified as:

$$PG_t = \beta_0 + \beta_1 VUL_t + \beta_2 SEAS_t + \beta_3 QG_t + \beta_4 INC_t + \beta_5 (SEAS * VUL)_t + \beta_6 (QG * SEAS)_t + \beta_7 LATX_t + \beta_8 LPG_t + \epsilon_t \quad (1)$$

where PG_t denotes the deflated Gulf oyster dockside price in quarter t , expressed in dollars per pound of meats (1997 Consumer Price Index equals base); VUL_t is a binary variable used to “capture” the change in demand due to warning labels and associated media attention (equal to 0 before 1991 and 1 thereafter)³; $SEAS_t$ is a binary variable

used to “capture” seasonality in the demand for Gulf oysters equal to 0 for the months April through September, (i.e. the 2nd and 3rd quarters) and 1 for all other months, (i.e. the 1st and 4th quarters); QG_t denotes the Gulf oyster harvest, expressed in millions of pounds of meats, in quarter t ; INC_t denotes the U.S. real disposable income in quarter t , expressed in billions of dollars; $LATX_t$ denotes the share of Gulf oyster production accounted for by Louisiana and Texas in quarter t ; LPG_t denotes the deflated Gulf price lagged one quarter; and ϵ_t denotes the error term. Parameters to be estimated range from β_0 to β_8 .

The equation, as specified, is price dependent. This reflects the fact that production in the Gulf tends to be determined, to a large degree, by the availability of oysters which, in turn, is largely dictated by environmental influences, particularly in the short run.⁴

The variable VUL_t was included to “capture” any decrease in demand as-

³ (continued) occurs in the away-from-home market, and much of the information appears to occur in trade journals. Hence, one would need to isolate the impact related to information in trade journals from that of the more common news media. Finally, most studies that have evaluated the impact of negative information on demand are based on products for which the duration was of only a limited period of time. With respect to the impact of *Vibrio vulnificus* on the demand for Gulf product, the publicity is of longer or continuing duration.

⁴ A reviewer suggested that, because of leasing activities in Louisiana and Texas, quantity harvested may not be exogenous to the system. To examine this issue, a vector autoregressive model between Gulf price (PG) and quantity (QG) was estimated as follows:

$$QG_t = \alpha_0 + \alpha_1 QG_{t-1} + \alpha_2 PG_t + \alpha_3 PG_{t-1} + \xi_{1t}$$

$$PG_t = \beta_0 + \beta_1 PG_{t-1} + \beta_2 QG_t + \beta_3 QG_{t-1} + \xi_{2t}$$

where QG_{t-1} represents the Gulf landings lagged one period and PG_{t-1} is the Gulf price lagged one period. The Gulf oyster price is said to be block exogenous with respect to Gulf landings if the elements in Gulf price are of no help in improving the forecast of Gulf landings based only on lagged values of PG. The null hypothesis is “PG is not exogenous to QG” which is equivalent to $\alpha_2 = \alpha_3 = 0$. The test statistic follows a chi square distribution with one degree of freedom. The associated chi square statistic of 0.01 (significance level is 3.84) at the 5% significance level implies that PG is not exogenous to QG. In contrast, the test statistic of 12.56 (significance level is 3.84) implies that QG is exogenous to PG. These results agree with the hypothesis that current Gulf landings contribute significantly to the improvement of the forecasted price based only on lagged prices. However, current and lagged prices do not statistically improve the forecasted landings based only on lagged landing values.

sociated with warning labels and media attention while the variable $SEAS_t$ was used to “capture” seasonal variation in demand. Since the incidence of *Vibrio* is temperature dependent and is higher in the warmer months of the year, it is further hypothesized that the impact of VUL_t may vary by season with the impact on demand being greater in the “summer” months. To account for the possible variation in impact by season, an interaction term between $SEAS_t$ and VUL_t is included in equation 1.

It is anticipated that price in quarter t responds inversely to changes in Gulf harvest (QG_t) and positively to changes in income (INC_t). Furthermore, given the interaction between harvest and season ($QG * SEAS_t$), the response in price to a change in the quantity harvested is permitted to vary by season.

Louisiana and Texas, as noted, generally account for the majority of Gulf oyster production. There appears to be a premium attached to the price of oysters harvested from these two states, perhaps due to a larger average size. Hence, one would expect that the average Gulf price is positively related to the share of production derived from these two states. The variable $LATX_t$ is included in equation 1 to “capture” the price effect resulting from product heterogeneity across states.

The variable LPG_t is used to model inertia in the change in dockside price (PG_t) to changes in exogenous variables. The value of β_8 is expected to fall between 0 and 1 with a value approaching 0 indicating instantaneous adjustment in price to changes in the value of exogenous variables, while a value approaching 1 suggests a high degree of inertia.

Finally, substitute products are often entered as exogenous variables in demand models of this nature. One would hypothesize that oysters produced in other regions of the country might constitute substitutes for the Gulf product. Chesapeake oysters, given the similarity in the type of oyster produced and the geographic relation, were considered a potential substitute product, a priori. Initial inclusion of Chesapeake production in the Gulf demand equation did not prove to be successful and, hence

the variable was not included in the final version of the model discussed in the following sections.⁵

Data and Estimation Issues

Data Issues

The Gulf dockside demand model developed in the previous section was estimated with quarterly data for the 1981–97 period. Where appropriate (i.e. prices and income), the data were deflated using the 1997 Consumer Price Index. Some summary statistics for the variables included in the model are presented in Table 1. The deflated Gulf oyster price averaged \$2.63 per pound, with the post 1990 price (\$2.13 per pound) being nearly 30% less than the pre 1991 price (\$2.98 per pound). The quantity harvested averaged 5.2 million pounds per quarter during the period of analysis, with the pre 1991 quarterly production (5.4 million pounds) averaging about 8% more than the post 1990 quarterly production (4.9 million pounds).⁶

In general, little price variation was evident during the 1981–97 period when examined on a seasonal basis, even though production during the

⁵ For comparison purposes, the model that includes Chesapeake production as an explanatory variable is included in the table that provides empirical results (Table 2).

⁶ Much of the difference in pre and post 1990 production can be attributed to abnormally low production in Louisiana in 1991 and 1992. Low production in those years reflects massive oyster mortalities from excessive rainfall and, hence, lower salinity.

“winter” season, which averaged 6.1 million pounds per quarter, exceeded the production during the “summer” season, which averaged 4.28 million pounds per quarter, by about 40%. Since 1991, “winter” season production has averaged 5.7 million pounds per quarter compared to 4.2 million pounds per quarter in the “summer” season.

Estimation Issues

The lagged dockside price (LPG_t), as noted, was included in the analysis, based on the premise that the response in price to a change in an exogenous variable may not be completed in that quarter in which the change in the exogenous variable occurred (i.e. there exists some inertia in the change in price). Assuming a geometric lag structure, this inertia, can be expressed as :

$$Y_t = \alpha + \beta (X_t + wX_{t-1} + w^2X_{t-2} + \dots) + \epsilon_t \quad (2)$$

where w is the lagged weight ($0 < w < 1$) which declines at a geometric rate over time. As specified, equation 2 is difficult to estimate due to the infinite series of lagged regressors.

As shown by Madalla (1977) and Pindyck and Rubinfeld (1991), equation 2 can be rewritten as:

$$Y_t = \alpha(1-w) + wY_{t-1} + \beta X_t + (\epsilon_t - w\epsilon_{t-1}) \quad (3)$$

Expressed in this manner, the geometric lag model can be easily estimated, given

the finite series of the lagged variable (i.e. Y_{t-1}).

The implications associated with equation 3 are twofold. First, all past values of the exogenous variable (X_t) are captured in the endogenous variable (Y_t) lagged one period with impact of a change in X_t on Y_t decaying at a geometric rate over time. Second, lagging the dependent variable results in the introduction of serial correlation of the error term, assuming ϵ_t in equation 2 does not exhibit an autocorrelation pattern.

Several methods have been proposed for estimating the geometric lag structured model in the presence of serial correlation. The most popular technique, and the one that is used in the current analysis, is the instrumental variable approach whereby an estimate of the lagged dependent variable is generated by regressing its value against the lagged values of the exogenous variables in the model. Then, the model is estimated using a maximum likelihood procedure.

Given the structure of a geometric lag model, it is useful to identify the long-run impact associated with a permanent change in the level of an exogenous variable. Madalla (1977) shows that this impact is equal to $\beta / (1-w)$. Hence, as the value for w increases ($0 < w < 1$), the greater will be the amount of time which expires before the full impact of a one-time change in an exogenous variable is recognized. This, in turn, implies that the difference between the immediate impact (β) and long-run impact ($\beta / (1-w)$) increases in relation to an increasing value of the lagged weight (w).

Empirical Results

Table 2 summarizes the regression results associated with the Gulf dockside demand model. The estimated parameters, in general, agreed with prior expectations and, with few exceptions, all estimated parameters were significant at the 90% confidence level. Furthermore, the estimated model explained almost 90% of the variation in the deflated Gulf dockside price (Table 2, Fig. 2).

Overall, increased information related to *Vibrio vulnificus* was found to significantly influence the demand (price) for Gulf oysters. Specifically,

Table 1.—Summary statistics pertaining to the Gulf of Mexico oyster demand model.

Variable	Overall mean ¹	“Winter” mean	“Summer” mean
1981–97			
PG (\$/lb)	2.63 (0.81)	2.59 (0.83)	2.66 (0.80)
QG (Mill lbs)	5.20 (1.91)	6.11 (2.08)	4.28 (1.17)
INC (\$ bill)	4,905.7 (588.0)	4,908.6 (593.3)	4,902.8 (591.6)
LATX (%)	0.77 (0.10)	0.74 (0.09)	0.79 (0.10)
1981–90			
PG (\$/lb)	2.98 (0.82)	2.93 (0.87)	3.02 (0.79)
QG (Mill lbs)	5.38 (2.20)	6.40 (2.48)	4.36 (1.27)
INC (\$ bill)	4,524.3 (442.2)	4,527.1 (447.8)	4,521.4 (448.1)
LATX (%)	0.76 (0.11)	0.73 (0.12)	0.78 (0.11)
1991–97			
PG (\$/lb)	2.13 (0.46)	2.11 (0.44)	2.15 (0.49)
QG (Mill lbs)	4.94 (1.40)	5.71 (1.31)	4.16 (1.05)
INC (\$ bill)	5,450.5 (228.6)	5,453.5 (238.3)	5,447.5 (227.5)
LATX (%)	0.78 (0.08)	0.75 (0.05)	0.81 (0.10)

¹ Standard errors of means are given in parentheses.

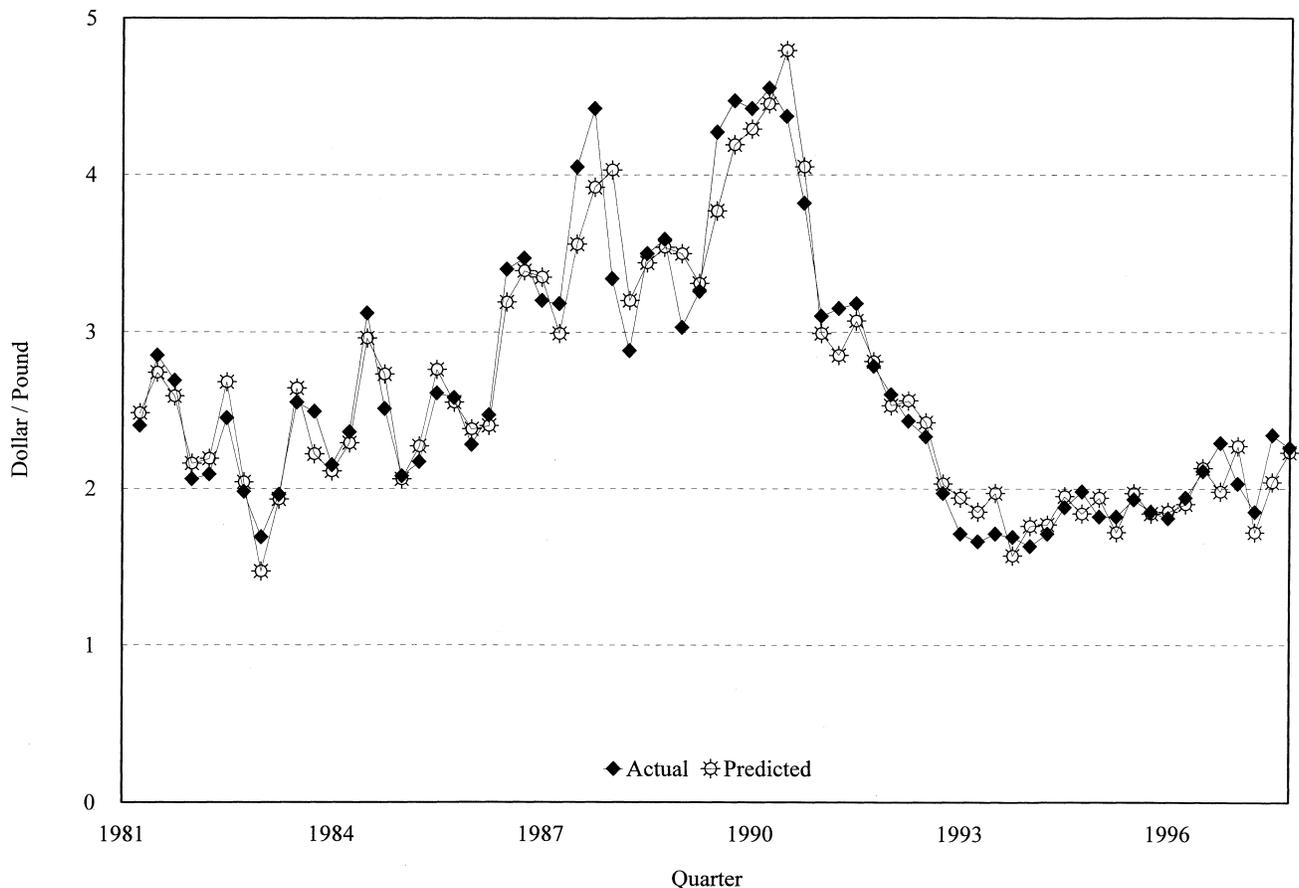


Figure 2.—Actual and predicted quarterly dockside Gulf oyster price (deflated), 1981–97.

the warning labels and associated media attention (VUL_t) resulted in an immediate reduction in the “summer” dockside price by \$0.93 per pound compared to a reduction in the “winter” price of \$0.72 per pound. These reductions, however, reflect only the initial impact. The fact that the estimate of β_8 , equal to 0.553, falls between 0 and 1 implies that as one moves further away from the date that warning labels were initially mandated, the greater the absolute value of the magnitude of the policy variable.

In the long-run, the impact of warning labels was estimated to result in a decline in the “summer” dockside price equal to \$2.07 per pound and a “winter” reduction in price equal to \$1.60 per pound. The actual “summer” price in 1997 equaled \$2.16 while the actual winter price equaled \$2.22, suggesting that the “summer” price has been

Table 2.—Estimated parameters and standard errors associated with the Gulf of Mexico oyster demand model.

Variable	Estimated ^{1,2} parameter	Standard error	Estimated ^{1,3} parameter	Standard error
Intercept	0.669	0.537	0.349	0.606
VUL_t	-0.929*	0.174	-0.955*	0.175
$SEAS_t$	-0.624*	0.203	-0.741*	0.227
QG_t	-0.217*	0.036	-0.217*	0.036
QC_t			0.027	0.024
INC_t	0.372E-3*	0.134E-3	0.427E-3*	0.142E-3
$(SEAS + VUL)_t$	0.213**	0.114	0.299*	0.137
$(QG + SEAS)_t$	0.109*	0.036	0.111*	0.036
$LATX_t$	0.165	0.416	0.209	0.417
LPG_t	0.553*	0.076	0.557*	0.076

¹ * = statistically significant at the $\alpha = 0.05$ level; ** = statistically significant at the $\alpha = 0.10$ level.

² Model estimated without Chesapeake landings (QC_t) as an exogenous variable; adj. $R^2 = 0.88$.

³ Model estimated with Chesapeake landings (QC_t) as an exogenous variable; adj. $R^2 = 0.88$.

reduced nearly 50% as a result of the warning labels and negative publicity, while the “winter” price has been reduced by about 30%.⁷

⁷ One could hypothesize that the impact of warning labels and the associated negative publicity

⁷ (continued) decays at some rate with the passage of time as consumers either forget about the negative publicity or overcome initial fears. To examine whether this was the case, the analysis was also conducted for the 1981–93 period. In general, the parameter estimates varied only marginally (e.g. $\beta_1 = -0.929$ and $\beta_5 = 0.265$), suggesting that the decay in the initial impact is, at most, minor.

With respect to the Gulf landings (QG), the results suggest that a 1,000,000 pound increase (decrease) in "summer" harvest results in an immediate \$0.22 decrease (increase) in price. An equivalent change in the "winter" harvest, by comparison, results in an immediate inverse price response of only \$0.11 per pound, or about half of that estimated for the "summer" season. In the long-run, a 1,000,000 pound increase (decrease) in "summer" harvest was found to result in a \$0.48 decrease (increase) in the Gulf dockside price, while a 1,000,000 pound increase (decrease) in the "winter" harvest was estimated to result in a price decrease (increase) of \$0.24 per pound.

With respect to seasonality, the results suggest that the demand for Gulf oysters in the "winter" season exceeds demand in the "summer" season, with the expected price differential equaling about \$0.07 per pound *ceteris paribus*, prior to 1991.⁸ After 1991, in association with the warning labels and media attention, the difference in demand between the "winter" and "summer" seasons resulted in an expected price differential of \$0.21 per pound.

Income, as indicated in Table 2, was found to significantly influence the Gulf oyster dockside demand. Overall, the results suggest that a \$100 billion dollar increase in real disposable income would result in an immediate \$0.04 increase in price and a price increase equal to \$0.08 increase in the long run.

Discussion and Conclusion

A model was developed and analyzed to examine the impact of mandatory warning labels and the associated negative publicity on dockside price of Gulf oysters. Results suggest that the impact has been significant. Specifically, the results suggest that the "summer" price has been reduced by about 50% as a result of the warning labels and associated negative publicity, while the "winter" price has been reduced by about 30%.

⁸ As indicated in Table 1, the observed "summer" price exceeded the "winter" price by \$0.05 per pound prior to 1991. Given the results of the current analysis, it appears as though the higher observed "summer" price reflects a lower level of production.

The results developed in this paper can be used to assess the impacts of various policy measures. For example, the FDA, as noted in the introduction, proposed a restriction on sales of raw oysters for consumption from April to October when the *Vibrio vulnificus* bacteria is most prevalent in Gulf waters. From a welfare economics perspective, such a ban would lead to a net increase in the welfare of society if the benefits of taking action (i.e. prohibiting raw oyster consumption) exceed the costs. Benefits reflect, primarily, the reduction in premature deaths and illnesses. Costs, on the other hand, reflect the reduction in consumer and producer welfare (i.e. surplus) which would be incurred as a result of the ban.

As noted by Corcoran (1998), at least 10 people die annually from the consumption of raw Gulf oysters, while more than 50 become ill (an average of 17 individuals died annually during 1996–98). While assigning an economic value to a statistical life is problematic (Kuchler and Golan, 1999), recent empirical work, based on labor market analysis, suggests that the value of a statistical life, expressed in 1997 dollars, falls in the neighborhood of about \$4–8 million (Viscusi, 1993, and Moore and Viscusi, 1988 provide details).⁹ This suggests that the benefits from the proposed ban, excluding the reduction in illnesses, would approximate \$40–80 million annually.

An "upper bound" estimate of the loss in consumer welfare associated with such a ban can be generated under the assumption that production is equal to zero in those months that would be impacted by the proposed ban.¹⁰ Based upon 1997 quarterly data and estimates, an "upper bound" estimate

⁹ The value of a life refers to the amount of money an individual is willing to trade for a small change in his or her probability of survival (Blomquist, 2001)

¹⁰ Only an "upper bound" estimate of the loss in consumer welfare can be derived, because an unknown percentage of the "summer" season harvest is currently processed, which is not subject to the proposed ban. Furthermore, if the ban were to be implemented, the demand for processed product would likely increase resulting in a greater proportion of the harvested "summer" product being directed towards the processing sector.

of the loss in consumer surplus in 1997 from the proposed ban would have been about \$6,500,000 based on the 1997 dockside value of \$21,200,000 (April through October).

While cost information on the Gulf oyster harvesting sector is insufficient to accurately estimate the loss in producer welfare associated with the proposed ban, it is obviously just a small fraction of the \$21,200,000 in revenues generated during the April through October 1997 period. This fraction and the \$6,500,000 loss in consumer welfare is considerably less than the \$40–80 million annual benefits that would be forthcoming as a result of the ban. Hence, one could conclude that the welfare of society would be enhanced if the eating of raw Gulf oysters were seasonally restricted.

The FDA, as previously indicated, chose not to institute a ban on the consumption of raw Gulf oysters in the "summer" season, opting instead for a "public awareness campaign" to notify and educate those consumers at risk. As noted by Henson and Caswell (1999: 591), policy interventions by governments reflect an "...outcome of a complex trade-off between alternative demands that reflect the interests of the different groups that might be affected. In the case of food policy this will include consumers, food manufacturers, food retailers, and farmers, both at home and abroad, as well as government itself and taxpayers." Whether the alternative strategy (i.e. the awareness and education program), derived via this complex trade-off between alternative demands, proves to be as successful as a seasonal restriction would be has yet to be determined.

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Vibrio vulnificus Infection: Diagnosis and Treatment

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Vibrio vulnificus infection is the leading cause of death related to seafood consumption in the United States. This virulent, gram-negative bacterium causes two distinct syndromes. The first is an overwhelming primary septicemia caused by consuming raw or undercooked seafood, particularly raw oysters. The second is a necrotizing wound infection acquired when an open wound is exposed to warm seawater with high concentrations of *V. vulnificus*. Most patients, including those with primary infection, develop sepsis and severe cellulitis with rapid development to ecchymoses and bullae. In severe cases, necrotizing fasciitis can develop. Case-fatality rates are greater than 50 percent for primary septicemia and about 15 percent for wound infections. Treatment of *V. vulnificus* infection includes antibiotics, aggressive wound therapy, and supportive care. Most patients who acquire the infection have at least one predisposing immunocompromising condition. Physician awareness of risk factors for *V. vulnificus* infection combined with prompt diagnosis and treatment can significantly improve patient outcomes. (Am Fam Physician 2007;76:539-44, 546. Copyright © 2007 American Academy of Family Physicians.)

► Patient information:

A handout on *Vibrio vulnificus* infection, written by the authors of this article, is provided on page 546.

V*ibrio vulnificus* is a species of gram-negative, motile, curved bacterium that is part of the *Vibrio* genus and the Vibrionaceae family. Other members of this family include *V. cholerae* (rare in the United States) and *V. parahaemolyticus*, both of which cause acute gastrointestinal illness characterized by severe diarrhea. Unlike other members of this family, *V. vulnificus* infection is extremely invasive. Even with prompt diagnosis and aggressive therapy, the case-fatality rate is 30 to 40 percent.¹⁻³

Epidemiology

V. vulnificus is common in warm seawater and thrives in water temperatures greater than 68°F (20°C). The organism is not associated with pollution or fecal waste. The taste, appearance, and odor of seafood are not affected by *V. vulnificus* contamination, and proper cooking methods readily kill the organism. Although it is found in all coastal waters of the United States, most *V. vulnificus* infections are attributed to consuming raw oysters harvested in the Gulf of Mexico during the summer.² Because these oysters are shipped throughout the United States, infections are not limited to endemic areas.⁴

Approximately 25 percent of *V. vulnificus*

infections are caused by direct exposure of an open wound to warm seawater containing the organism. Exposure typically occurs when the patient is participating in water activities such as boating, fishing, or swimming. Infections are occasionally attributed to contact with raw seafood or marine wildlife.¹

V. vulnificus is one of the few foodborne illnesses with an increasing incidence. The Centers for Disease Control and Prevention estimates that the average annual incidence of all *Vibrio* infections increased by 41 percent between 1996 and 2005.⁵ In 2004, *V. vulnificus* was documented in 92 infections; 64 patients with the infection had septicemia, and 28 patients had wound infections.¹ These data emphasize the need for physicians to familiarize themselves with the risk factors and clinical characteristics of *V. vulnificus* infection.

Risk Factors

Table 1² includes risk factors for developing *V. vulnificus* infection. After the organism enters the body, several factors determine if significant illness develops. Patients with immunocompromising conditions, especially alcoholic liver disease or hepatitis B or C, have a higher risk of infection.³

SORT: KEY RECOMMENDATIONS FOR PRACTICE

Clinical recommendation	Evidence rating	References	Comments
Physicians should consider <i>Vibrio vulnificus</i> infection in patients with sepsis and severe skin lesions and should ask them about recent raw oyster consumption.	C	2, 12-14	Case series demonstrate high morbidity and mortality with <i>V. vulnificus</i> infection, and physician awareness is recommended.
Patients presenting with painful, rapidly progressive hemorrhagic bullae should receive prompt surgical evaluation for possible debridement.	C	20, 27, 28	Case series show a benefit from aggressive surgical management of necrotizing soft tissue infections.
Patients with chronic liver disease or immunocompromising conditions should avoid eating raw or undercooked seafood and open wound exposure to warm seawater.	C	4, 29, 30	Consensus guidelines

A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, see page 483 or <http://www.aafp.org/afpsort.xml>.

Table 1. Risk Factors for *Vibrio vulnificus* Infection

Risk factor	Patients with primary septicemia and the risk factor (%)	Patients with a wound infection and the risk factor (%)
Consumption of raw oysters in the week before becoming ill	96	—
Wound exposure to warm seawater or raw seafood juice in the week before becoming ill	—	100
Any chronic disease	97	68
Liver disease	80	22
Alcoholism	65	32
Diabetes	35	20
Malignancy	17	10
Renal disease	7	7

NOTE: Data are from the Centers for Disease Control and Prevention Gulf Coast Surveillance System.

Information from reference 2.

Iron overload, documented by high transferrin saturation, is common in patients with liver disease and other immunocompromising conditions who develop *V. vulnificus* infection.² In human and animal studies, high levels of free iron have markedly increased the growth and lethality of *V. vulnificus*.^{6,7} Patients with chronic liver disease have a much higher risk of septicemia and death; approximately 80 percent of deaths occur in patients with liver disease.²

Several characteristics of the organism facilitate the development of clinical disease. *V. vulnificus* strains with capsular materials are associated with high bacterial virulence.⁸ In addition, *V. vulnificus* produces several extracellular enzymes, including metalloproteinase, lecithinase, lipase, caseinolytic protease, deoxyribonuclease, mucinase, and elastase.^{9,10} Metalloproteinase destroys basement membrane collagen in blood vessels¹⁰ and has fibrinolytic properties¹¹ that cause hemorrhage and edematous skin changes.

Clinical Presentations

Patients with primary septicemia caused by *V. vulnificus* infection require hospitalization. Characteristic symptoms include fever, diarrhea, nausea, and vomiting. One half of patients have changes in mental status, and almost one third are in septic shock at hospital admission.¹² Within 24 hours of symptom onset, more than one half of patients develop the characteristic skin lesions of severe cellulitis with ecchymoses and bullae.^{12,13} *V. vulnificus* infection should be considered in patients with sepsis and severe skin lesions, and patients should be asked about raw oyster consumption and seawater exposure.^{2,12-14}

Patients with primary wound infections caused by *V. vulnificus* develop painful cellulitis that progresses rapidly. Marked local tissue swelling with hemorrhagic bullae is characteristic (Figure 1). Systemic symptoms include fever and chills.^{12,13} Almost one half of patients develop bacteremia,^{13,14} more

than 10 percent develop hypotension, and almost one third develop changes in mental status.¹²

Rarely, patients with *V. vulnificus* infection present with common gastroenteritis.¹² *V. vulnificus* infection should be considered in immunocompromised patients who have recently been exposed to seawater or consumed raw seafood.

Other presentations have occurred less often: infection of mucosal sites and corneal ulcers after handling seafood,¹⁵ tubo-ovarian abscesses after sexual activity in seawater,¹⁶ and peritoneal infection after receiving dialysis from seawater-contaminated equipment.¹⁷ A high index of suspicion is required to diagnose *V. vulnificus* infection with these rare presentations.

Illustrative Case

An 80-year-old man presented to the emergency department with excruciating pain in his right forearm. He reported spending the previous night fishing in Corpus Christi Bay (Tex.), where he accidentally pierced his right index finger with a live shrimp. Hemorrhagic bullae were present, extending from the hand to the upper arm. He also presented with confusion. His vital signs were a temperature of 100°F (38°C), blood pressure of 88/44 mm Hg, pulse rate of 113 beats per minute, and respiratory rate of 20 breaths per minute. The patient had a history of hypertension, chronic renal failure that did not require dialysis, congestive heart failure, and cirrhosis secondary to alcohol abuse. Laboratory studies revealed a white blood cell count of 6,600 per mm³ (6.6×10^9 per L) with 26 percent bands, hemoglobin level of 13.1 g per dL (131 g per L), platelet count of 33,000 per mm³ (33×10^9 per L), blood urea nitrogen level of 63 mg per dL (22.5 mmol per L), and creatinine level of 4.4 mg per dL (390 μmol per L). A Gram stain of the exudate showed a curved, gram-negative rod. Blood and wound cultures were obtained.

The patient was admitted to the intensive care unit and was treated with oxygen, fluid resuscitation, and intravenous ceftriaxone (Rocephin) and doxycycline (Doxy 100). Within six hours of admission, he



Figure 1. *Vibrio vulnificus* infection presenting as edema; ecchymoses; and hemorrhagic, serous bullae on the lower legs.

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required norepinephrine for blood pressure support. By the third day of hospitalization, dialysis was required because of worsening renal failure. On the fourth day of hospitalization, the patient markedly improved, answered questions appropriately, and no longer required pressor support. Wound culture confirmed the clinical diagnosis of *V. vulnificus* infection. After five days in the intensive care unit, he was in stable condition and was transferred to a local hospital.

Diagnosis

Table 2^{18,19} presents etiologies for the differential diagnosis of aggressive soft tissue infection. Most of these infections involve a group A *Streptococcus* species or *Staphylococcus aureus*. Infections with necrotizing fasciitis are predominantly polymicrobial.^{20,21}

At hospital admission, laboratory results of patients with *V. vulnificus* infection are indicative of severe bacterial infection, with a marked left shift in the white blood cell count. Renal injury with a rising serum creatinine level is common.²² With severe

Table 2. Etiologies of Aggressive Soft Tissue Infections

Infection	Patient history	Underlying conditions	Physical examination findings
Group A <i>Streptococcus</i> species	Skin abrasion, trauma, recent herpes zoster infection, human bite, intravenous drug abuse	Diabetes, cancer, alcoholism, stasis dermatitis	Intense erythema, edema, lymphadenopathy, hemorrhagic and necrotic bullae
<i>Staphylococcus aureus</i>	Skin trauma, recent hospitalization or surgery, intravenous drug abuse	Obesity, diabetes, immunocompromising condition	Furuncles, local abscesses, diffuse macular erythroderma
Polymicrobial	Diabetic foot ulcer, recent surgery	Diabetes, immunocompromising condition, vascular disease	Moist gangrene with a foul odor
<i>Pseudomonas</i> species	Bacteremia, moist skin infection, severe burn, recent hospitalization	Immunocompromising condition	Hemorrhagic and necrotic bullae
<i>Vibrio vulnificus</i>	Exposure to raw or undercooked seafood or seawater	Liver disease, immunocompromising condition	Hemorrhagic and necrotic bullae, ecchymoses
<i>Clostridium perfringens</i>	Severe trauma with wound contamination, recent surgery, intravenous drug abuse	None	Pale skin, edema, hemorrhagic and necrotic bullae, foul-smelling discharge, gas formation
<i>Pasteurella multocida</i>	Cat or dog bite	None	Erythema, edema, serosanguineous discharge, lymphadenitis, tenosynovitis
<i>Aeromonas hydrophila</i>	Exposure to freshwater, skin abrasion	Usually none; sometimes an immunocompromising condition	Erythema, bullae, necrosis, possible gas formation

Information from references 18 and 19.

V. vulnificus or *Streptococcus pyogenes* infection, the creatine kinase level is often elevated when necrotizing fasciitis or myonecrosis is present.²³

Radiographic studies (e.g., ultrasonography, computed tomography, magnetic resonance imaging) of affected tissues typically show nonspecific changes such as soft tissue edema and pockets of fluid. These findings may help exclude other conditions and guide aspiration attempts and the timing of surgical intervention.

Because sepsis is common, routine blood cultures should be performed when *V. vulnificus* is suspected. Bullae, ecchymoses, and abscesses are often productive sites to aspirate material for Gram stain and culture. In addition, Gram stain, culture, and frozen-section analysis of tissue is helpful to rapidly visualize bacteria and diagnose necrotizing fasciitis.²⁰ Additional cultures are guided by clinical symptoms and may

include ocular, peritoneal, sputum, cervical, and stool cultures. Stool cultures require a thiosulfate citrate bile salts sucrose agar for isolation.²⁴

Treatment and Prognosis

The recommended antibiotic therapy for *V. vulnificus* infection is doxycycline, 100 mg intravenously or orally (Vibramycin) twice a day; plus ceftazidime (Fortaz), 2 g intravenously every eight hours. Alternative antibiotic therapies are cefotaxime (Claforan), 2 g intravenously every eight hours; or ciprofloxacin (Cipro), 750 mg orally or 400 mg intravenously twice a day.^{25,26}

In addition to antibiotics, many patients require aggressive supportive therapy in the intensive care setting. Aggressive and prompt wound care is essential. Surgical debridement; incision and drainage of abscesses; and, sometimes, amputation have been shown to reduce mortality and shorten

Table 3. Recommendations for Reducing the Risk of *Vibrio vulnificus* Infection

- Avoid contact with raw seafood juices; use separate cutting boards and knives for seafood and nonseafood
- Avoid eating raw oysters or seafood, especially if an immunocompromising condition or chronic liver disease is present; the risk is highest with seafood harvested in the summer
- Cook shellfish thoroughly:
 - In the shell: boil until the shells open, then boil for another five minutes; or steam until the shells open, then steam for another nine minutes (do not eat shellfish that do not open during cooking)
 - Shucked oysters: boil for at least three minutes, or fry for at least 10 minutes at 375°F (191°C)
- Promptly refrigerate leftover seafood
- Wear gloves when handling raw oysters or shellfish
- Persons with open wounds:
 - Avoid contact between open wounds and seawater, especially if water temperature is more than 68°F (20°C), or raw seafood
 - Wash any wound that is exposed to seawater with soap and clean water
 - Immediately seek medical care for any wound that appears infected

Information from reference 29 and 30.

hospitalization.^{20,27,28} Patients presenting with painful, rapidly progressive hemorrhagic bullae should receive prompt surgical evaluation for possible debridement.^{20,27,28}

V. vulnificus infections are commonly fatal, and the prognosis is directly linked to the speed and accuracy of diagnosis and treatment. When treatment was delayed by as little as 24 hours in patients with septicemia, mortality rates increased from 33 to 53 percent. Mortality rates increased to 100 percent in patients who were not treated within 72 hours.¹² Recent data show that when all types of *V. vulnificus* infections are combined, the overall mortality rate is 35 percent.¹

Prevention

Table 3^{29,30} includes recommendations for reducing the risk of *V. vulnificus* infection. Because *V. vulnificus*-related septicemia is usually caused by consuming raw oysters, most disease can be prevented by not eating this food. Limiting consumption of raw oysters to the winter months also can reduce the risk of infection. Patients with chronic liver disease or immunocompromising conditions are particularly vulnerable to infection and should be advised to avoid raw or undercooked seafood. Persons with open wounds should avoid contact with warm seawater.^{4,29,30}

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Vibrio vulnificus Infection: What You Should Know

What is *Vibrio vulnificus* infection?

Vibrio vulnificus (VIB-ree-oh vul-NIF-i-cus) is a germ found in warm seawater. If you eat shellfish (especially oysters) or other seafood that has the germ, you can get an infection.

Who gets infected?

V. vulnificus infection is uncommon. Most people get it by eating raw oysters. If you have an open cut, you can get the germ by going in the ocean or touching raw seafood. You can't get it from other people.

What are the symptoms?

Most healthy people don't get sick even if they are infected. People with liver disease, kidney disease, or diabetes can get very sick if they are infected.

If you get sick from *V. vulnificus*, you might have a fever, vomiting, and diarrhea. You may also have redness, swelling, blisters, and bruising on your skin. If you have a cut, it could get infected.

What if I think I am infected?

Go to your doctor or the hospital right away. Do not wait because the infection spreads quickly.

Your doctor may test your blood or the blisters to tell if the infection is caused by *V. vulnificus*. Your doctor may give you medicine to stop the infection. Some patients need surgery.

How can I avoid getting infected?

Be sure to cook seafood thoroughly to kill the germ. Try not to touch raw seafood juices, and make sure to wash kitchen utensils in hot, soapy water.

If you have an illness that makes it more likely that you will get sick, avoid eating raw or undercooked seafood. If you have an open cut, you shouldn't do activities in seawater (for example, swimming, fishing, or boating).

Where can I get more information?

Your doctor

Centers for Disease Control and Prevention
Web site: <http://www.cdc.gov/ncidod/dbmd/diseaseinfo> (go to *Vibrio vulnificus*)

U.S. Food and Drug Administration
Web site: <http://www.cfsan.fda.gov/~dms/vvfact.html>

August 2007

This handout is provided to you by your family doctor and the American Academy of Family Physicians. Other health-related information is available from the AAFP online at <http://familydoctor.org>.

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**American Academy
of Family Physicians**

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 073
Issue: 2010 I-025**

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

Delegate Action: Accepted _____ Rejected _____

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Title:

Addition to S. 2-103.11 of the Model Food Code, Duties: Person in Charge

Issue you would like the Conference to consider:

The Model 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 in both the logistics of cleaning and the importance of rigorous cleaning for the prevention of foodborne illness.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending the addition of the underlined language to Section 2-103.11 of the Model 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; specifically and especially those employees who may be responsible for production and handling of "in house" ground beef, such as the grinding of PRIMAL CUTS and WHOLE MUSCLE, INTACT BEEF; and

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 077
Issue: 2010 I-026**

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Delegate Action:	Accepted _____	Rejected _____	

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Title:

Mandatory Food Protection Manager Certification for Persons in Charge

Issue you would like the Conference to consider:

The FDA is considering modifying the FDA Food Code so as to require that the designated "Person in Charge" of a Food Establishment be a Food Protection Manager that is certified by a recognized Food Protection Manager Certification program.

Recent studies seem to confirm that the presence of a Certified Food Protection Manager can help to improve food safety practices in a food establishment. FDA supports the efforts made by State, local and tribal agencies toward requiring such certification of the Person In Charge (as defined in the Food Code). FDA also believes it is important that the Food Code continue to identify the types of knowledge that the Person in Charge must possess as they relate to the specific food establishment. Further, FDA believes code compliance during a specific inspection should be considered one of the desired outcomes of, rather than an alternative to, the possession of food safety knowledge and a Food Protection Manager Certification for the Person in Charge.

Since the 1995 edition of the Food Code, certification as a food protection manager has simply been an option for the Person in Charge as a means of demonstrating the basic food safety knowledge that is required of that position. FDA is seeking the Conference's recommendations on how mandatory Food Protection Manager Certification can best be incorporated into the Food Code so as to achieve its effective adoption and implementation at the State, local and tribal level.

Public Health Significance:

The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks and other economic, staffing, cultural and behavioral challenges make it imperative that food protection managers know and control the factors that impact the safety of the food they sell or serve.

Food handling procedures and behaviors that may contribute to foodborne illness are well documented in FDA's retail risk factor studies (9, 10) See Attachment B, and in the CDC Environmental Health Specialists Network (EHS-Net) survey of food service workers' self-reported food preparation practices (4). Frank Bryan identified significant activities that make food safer including knowledge of the *Food Code* and training of industry food workers and managers (1). Certified food protection managers can have an important role

in formulating policies and communicating information to food employees about recommended practices to reduce the risk of foodborne illness and verifying they do so (2).

The results of a number of studies that have shown the prospective benefits associated with the certification of food protection managers. Published studies (See Attachment B, References) that show some of the benefits include:

- A CDC EHS-Net study suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak for an establishment and was a distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had not. (5).
- Kneller found a statistically significant decrease in critical violations and increase in restaurant inspection scores after managers completed a 15-hour food safety training and certification program (6).
- Cotterchio showed a significant increase in inspection scores and decrease in critical violations which was maintained after two years in facilities with a certified food protection manager (3).
- FDA's 2004 retail risk factor study suggests that the presence of a certified manager has a positive correlation with more effective control of certain risk factors, such as poor personal hygiene, especially in different facility types (9). FDA's 2009 risk factor study also indicates that the presence of certified food managers is positively correlated to improved compliance in certain facility types (10)
- Cates found the presence of certified food managers is protective for most types of critical violations including a lower likelihood of violations for personnel, food source and handling, facilities and equipment and warewashing. They were also more likely to be more knowledgeable about relationships between foodborne illness risk factors and safe food handling practices (2).

FDA is aware that there are a number state and local agencies that currently mandate food protection manager certification for certain food establishment personnel. For example, in 2002, Schilling found there were 16 states that mandated food protection manager certification and 34 states with some form of voluntary program (8). By 2009, National Restaurant Association's ServSafe website showed 23 states with a mandatory statewide food protection manager certification (7).

Attachment A contains an example of revisions to the Food Code that would recognize the importance of having a person in charge during all hours of operation that is knowledgeable in food safety and certified as a food protection manager. The suggested edits also recognize that the enhanced level of food protection afforded by having a knowledgeable and certified food protection manager present is not made unnecessary simply because no violations of the Code were observed during a single inspection.

FDA is interested in learning if the Conference believes there are certain types of food establishments or other conditions for which exceptions to the recommended solution are appropriate.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending modification to the next edition of the FDA Food Code, so as to

- 1) Require that the Person in Charge, as currently defined in the 2009 Food Code, possess certification by a food protection manager certification program that is recognized under 2009 Food Code section 2-102.20.
- 2) Require that the Person in Charge also possess and be capable of demonstrating knowledge of the key food safety principles that are identified in 2009 Food Code Paragraph 2-102.11(C))
- 3) Eliminate the recognition of the achievement of full compliance with the Food Code during a single inspection as a suitable alternative to the requirements recommended in items 1) and 2), above.

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Attachments:

- "Attachment A-Manager Certification-Suggested Changes for the PIC"
- "Attachment B - Manager Certification - References"

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Attachment A –Suggested Changes to 2009 Food Code - Mandatory Food Protection Manager Certification for Person in Charge

Responsibility

2-101.11 Assignment. (unchanged)

1. (A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall be the PERSON IN CHARGE or shall designate a PERSON IN CHARGE and shall ensure that a PERSON IN CHARGE is present at the FOOD ESTABLISHMENT during all hours of operation.^{Pf}
2. (B) *In a FOOD ESTABLISHMENT with two or more separately PERMITTED departments that are the legal responsibility of the same PERMIT HOLDER and that are located on the same PREMISES, the PERMIT HOLDER may, during specific time periods when food is not being prepared, packaged, or served, designate a single PERSON IN CHARGE who is present on the PREMISES during all hours of operation, and who is responsible for each separately PERMITTED FOOD ESTABLISHMENT on the PREMISES.*^{Pf}

Knowledge

2-102.11 Demonstration. (proposed changes in underline and strikeout)

Based on the RISKS inherent to the FOOD operation, ~~during inspections and upon request~~ the PERSON IN CHARGE shall ~~demonstrate to the REGULATORY AUTHORITY~~ possess knowledge of foodborne disease prevention, the application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. As it relates to the operation of the specific FOOD ESTABLISHMENT and in response to questions that may be posed by the REGULATORY AUTHORITY, ~~¶~~ the PERSON IN CHARGE shall demonstrate this knowledge by:

~~(A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection;~~^{Pf}

~~(B) Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM;~~^{Pf} ~~or~~

~~(C) Responding correctly to the inspector's questions as they relate to the specific food operation. The areas of knowledge include:~~

- (1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE;^{Pf}
- (2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease;^{Pf}

- (3) Describing the symptoms associated with the diseases that are transmissible through FOOD; ^{Pf}
- (4) Explaining the significance of the relationship between maintaining the time and temperature of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) and the prevention of foodborne illness; ^{Pf}
- (5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH; ^{Pf}
- (6) Stating the required FOOD temperatures and times for safe cooking of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) including MEAT, POULTRY, EGGS, and FISH; ^{Pf}
- (7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD); ^{Pf}
- (8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:
- (a) Cross contamination, ^{Pf}
 - (b) Hand contact with READY-TO-EAT FOODS, ^{Pf}
 - (c) Handwashing, ^{Pf} and
 - (d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair; ^{Pf}
- (9) Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction. ^{Pf}
- (10) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:
- (a) Sufficient in number and capacity, ^{Pf} and
 - (b) Properly designed, constructed, located, installed, operated, maintained, and cleaned; ^{Pf}
- (11) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT; ^{Pf}

(12) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; ^{Pf}

(13) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW; ^{Pf}

(14) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code; ^{Pf}

(15) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the FOOD ESTABLISHMENT; ^{Pf}

(16) Explaining the responsibilities, rights, and authorities assigned by this Code to the:

(a) FOOD EMPLOYEE, ^{Pf}

(b) CONDITIONAL EMPLOYEE, ^{Pf}

(c) PERSON IN CHARGE, ^{Pf}

(d) REGULATORY AUTHORITY; ^{Pf} and

(17) Explaining how the PERSON IN CHARGE, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION OF RESTRICTION of FOOD EMPLOYEES. ^{Pf}

2-102.20 12 Food Protection Manager Certification.

~~A~~ The PERSON IN CHARGE ~~who demonstrates knowledge by being~~ shall be a FOOD protection manager that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs ~~is deemed to comply with ¶ 2-102.11(B).~~

Attachment B - References related to Certified Food Protection Managers

Page 1 of 2

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10. U.S. Food and Drug Administration. 2009. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009). To be made Available at <http://www.fda.gov/Food.FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/default.htm>

Attachment B - References related to Certified Food Protection Managers

Page 2 of 2

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12. York, V.K., L.A.Brannon, C.W. Shanklin, K.R. Roberts, A.D. Howells, E.B. Barrett. 2009. Foodservice Employees Benefit from Interventions Targeting Barriers to Food Safety. J. Am. Dietetic Assoc. 109(9): 1576-1581.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 089
Issue: 2010 I-023**

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

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Title:

Proper Identification of Seafood Species

Issue you would like the Conference to consider:

The Food Code requires that food offered for human consumption be honestly presented in a manner that does not mislead or misinform the consumer (3-601.12). There are hundreds of different species of FISH that are marketed in the United States. Identifying species of FISH with incorrect names (often referred to as "species substitution") 1) misleads the consumer by representing a less expensive or valued species as a more expensive or valued species or 2) negatively impacts the ability of the consumer, FOOD ESTABLISHMENT and REGULATORY AUTHORITY to accurately assess the potential inherent food safety hazards associated with specific species.

The Food Code currently does not emphasize the importance of properly identifying FISH names.

Public Health Significance:

While species substitution is often viewed as an economic fraud or misbranding issue, the practice can also have public health implications. Proper identification of species of FISH is essential for the correct identification and control of food safety hazards pertinent to specific species and for accurate traceback during foodborne disease outbreak investigations.

CDC analyses of foodborne disease outbreak surveillance data consistently indicate that the primary cause of foodborne disease outbreaks associated with finfish are chemical agents - specifically ciguatoxin and scombrototoxin. Ciguatoxin and scombrototoxin are food safety hazards each associated with specific species. Correct identification of the species that are associated with either ciguatoxin or scombrototoxin formation is essential for proper hazard control as well as proper traceback during foodborne disease outbreak investigations.

Some species of fish may cause illness due to naturally occurring toxins in the fish. Escolar or oilfish naturally contains a strong purgative oil, called gempylotoxin, which may cause intestinal cramping and diarrhea. Print media stories investigating species substitution at restaurants frequently find escolar being represented as tuna. Puffer fish or fugu may contain tetrodotoxin, a potent, sometimes lethal neurotoxin. In 2007 two individuals were sickened by the tetrodotoxin from Puffer fish that was misidentified as monkfish.

Paragraph B of section 3-402.11 of the Food Code identifies specific species of FISH that do not require parasite destruction when the READY-TO-EAT form is raw, raw-marinated, partially cooked, or marinated-partially cooked. Misidentification of a species (for example, escolar being labeled as albacore tuna (*Thunnus alalunga*)) would give the PERSON IN CHARGE at the FOOD ESTABLISHMENT and REGULATORY AUTHORITY the false impression that the parasite destruction controls outlined in the Food Code do not apply.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending the following additions to the Food Code:

1. That section 3-601.12 be amended as follows:

3-601.12 Honestly Presented.

(A) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

(1) FISH shall be identified by the appropriate FDA-acceptable market name or scientific common name.

(B) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food.

2. That section 3-601.12 of Annex 2 - References be amended as follows:

3-601.12 Honestly Presented.

1. Food and Drug Administration, 2009. Guidance for Industry: The Seafood List - FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 090
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Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

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Title:

Grocery Seafood Advisory for Women of Childbearing Age and Children

Issue you would like the Conference to consider:

This proposal asks the Conference to require grocery stores to post fish advisory information aimed at Women of Childbearing Age and Children (the "TARGET GROUP"). This "FISH ADVISORY" will apply only to retail seafood purchases in grocery stores, excluding "ready to eat" food, and would not apply to ready to eat food provided by other non-grocery FOOD ESTABLISHMENTS. The purpose of the proposal is to communicate to the TARGET GROUP federal Food and Drug Administration and Environmental Protection Agency consumption advice regarding the benefits of fish and the relative presence of methylmercury in seafood species. This information is primarily only available online through these agencies and should be communicated to the TARGET GROUP at grocery stores.

Public Health Significance:

This issue represents a public health matter of the highest order: protecting children's developing brains and cognitive health. Women of childbearing age need this information posted at grocery stores rather than online. First, this will reduce the problem of concerned women avoiding otherwise-healthy seafood that is important for fetal development when they are unsure about which seafood is safe to eat. Second, it will address the problem of ill-informed consumers in the TARGET GROUP unknowingly exposing developing fetuses and children to seafood that contains high amounts of methylmercury.

Though most people do not have elevated mercury levels, developing fetuses are particularly susceptible to mercury exposure and consumption of contaminated fish is the main source of exposure to methylmercury. As the EPA explains on its website, studies in other countries have shown that "mothers with no symptoms of nervous system damage [have given] birth to infants with severe disabilities, [from which] it became clear that the developing nervous system of the fetus may be more vulnerable to methylmercury than is the adult nervous system" (Attachment 3, EPA Health Effects). Most children do not exhibit such disabilities but instead may suffer from subtle, sub-clinical neurological deficits that can lower their IQ and educational attainment.

Studies analyzing data from the Centers for Disease Control's National Health and Nutrition Examination Survey ("NHANES") have shown that perhaps 400,000 children each year

may have mercury levels at or above the Reference Dose level set by the EPA (Mahaffey et al. 2005, Transande et al. 2005). Further, these figures are significantly higher if the recent studies on the higher ratio of fetal cord blood to maternal blood are taken into account.[1] Recent studies from the more comprehensive 1999-2004 NHANES results show that overall, 4.7% of women of childbearing age exceed the EPA's 5.8ug/L standard and 10.4% exceed the suggested, more sensitive 3.5ug/L level (Mahaffey et al. 2009)(See also Attachment 5, CDC NHANES Data on Levels Exceeding EPA RfD).

This burden on the population can have long-range health and economic implications for states and the nation as a whole. Seafood has nutritional benefits which can enhance cognitive function in children, however, so it is important from a public health perspective that women of childbearing age and children not eliminate seafood from their diets. To ensure this, consumers need better information on the relative mercury contents of fish so they can enjoy fish consumption while lowering their mercury exposure by consuming lower-mercury seafood. For this reason it is imperative that the TARGET GROUP have access at grocery stores to the federal fish consumption advice that the FDA and EPA jointly publish online (Attachment 1, Online Advisory).

The proposed changes first reflect the recommendations of the FDA-EPA's 2004 Online Advisory in an easy-to-understand format. The FISH ADVISORY also facilitates these recommendations by containing a chart that categorizes seafood by relative mercury content, the majority of this seafood being low in mercury. These proposed changes are intended to better protect the public health of fetal and child cognitive development by disseminating to the TARGET GROUP the federal Online Advisory. This proposal will thereby also restore consumer confidence in the safety of the commercial seafood supply by expanding awareness among the TARGET GROUP of healthy, lower mercury seafood products.

Currently, the online FDA-EPA Advisory does not effectively reach consumers. Indeed, most women of childbearing age either do not know of the risks of mercury or, if they do, they are confused about the extent of their exposure and which fish species represent safe, healthy choices. While the Online Advisory lists four "DO NOT EAT" fish and a handful of lower-mercury choices, it leaves consumers in the dark about the vast majority of other fish, most of which are low in mercury. This limits consumer choice and undermines confidence in the seafood industry, which in turn may jeopardize public health.

Background

Since 2004, the FDA and EPA have jointly published an Online Advisory to communicate recommended guidelines for the consumption of seafood by women of childbearing age (ages 45 or under) and children (the TARGET GROUP)(Attachment 1, Online Advisory). The Online Advisory states that the TARGET GROUP should not eat certain high-mercury species (shark, swordfish, tilefish, and king mackerel), and should limit albacore tuna to six ounces per week, to reduce fetal and childhood exposure to methylmercury. Methylmercury is present in most seafood in varying amounts and is a neurotoxin that can impair child neurodevelopment when consumed at certain levels.

The FDA-EPA's Online Advisory is designed to reduce methylmercury exposure within the TARGET GROUP, to generally keep levels generally at or below the EPA's Reference Level of 5.8 ug of mercury per liter of blood, which corresponds to a Reference Dose of 0.1 ug Hg/kg-bw/day (the "RfD"). The EPA established this RfD for methylmercury in 1999, based on the best evidence then available, using data from a long-term epidemiological study in the Faeroe Islands carried out by researchers at Harvard University and elsewhere.

Research since then confirms that public health concern over methylmercury exposure is justified, and that efforts to guide women to pick low-mercury fish must be expanded and improved (Attachment 6, Review of Recent Scientific Studies). Since women are advised to consume fish while pregnant, for nutritional benefits, it is vitally important that women have information to help them identify low-mercury fish, so they (and their babies) can simultaneously enjoy these nutritional benefits while minimizing their exposure to methylmercury.

The federal commercial fish Online Advisory translates the EPA's Reference Dose into consumption recommendations based on the relative average mercury content of various seafood species. Based on this, for example, the federal Online Advisory (Attachment 1) makes the following three major recommendations to the TARGET GROUP:

- Do not eat very high-mercury species such as shark, swordfish, tilefish, and king mackerel;
- Limit canned albacore tuna to 6-ounces per week; and
- Eat two servings (up to 12-ounces) of lower mercury fish per week, including shrimp, salmon, and light canned tuna.

For example, as to the recommendation for lower-mercury fish, for an average-weight woman this consumption recommendation comports with the EPA's RfD guidelines for seafood that contain 0.12 ppm or less of methylmercury. This grouping includes light canned tuna, which contains an average of 0.118 ppm of methylmercury and thus can be consumed by the TARGET GROUP up to two times a week (Attachment 4, FDA Fish Data).

It is also key to note that the EPA's RfD is based on weight, whereas the consumption recommendations by the EPA and FDA are based on a hypothetical, average-weight woman. Therefore, lighter-weight individuals in the TARGET GROUP—such as children and smaller women—who follow the ounce recommendations would have mercury exposure above the EPA's RfD.[2] The federal Online Advisory addresses this by advising that children eat smaller-sized portions, though women with below-average weight also should eat smaller portion sizes to remain within the EPA's RfD.

The federal Online Advisory does not give any information on other fish, other than the very high-mercury fish and a handful of lower mercury species of seafood; it leaves out, for example, both other fish in the low mercury category and fish with moderate mercury. The proposed FISH ADVISORY will remedy this to give women the information they need to make informed health decisions. (Attachment 7, Proposed Fish Advisory)

Proposed Changes

The proposed changes to the Model Food Code solve this problem by giving consumers expanded species-specific information about the relative mercury levels in most seafood sold commercially in the U.S., based on FDA seafood data. It also gives the TARGET GROUP more comprehensive EPA consumption guidelines to allow for a broader range of seafood choices than does the Online Advisory. These changes seek to better promote public health not only by giving the TARGET GROUP this federal advice where they need it - *in grocery stores* - rather than online, but also by filling in the information gaps that the Online Advisory left unanswered.

Seafood contains important nutrients, which for many seafood species include high amounts of beneficial Omega-3 fatty acids. The majority of the nation's seafood market is in fact low in mercury, and consumers in the TARGET GROUP need greater awareness of the array of low-mercury seafood choices from which they can consume healthy seafood while

at the same time protecting fetal and childhood development. For these reasons it is vital to effectively communicate to the TARGET GROUP not only the recommended consumption limits but also which seafood species are low in mercury and thus meet the consumption limits.

In providing this information, the proposed FISH ADVISORY presents a simple, color-code chart displaying the relative mercury levels in the majority of commercial seafood, divided into high, moderate, and lower-mercury categories. These categories are based on EPA calculations of recommended fish consumption, based on the EPA's RfD for the average woman, which also serves as the foundation for the FDA-EPA joint advice in the 2004 Online Advisory. (Attachment 2, EPA Consumption Recommendations by PPM Level) Specifically, the changes expand the range of seafood choices for the TARGET GROUP beyond the Online Advisory's current, limited list of low-mercury species. Further, these changes are based strictly on federal information available through the FDA and EPA, including FDA data on the mercury content in commercial fish species and EPA consumption guidelines for the TARGET GROUP (Attachment 2, EPA Consumption Recommendations). The EPA has six consumption categories, but for ease of understanding the proposed FISH ADVISORY uses a chart with only three "red-yellow-green" groupings:

1. The proposal eliminates the gap left by the FDA-EPA Online Advisory, by giving the complete list of low mercury seafood (defined as containing 0.12 ppm or less of methylmercury) that can be consumed twice a week by average-weight individuals in the TARGET GROUP;

2. It expands the list to include moderate-mercury seafood (containing 0.13 - 0.31 ppm of mercury), which are not mentioned on the Online Advisory despite the fact that under EPA guidelines the TARGET GROUP may safely consume fish from this category up to once a week;^[3] and

3. It identifies higher-mercury species (above 0.31 ppm), which under EPA guidelines the TARGET GROUP should avoid. (The higher-mercury grouping in the current proposal does not contain albacore tuna, since the FDA-EPA Online Advisory issues specific consumption advice for albacore which the proposed FISH ADVISORY communicates elsewhere.)^[4] The EPA guidelines specify that fish in excess of 0.31 ppm of mercury should only be eaten once every two weeks, or once a month or less for fish with higher levels, with no other fish eaten during that period. Such infrequent seafood intake by the TARGET GROUP would deprive developing fetuses and children of the benefits of seafood, which the FDA recommends should ideally be consumed (from lower mercury species) twice a week, for up to a total of 12 ounces per week. Members of the TARGET GROUP who follow the proposed chart's "avoid" advice for these higher-mercury species will thus be able to more frequently consume seafood in the moderate- and lower-mercury categories. (Attachment 7, Proposed Fish Advisory Chart)

These figures were derived from the Online Advisory and/or the EPA's RfD consumption recommendations on which the Online Advisory is based. As the EPA stated in its 2004 Derivation of Safe Fish Consumption Rate (for noncommercial fish, which has the same RfD standard as commercial seafood), "one can safely consume 2 meals/week at concentrations ranging from >0.078 ppm to 0.12 ppm, and should consume no more than 1 meal/month at concentrations ranging from >.47 ppm to 0.94 ppm" (Attachment 2, EPA Consumption Recommendations by PPM Level). These breakdowns are also found in the

EPA's "Monthly Fish Consumption Limits for Noncarcinogenic Health Endpoint - Methylmercury." (Attachment ___????___)

The EPA further sets forth that moderate-mercury fish with $>0.12 - 0.23$ ppm be consumed once a week (four times a month) and fish with $0.23 - 0.31$ ppm be consumed slightly less than once a week (three times a month) [4] (Attachment 2). The proposed FISH ADVISORY reflects this consumption limit on the "moderate"-mercury (or yellow-designated) portion of the chart, to be consumed only once a week.

Including the full range of seafood in this way, which THE REGULATORY AUTHORITY may expand by adding information about locally-caught noncommercial fish), will further enable members of the TARGET GROUP to accurately assess their overall mercury exposure to make better-informed decisions about which seafood to purchase at the grocery store. This expanded information will eliminate uncertainty among consumers in the TARGET GROUP and restore their confidence in the safety of seafood products. In the absence of this information, confusion might lead some consumers to otherwise avoid healthy seafood products.

Moreover, the proposed FISH ADVISORY communicates this information in the clear, easily-understood format of a color-coded chart. This method will quickly convey information to TARGET GROUP consumers and is supported by a study on the effectiveness of advisories, which showed that such red-yellow-green designations are a preferred format for communicating fish advisory information (Ujihara). Most importantly, the proposal gives consumers this information where they need it most, at the point of sale in the grocery store. With these changes, consumers within the TARGET GROUP can be confident that the seafood products they purchase are safe based on their individual consumption patterns.

Notes:

[1] Several studies have estimated would lower the EPA Reference Dose level from 5.8 ug of mercury per liter of blood to 3.5 ug/L[1] (Stern and Smith 2003) and that 15.7% of women of childbearing age were found in the 1999-2001 NHANES study to exceed this level (NRC 2006, Mahaffey et al.2004, Trasande et al. 2005).

[2] *Mercury Update: Impact on Fish Advisories* (EPA 2001), found at: www.epa.gov/ost/fishadvice/mercupd.

[3] This category is technically not as protective as the EPA guidelines, since the proposal for the moderate-mercury category includes fish with $0.23-0.31$ ppm of mercury, which the EPA recommends that the target group consume only three times a month, rather than the current proposal's higher, once per week recommendation.

[4] The instant FISH ADVISORY is not designed to establish the most protective mercury consumption advice, but simply to convey the current federal advice.

[5] Table 4-3 from US EPA, 2000, cited in 2004 EPA Derivation of Safe Fish Consumption Rate, National Noncommercial Fish Advisory.

Recommended Solution: The Conference recommends...:

that the Conference Chair send a letter to the FDA Commissioner to urge the following addition to the 2009 Food Code to require grocery stores to post a FISH ADVISORY for

Women of Childbearing Age and Children (the "TARGET GROUP") to communicate to the TARGET GROUP:

- 1) the FDA-EPA 2004 Advisory recommendations ("Online Advisory", see Attachment 1);
- 2) EPA consumption recommendations for moderate and higher-mercury fish; and,
- 3) a chart displaying the relative mercury content of commercial seafood..

The specific proposed language to add NEW sections to the Model Food Code as follows:
3-603.12 Seafood Methylmercury Disclosure for Consumption of Seafood Products by Women of Childbearing Age and Children.

(A) GROCERY STORES shall post a commercial Fish Advisory to inform consumers of the recommended FDA-EPA consumption guidelines for Women of Childbearing Age (Under Age 45) and Children (collectively the "TARGET GROUP") and the relative amounts of methylmercury in various seafood species using written advisories and/or placards posted at the point of sale (the "FISH ADVISORY") as specified in paragraphs (B) - (F) of this section.

(B) CONTENT OF DISCLOSURE. The FISH ADVISORY shall contain the following primary components, conform to the format set forth below, and shall essentially follow the sample sign presented below in section (F).

(1) Title. The sign shall be entitled "FISH ADVISORY", depicted in bold 48-point font size and be immediately followed by the underlined heading "Women Under Age 45 and Children" in bold 36-point font size.

(2) Explanatory Information. Immediately below this title, the FISH ADVISORY must contain the following prefatory statement to explain the purpose and the intended TARGET GROUP. This statement, in large type (at least 20-point font size) for ease of visibility, shall state: "Seafood contains important nutrients, including Omega-3 fatty acids, but also contains mercury, which can be harmful to women and children."

(3) Key Consumption Limits. The sign shall then post the following key consumption recommendations by the FDA-EPA Joint Fish Advisory for the TARGET GROUP:

(a) The first statement, boxed and in at least 28-point font size, shall state the "DO NOT EAT" list of fish which includes the following high-mercury species: swordfish, shark, tilefish, and king mackerel.

(b) A second statement, boxed and in at least 17-point font size, shall state to the TARGET GROUP: "Limit albacore tuna to one, 6-ounce serving per week, and eat no other fish that week. Light canned tuna, however, may be eaten twice per week."

(4) Seafood Chart. Second, the FISH ADVISORY shall contain a simple, color-coded chart that groups seafood species by methylmercury content into three, easily-understood high, medium, and low categories. These three categories, separated into three columns, shall be correspondingly delineated by red, yellow and green color designations and by the accompanying consumption recommendations, as set forth below in paragraphs (a)-(c).

(a) Lower-Mercury Seafood:

(i) The first column on the chart shall list those species which contain 0.12 parts per million ("ppm") or less of methylmercury, according to FDA monitoring data or more recent data obtained by the REGULATORY AUTHORITY;

(ii) These species shall include, in ascending value of mercury content, fish that contain above 0.05% of market share and are listed on Table 2 of the FDA's information on Mercury Levels in Commercial Fish and Shellfish as "Fish and Shellfish With Lower Levels of Mercury" (at or below 0.12 ppm of methylmercury): shrimp, sardines, tilapia,

clams/oysters, scallops/mussels, salmon, crayfish, freshwater trout, ocean perch/mullet, pollock, Atlantic mackerel, anchovy/herring, sole/flounder, crab, pike, butterfish, catfish, squid, Atlantic croaker, whitefish, Pacific mackerel/chub, smelt, cod, canned light tuna and spiny lobster;

(iii) The chart shall entitle this group "lower" mercury seafood, designate this category by a green color coding, and state that these fish should be eaten by the TARGET GROUP no more than 12-ounces per week.

(b) Moderate-Mercury Seafood:

(i) The second column on the chart shall list those species which contain 0.13 - 0.31 ppm of methylmercury, according to FDA monitoring data or more recent data obtained by the REGULATORY AUTHORITY;

(ii) These species shall include, in ascending value of mercury content: snapper, skate, freshwater perch, monkfish, halibut, sablefish, sea bass, sea trout, and American lobster;

(iii) The chart shall entitle this group "Moderate" mercury seafood, designate this category by a yellow color coding, and state the EPA Reference Dose advice that these fish should be eaten by the TARGET GROUP no more than one serving per week, with no other fish eaten that week.

(c) High-Mercury Seafood:

(i) The third column shall list those commercial seafood species which contain above 0.31 ppm of methylmercury, according to FDA monitoring data or more recent data obtained by the REGULATORY AUTHORITY, subject to section (iv) below.

(ii) These species shall include, in ascending value of mercury content: fresh/frozen tuna, Spanish mackerel (South Atlantic), Chilean bass, grouper, marlin, and orange roughy;

(iii) The chart shall entitle this group "High" mercury seafood, delineate this category by a red color coding, and label on the chart that the TARGET GROUP should "Avoid" these fish.

(iv) This "High" category shall exclude canned albacore tuna, given that the FISH ADVISORY set forth in this section specifies per paragraph (B)(3)(b) above that the TARGET GROUP may consume up to 6-ounces of albacore tuna. It shall also exclude the "DO NOT EAT" fish that are highlighted at the top of the FISH ADVISORY per paragraph (B)(3)(a) above.

(5) In addition to the provisions of paragraphs (B)(1)-(B)(3) above, the FISH ADVISORY shall generally follow the content and format set forth in section (F).

(C) LOCATION OF FISH ADVISORY. The FISH ADVISORY shall be posted in GROCERY STORES as follows:

(1) The FISH ADVISORY shall be displayed on a laminated, 8.5-inch by 11-inch sign or placard; and

(2) The FISH ADVISORY shall be displayed prominently at the point-of-sale, at or immediately adjacent to the specific location where the seafood is being sold, as close as reasonably possible to the seafood product.

(a) Disclosure for frozen SEAFOOD PRODUCTS shall be centrally affixed to the glass display case that contains the SEAFOOD PRODUCTS or, if there is no glass display case, otherwise in a prominent location within the display case that is clearly visible to consumers.

(b) Disclosure for SEAFOOD PRODUCTS sold at the fresh seafood counter in GROCERY STORES shall be displayed on the display case and also posted atop the seafood counter at the point-of-sale.

(c) Disclosure for canned or nonperishable, packaged SEAFOOD PRODUCTS shall be affixed prominently to the shelving or, if none, otherwise at or within two feet of the display area where they are located.

(D) DEFINITIONS.

(1) Under this section "SEAFOOD PRODUCT" shall be defined to include any food product offered for sale in a GROCERY STORE that contains two or more ounces of seafood per serving size.

(2) Under this section "GROCERY STORE" shall be defined in the normal sense of the word, to exclude retail FOOD ESTABLISHMENTS other than restaurants and other entities that sell "ready to eat" products.

(E) MODIFICATIONS. The REGULATORY AUTHORITY may modify the FISH ADVISORY in any of the following ways:

(1) To designate by an asterisk the seafood species that contain high Omega-3s;

(2) To add to the lists of high-, moderate-, or lower-mercury categories locally-caught fish from local lakes, streams, or coastal areas, so that consumers may more accurately assess their total mercury exposure when buying commercial seafood products;

(3) To add information on serving or portion sizes for children;

(4) To add a state contact phone number or state governmental website address for consumers to contact for more information concerning seafood consumption.

(5) To add other information that the REGULATORY AUTHORITY may reasonably deem important for the health of or seafood purchasing decisions of members of the TARGET GROUP.

(F) SAMPLE CHART. [See Attachment 7, Proposed Fish Advisory Chart]

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Attachments:

- "ONLINE ADVISORY, JOINT EPA-FDA FISH ADVISORY"
- "ATTACHMENT 2: EPA CONSUMPTION RECOMMENDATION BY PPM LEVEL"
- "ATTACHMENT 3: EPA, HEALTH EFFECTS"
- "ATTACHMENT 4: FDA FISH DATA"
- "ATTACHMENT 5: CDC, NHANES DATA ON MERCURY LEVELS EXCEEDING EPA RfD"
- "ATTACHMENT 6: REVIEW OF RECENT SCIENTIFIC STUDIES"
- "ATTACHMENT 7: PROPOSED FISH ADVISORY CHART"

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

ATTACHMENT 1

FDA- EPA ADVISORY (“ONLINE ADVISORY”)

<http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm110591.htm>

What You Need to Know About Mercury in Fish and Shellfish (Brochure)

March 2004

EPA-823-R-04-005

(This document is also available in [PDF](#) (228 KB) and [en Español \(Spanish\)](#))



Advice for
**Women Who Might Become
Pregnant
Women Who are Pregnant
Nursing Mothers
Young Children**

from the
**U.S. Food and Drug Administration
U.S. Environmental Protection Agency**

The Facts

Fish and shellfish are an important part of a healthy diet. Fish and shellfish contain high-quality protein and other essential nutrients, are low in saturated fat, and contain omega-3 fatty acids. A well-balanced diet that includes a variety of fish and shellfish can contribute to heart health and children's proper growth and development. So, women and young children in particular should include fish or shellfish in their diets due to the many nutritional benefits.

However, nearly all fish and shellfish contain traces of mercury. For most people, the risk from mercury by eating fish and shellfish 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. The risks from mercury in fish and shellfish depend on the amount of fish and shellfish eaten and the levels of mercury in the fish and shellfish. Therefore, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) are advising 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.

3 Safety Tips

By following these 3 recommendations for selecting and eating fish or shellfish, women and young children will receive the benefits of eating fish and shellfish and be confident that they have reduced their exposure to the harmful effects of mercury.

1. **Do not eat**
 - **Shark**
 - **Swordfish**
 - **King Mackerel**
 - **Tilefish**

They contain high levels of mercury.

2. **Eat up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury.**
 - Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon, pollock, and catfish.
 - Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to 6 ounces (one average meal) of albacore tuna per week.
3. **Check local advisories about the safety of fish caught by family and friends in your local lakes, rivers, and coastal areas.**

If no advice is available, eat up to 6 ounces (one average meal) per week of fish you catch from local waters, but don't consume any other fish during that week.

Follow these same recommendations when feeding fish and shellfish to your young child, but serve smaller portions.

Frequently Asked Questions *about Mercury in Fish and Shellfish:*



Note:

If you have questions or think you've been exposed to large amounts of methylmercury, see your doctor or health care provider immediately.

1. **What is mercury and methylmercury?**

Mercury occurs naturally in the environment and can also be released into the air through industrial pollution. Mercury falls from the air and can accumulate in streams and oceans and is turned into methylmercury in the water. It is this type of mercury that can be harmful to your unborn baby and young child. Fish absorb the methylmercury as they feed in these waters and so it builds up in them. It builds up more in some types of fish and shellfish than others, depending on what the fish eat, which is why the levels vary.

2. **I'm a woman who could have children but I'm not pregnant - so why should I be concerned about methylmercury?**

If you regularly eat types of fish that are high in methylmercury, it can accumulate in your blood stream over time. Methylmercury is removed from the body naturally, but it may take over a year for the levels to drop significantly. Thus, it may be present in a woman even before she becomes pregnant. This is the reason why women who are trying to become pregnant should also avoid eating certain types of fish.

3. **Is there methylmercury in all fish and shellfish?**

Nearly all fish and shellfish contain traces of methylmercury. However, larger fish that have lived longer have the highest levels of methylmercury because they've had more time to accumulate it. These large fish (swordfish, shark, king mackerel and tilefish) pose the greatest risk. Other types of fish and shellfish may be eaten in the amounts recommended by FDA and EPA.

4. **I don't see the fish I eat in the advisory. What should I do?**

If you want more information about the levels in the various types of fish you eat, see the FDA food safety website or the EPA website at www.epa.gov/ost/fish.

5. **What about fish sticks and fast food sandwiches?**

Fish sticks and "fast-food" sandwiches are commonly made from fish that are low in mercury.

6. **The advice about canned tuna is in the advisory, but what's the advice about tuna steaks?**

Because tuna steak generally contains higher levels of mercury than canned light tuna, when choosing your two meals of fish and shellfish, you may eat up to 6 ounces (one average meal) of tuna steak per week.

7. **What if I eat more than the recommended amount of fish and shellfish in a week?**

One week's consumption of fish does not change the level of methylmercury in the body much at all. If you eat a lot of fish one week, you can cut back for the next week or two. Just make sure you average the recommended amount per week.

8. **Where do I get information about the safety of fish caught recreationally by family or friends?**

Before you go fishing, check your Fishing Regulations Booklet for information about recreationally caught fish. You can also contact your local health department for information about local advisories. You need to check local advisories because some kinds of fish and shellfish caught in your local waters may have higher or much lower than average levels of mercury. This depends on the levels of mercury in the water in which the fish are caught. Those fish with much lower levels may be eaten more frequently and in larger amounts.

For further information about the risks of mercury in fish and shellfish call the U.S. Food and Drug Administration's food information line toll-free at 1-888-SAFEFOOD or visit [FDA's Food Safety](#) website.

For further information about the safety of locally caught fish and shellfish, visit the [Environmental Protection Agency's Fish Advisory website](#) or contact your State or Local Health Department. A [list of state or local health department contacts](#) is available. Click on Federal, State, and Tribal Contacts. For information on EPA's actions to control mercury, visit [EPA's mercury website](#).

ATTACHMENT 2

EPA CONSUMPTION RECOMMENDATIONS BY PPM LEVEL

<http://www.epa.gov/fishadvisories/advice/1-meal-per-week.pdf>

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
WATER

TECHNICAL MEMORANDUM

DATE: March 11, 2004

RE: Origin of 1 Meal/Week Noncommercial Fish Consumption Rate in National

Advisory for Mercury

Background

The national advisory states that, for noncommercial fish, consumers should first consult any local advisories that may pertain to their catch. In case of no local advisory, consumers are advised to restrict consumption to 1 meal/week. Because states and tribes have not monitored nor posted advisories on all waters in the U.S., the noncommercial fish consumption advice is provided as a baseline of protection. This technical memorandum provides the methodology from which the default safe consumption rate is derived.

Introduction

Statistics on mercury concentrations in noncommercial fish were calculated from a national database. Mean fish tissue concentrations were compared against default fish consumption limits for mercury, as presented in EPA guidance. Noncommercial fish can be consumed at a rate of one 6-oz. meal of fish per week for the vast majority of species.

Fish Tissue Database

Database: National Listing of Fish and Wildlife Advisories (NLFWA), US EPA, 2003.

Date range: All dates covering a range of years from 1987 to 2003.

Species selected: All species with data from at least 100 sampling stations in the database.

Sample type: Fillet only. Whole fish samples not included, as these are relevant for ecological risk.

Additional Notes: The NLFWA fish tissue database is data voluntarily provided to EPA, representing sampling and analysis performed by States and Tribes for the purpose of fish consumption advisory assessments. Thus the data collection is targeted to those areas of concern for increased fish contaminant levels. All fish data are from adult fish. Juveniles and fish organs are not included in the database as such data are relevant for ecological risk assessments, rather than human health risk assessments.

Fish Tissue Statistics

Statistics for each species are provided in Table 1. All of the statistics calculated for Table 1 are based on sampling station averages (means). That is, the mean value was calculated at each sampling station for each species. The statistics shown in Table 1 (count, mean, median, minimum, and maximum), then are calculated based on the station level averages. While some stations had as few as a single sample per species, others might have hundreds of samples. Thus, using station-level averages eliminates biasing toward stations with a large number of samples, and produces statistics that are more representative of the

ATTACHMENT 2, page:
EPA CONSUMPTION RECOMMENDATION BY PPM LEVEL

entire population of sampling stations. From Table 1, one can see that species means range from 0.06 ppm to 0.96 ppm, but that the bulk of the species (27 out of 34) have average mercury concentrations between 0.13 ppm and 0.43 ppm.

Risk Based Fish Consumption Limits

US EPA, 2000, Table 4-3 (see attachment) presents risk-based fish consumption limits which relate the number of fish meals that can be eaten per month to fish tissue concentrations of methylmercury. The inputs used in the development of Table 4-3, are described in Section 3.3 of the same document (US EPA, 2000). These include:

Reference Dose (RfD): 1×10^{-4} mg/kg-d.

Meal Size: 8 oz., uncooked corresponding with 6 oz. cooked as used in the national advisory.

Body Weight: 70 kg, average body weight of adult males and females combined, in the U.S. population.

Derivation of Safe Fish Consumption Rate

US EPA, 2000, Table 4-3 (see attachment) presents safe fish consumption rates corresponding to various ranges of mercury contaminant concentrations. While Table 4-3 is quite detailed, most states have issued fish consumption advisories according to a more coarse consumption rate categorization, i.e.: no consumption, 1 meal/month, 1 meal/week, and 2 meals/week. At this categorization, states typically collapse the 2-4 meals/month consumption rates to a single 1 meal/week category. That is, by Table 4-3 (US EPA, 2000), one can safely consume 2 meals/week at concentrations ranging from >0.078 ppm to 0.12 ppm, and should consume no more than 1 meal/month at concentrations ranging from >0.47 ppm to 0.94 ppm. As can be seen from Table 1, below, the vast majority of fish species with contamination data (27 out of 34 species) have concentrations within the coarse 1 meal/week range (i.e. 2-4 meals/month range or > 0.12 ppm - 0.47 ppm). Thus, the general consumer should be advised to eat no more than 1 meal/week of noncommercial fish in the U.S. *Note:* Collapsing the 2-4 meal/month consumption rate to a 1 meal/week consumption rate strikes a balance between a too detailed advisory that would overwhelm or confuse most consumers, and simplified advice that balances risks from mercury with the benefits of fish. Consumers are encouraged to use more detailed information where available for the waterbodies on which they fish, and the fish species they choose to consume. Also, as can be seen from the minimum and maximum values in Table 1, mercury concentrations in fish vary considerably from waterbody to waterbody and region to region. Consumers should, first and foremost, consider any local advisories.

Derivation of Safe Fish Consumption Rate

US EPA, 2000, Table 4-3 (see attachment) presents safe fish consumption rates corresponding to various ranges of mercury contaminant concentrations. While Table 4-3 is quite detailed, most states have issued fish consumption advisories according to a more coarse consumption rate categorization, i.e.: no consumption, 1 meal/month, 1 meal/week, and 2 meals/week. At this categorization, states typically collapse the 2-4 meals/month consumption rates to a single 1 meal/week category. That is, by Table 4-3 (US EPA, 2000), one can safely consume 2 meals/week at concentrations ranging from >0.078 ppm to 0.12 ppm, and should consume no more than 1 meal/month at concentrations ranging from >0.47 ppm to 0.94 ppm. As can be seen from Table 1, below, the vast majority of fish species with contamination data (27 out of 34 species) have concentrations within the coarse 1 meal/week range (i.e. 2-4 meals/month range or > 0.12 ppm - 0.47 ppm). Thus, the general consumer should be advised to eat no more than 1 meal/week of noncommercial fish in the U.S.

Note: Collapsing the 2-4 meal/month consumption rate to a 1 meal/week consumption rate strikes a balance between a too detailed advisory that would overwhelm or confuse most consumers, and simplified advice that balances risks from mercury with the benefits of fish. Consumers are encouraged to use more detailed information where available for the waterbodies on which they fish, and the fish species they choose to consume. Also, as can be seen from the minimum and maximum values in Table 1, mercury concentrations in fish vary considerably from waterbody to waterbody and region to region. Consumers should, first and foremost, consider any local advisories.

Table 1. Mercury Contamination Statistics by Species* [NONCOMMERCIAL]

Concentration Statistics (ppm)					
Species #	Stations	Mean	Median	Minimum	Maximum
Bowfin	358	0.96	0.82	0.02	4.80
Chain pickerel	250	0.61	0.54	0.05	2.25
Largemouth bass	2,425	0.43	0.34	0.00	4.47
Walleye	1,520	0.40	0.34	0.02	3.30
Warmouth sunfish	147	0.39	0.34	0.02	1.36
Flathead catfish	158	0.37	0.21	0.02	2.31
Spotted bass	163	0.36	0.28	0.02	1.72
Northern pike	1,322	0.35	0.30	0.01	1.78
Lake trout	160	0.30	0.25	0.05	1.70
Sauger	109	0.28	0.18	0.03	1.40
Smallmouth bass	738	0.27	0.22	0.01	2.50
Yellow bullhead	185	0.27	0.18	0.00	1.38
Striped bass	146	0.27	0.25	0.01	1.05
Redear sunfish	215	0.26	0.21	0.01	1.58
Yellow perch	604	0.22	0.17	0.01	1.55
White perch	133	0.22	0.15	0.01	1.05
Freshwater drum	226	0.22	0.16	0.01	1.91
White bass	212	0.21	0.14	0.01	1.30
White crappie	352	0.19	0.11	0.01	1.70
Black crappie	652	0.19	0.14	0.00	1.50
Rock bass	376	0.19	0.17	0.01	0.69
Channel catfish	1,213	0.18	0.12	0.00	7.00
Rainbow smelt	116	0.18	0.14	0.02	0.67
Brown trout	131	0.16	0.12	0.01	1.25
Bluegill sunfish	1,062	0.15	0.10	0.01	4.49
Carp	426	0.14	0.10	0.01	1.84
Common carp	737	0.14	0.12	0.00	1.80
Pumpkinseed sunfish	107	0.13	0.09	0.01	1.02
Brown bullhead	214	0.13	0.08	0.01	2.46
White sucker	714	0.11	0.09	0.01	0.68
Rainbow trout	119	0.11	0.10	0.01	0.51
Black bullhead	130	0.10	0.07	0.01	0.68
Gizzard shad	151	0.09	0.10	0.01	0.40
English sole	241	0.06	0.06	0.02	0.13

* Data source: U.S. EPA NLFWA fish tissue database. October 2003.
Concentration statistics based on sampling station averages.
Shading indicates safe consumption rate associated with mean conc.:
1 meal/mo. 2 meal/mo. 3 meal/mo. 4 meal/mo. 8 meal/mo. 12 meal/mo.

References

US EPA, 2000. *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume 2: Risk Assessment and Fish Consumption Limits, Third Edition*, Office of Water, November 2000, EPA-823-B-00-008.

US EPA, 2003. National Listing of Fish and Wildlife Advisories (NLFWA): Fish Tissue Database. Data export October 2003. Available at: <http://www.epa.gov/ost/fish/>.

Table 4-3. Monthly Fish Consumption Limits for Noncarcinogenic Health Endpoint - Methylmercury

Risk Based Consumption Limit ^a	Noncancer Health Endpoints ^b
Fish Meals/Month	Fish Tissue Concentrations (ppm, wet weight)
Unrestricted (>16)	0 - 0.029
16	>0.029 - 0.059
12	>0.059 - 0.078
8	>0.078 - 0.12
4	>0.12 - 0.23
3	>0.23 - 0.31
2	>0.31 - 0.47
1	>0.47 - 0.94
0.5	>0.94 - 1.9
None (<0.5)	>1.9

^a The assumed meal size is 8 oz (0.227 kg). The ranges of chemical concentrations presented are conservative, e.g., the 12-meal-per-month levels represent the concentrations associated with 12 to 15.9 meals.

^b Chronic, systemic effects.

Notes:

1. Consumption limits are based on an adult body weight of 70 kg and an interim RfD of 1×10^{-4} mg/kg-d.
2. None = No consumption recommended.
3. In cases where >16 meals per month are consumed, refer to Equations 3-1 and 3-2, Section 3.2.1.2, for methods to determine safe consumption limits.
4. The detection limit for methylmercury is 1×10^{-3} mg/kg.
5. Instructions for modifying the variables in this table are found in Section 3.3.
6. Monthly limits are based on the total dose allowable over a 1-month period (based on the RfD). When the monthly limit is consumed in less than 1 month (e.g., in a few large meals), the daily dose may exceed the RfD (see Section 2.3).

ATTACHMENT 3

EPA, HEALTH EFFECTS

<http://www.epa.gov/mercury/effects.htm#meth>

Mercury

Health Effects

People in the U.S. are mainly exposed to methylmercury, an organic compound, when they eat fish and shellfish that contain methylmercury. Whether an exposure to the various forms of mercury will harm a person's health depends on a number of factors (below). Almost all people have at least trace amounts of methylmercury in their tissues, reflecting methylmercury's widespread presence in the environment and people's exposure through the consumption of fish and shellfish. People may be exposed to mercury in any of its forms under different circumstances. The factors that determine how severe the health effects are from mercury exposure include these:

- the chemical form of mercury;
- the dose;
- the age of the person exposed (the fetus is the most susceptible);
- the duration of exposure;
- the route of exposure -- inhalation, ingestion, dermal contact, etc.; and
- the health of the person exposed.

Mercury exists in three chemical forms. They each have specific effects on human health.

- [Methylmercury](#)
- [Elemental mercury](#)
- [Other mercury compounds](#) (inorganic and organic)

Methylmercury effects

For fetuses, infants, and children, the primary health effect of methylmercury is impaired neurological development. Methylmercury exposure in the womb, which can result from a mother's consumption of fish and shellfish that contain methylmercury, can adversely affect a baby's growing brain and nervous system. Impacts on cognitive thinking, memory, attention, language, and fine motor and visual spatial skills have been seen in children exposed to methylmercury in the womb. Recent human biological monitoring by the [Centers for Disease Control and Prevention in 1999 and 2000 \(PDF\)](#) (3 pp., 42 KB,

[About PDF](#)) shows that most people have blood mercury levels below a level associated with possible health effects. [More recent data](#) from the CDC support this general finding.

Outbreaks of methylmercury poisonings have made it clear that adults, children, and developing fetuses are at risk from ingestion exposure to methylmercury. During these poisoning outbreaks some mothers with no symptoms of nervous system damage gave birth to infants with severe disabilities, it became clear that the developing nervous system of the fetus may be more vulnerable to methylmercury than is the adult nervous system.

For more information on fish consumption advisories across the country, visit [EPA's fish consumption web pages](#).

In addition to the subtle impairments noted above, symptoms of methylmercury poisoning may include; impairment of the peripheral vision; disturbances in sensations ("pins and needles" feelings, usually in the hands, feet, and around the mouth); lack of coordination of movements; impairment of speech, hearing, walking; and muscle weakness. People concerned about their exposure to methylmercury should consult their physician.

Mercury and Cancer. No human data indicate that exposure to any form of mercury causes cancer, but the human data currently available are very limited. Mercuric chloride has caused increases in several types of tumors in rats and mice, and methylmercury has caused kidney tumors in male mice. Scientists only observed these health effects at extremely high doses, above levels that produced other effects. When EPA revised its [Cancer Guidelines](#) in 2005, the Agency concluded that neither inorganic mercury nor methylmercury from environmental exposures are likely to cause cancer in humans. More technical information is available in [volume V of the 1997 Mercury Study Report to Congress \(PDF\)](#) (349 pp., 1.2 MB, [about PDF](#)) (see especially pages 47, 80, 107, and 161 of the file).

Additional Information:

Additional information on the health effects of methylmercury is available from the IRIS database at <http://www.epa.gov/iris/subst/0073.htm> and EPA's Methylmercury Water Quality Criterion Web site at <http://www.epa.gov/waterscience/criteria/methylmercury/index.html>. You can also visit the Agency for Toxic Substances and Disease Registry (ATSDR) [toxicological profile for mercury](#).

ATTACHMENT 4

FDA FISH DATA

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm115644.htm>

Mercury Levels in Commercial Fish and Shellfish

Return to [Advisory on Mercury in Seafood](#)

See also [Mercury Concentrations in Fish: FDA Monitoring Program](#)

Table 1. Fish and Shellfish With Highest Levels of Mercury

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
MACKEREL KING	0.730	N/A	N/A	0.230	1.670	213	GULF OF MEXICO REPORT 2000
SHARK	0.988	0.830	0.631	ND	4.540	351	FDA 1990-02
SWORDFISH	0.976	0.860	0.510	ND	3.220	618	FDA 1990-04
TILEFISH (Gulf of Mexico)	1.450	N/A	N/A	0.650	3.730	60	NMFS REPORT 1978

Table 2. Fish and Shellfish With Lower Levels of Mercury[†]

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
ANCHOVIES	0.043	N/A	N/A	ND	0.340	40	NMFS REPORT 1978
BUTTERFISH	0.058	N/A	N/A	ND	0.360	89	NMFS

Table 2. Fish and Shellfish With Lower Levels of Mercury[†]

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
							REPORT 1978
CATFISH	0.049	ND	0.084	ND	0.314	23	FDA 1990-04
CLAM *	ND	ND	ND	ND	ND	6	FDA 1990-02
COD	0.095	0.087	0.080	ND	0.420	39	FDA 1990-04
CRAB ¹	0.060	0.030	0.112	ND	0.610	63	FDA 1990-04
CRAWFISH	0.033	0.035	0.012	ND	0.051	44	FDA 2002-04
CROAKER ATLANTIC (Atlantic)	0.072	0.073	0.036	0.013	0.148	35	FDA 1990-03
FLATFISH ^{2*}	0.045	0.035	0.049	ND	0.180	23	FDA 1990-04
HADDOCK (Atlantic)	0.031	0.041	0.021	ND	0.041	4	FDA 1990-02
HAKE	0.014	ND	0.021	ND	0.048	9	FDA 1990-02
HERRING	0.044	N/A	N/A	ND	0.135	38	NMFS REPORT 1978
JACKSMELT	0.108	0.060	0.115	0.040	0.500	16	FDA 1990-02
LOBSTER (Spiny)	0.09	0.14	‡	ND	0.27	9	FDA SURVEY 1990-02
MACKEREL ATLANTIC (N.Atlantic)	0.050	N/A	N/A	0.020	0.160	80	NMFS REPORT 1978
MACKEREL CHUB (Pacific)	0.088	N/A	N/A	0.030	0.190	30	NMFS REPORT 1978
MULLET	0.046	N/A	N/A	ND	0.130	191	NMFS REPORT

Table 2. Fish and Shellfish With Lower Levels of Mercury[†]

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
							1978
OYSTER	0.013	ND	0.042	ND	0.250	38	FDA 1990-04
PERCH OCEAN *	ND	ND	ND	ND	0.030	6	FDA 1990-02
POLLOCK	0.041	ND	0.106	ND	0.780	62	FDA 1990-04
SALMON (CANNED) *	ND	ND	ND	ND	ND	23	FDA 1990-02
SALMON (FRESH/FROZEN) *	0.014	ND	0.041	ND	0.190	34	FDA 1990-02
SARDINE	0.016	0.013	0.007	0.004	0.035	29	FDA 2002-04
SCALLOP	0.050	N/A	N/A	ND	0.220	66	NMFS REPORT 1978
SHAD AMERICAN	0.065	N/A	N/A	ND	0.220	59	NMFS REPORT 1978
SHRIMP *	ND	ND	ND	ND	0.050	24	FDA 1990-02
SQUID	0.070	N/A	N/A	ND	0.400	200	NMFS REPORT 1978
TILAPIA *	0.010	ND	0.023	ND	0.070	9	FDA 1990-02
TROUT (FRESHWATER)	0.072	0.025	0.143	ND	0.678	34	FDA 2002-04
TUNA (CANNED, LIGHT)	0.118	0.075	0.119	ND	0.852	347	FDA 2002-04
WHITEFISH	0.069	0.054	0.067	ND	0.310	28	FDA 2002-04
WHITING	ND	ND	‡	ND	ND	2	FDA SURVEY 1990-02

Table 3. Mercury Levels of Other Fish and Shellfish[†]

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
BASS (SALTWATER, BLACK, STRIPED) ³	0.219	0.130	0.227	ND	0.960	47	FDA 1990-04
BASS CHILEAN	0.386	0.303	0.364	0.085	2.180	40	FDA 1990-04
BLUEFISH	0.337	0.303	0.127	0.139	0.634	52	FDA 2002-04
BUFFALOFISH	0.19	0.14	‡	0.05	0.43	4	FDA SURVEY 1990-02
CARP	0.14	0.14	‡	0.01	0.27	2	FDA SURVEY 1990-02
CROAKER WHITE (Pacific)	0.287	0.280	0.069	0.180	0.410	15	FDA 1990-03
GROUPEL (ALL SPECIES)	0.465	0.410	0.293	0.053	1.205	43	FDA 2002-04
HALIBUT	0.252	0.200	0.233	ND	1.520	46	FDA 1990-04
LOBSTER (NORTHERN/AMERICAN)	0.310	N/A	N/A	0.050	1.310	88	NMFS REPORT 1978
LOBSTER (Species Unknown)	0.169	0.182	0.089	ND	0.309	16	FDA 1991-2004
MACKEREL SPANISH (Gulf of Mexico)	0.454	N/A	N/A	0.070	1.560	66	NMFS REPORT 1978
MACKEREL SPANISH (S. Atlantic)	0.182	N/A	N/A	0.050	0.730	43	NMFS REPORT 1978
MARLIN *	0.485	0.390	0.237	0.100	0.920	16	FDA 1990-02
MONKFISH	0.180	N/A	N/A	0.020	1.020	81	NMFS REPORT 1978

Table 3. Mercury Levels of Other Fish and Shellfish[†]

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
ORANGE ROUGHY	0.554	0.563	0.148	0.296	0.855	49	FDA 1990-04
PERCH (Freshwater)	0.14	0.15	‡	ND	0.31	5	FDA SURVEY 1990-02
SABLEFISH	0.220	N/A	N/A	ND	0.700	102	NMFS REPORT 1978
SCORPIONFISH	0.286	N/A	N/A	0.020	1.345	78	NMFS REPORT 1978
SHEEPSHEAD	0.128	N/A	N/A	0.020	0.625	59	NMFS REPORT 1978
SKATE	0.137	N/A	N/A	0.040	0.360	56	NMFS REPORT 1978
SNAPPER	0.189	0.114	0.274	ND	1.366	43	FDA 2002-04
TILEFISH (Atlantic)	0.144	0.099	0.122	0.042	0.533	32	FDA 2002-04
TUNA (CANNED, ALBACORE)	0.353	0.339	0.126	ND	0.853	399	FDA 2002-04
TUNA(FRESH/FROZEN, ALL)	0.383	0.322	0.269	ND	1.300	228	FDA 2002-04
TUNA (FRESH/FROZEN, ALBACORE)	0.357	0.355	0.152	ND	0.820	26	FDA 2002-04
TUNA (FRESH/FROZEN, BIGEYE)	0.639	0.560	0.184	0.410	1.040	13	FDA 2002-04
TUNA (FRESH/FROZEN, SKIPJACK)	0.205	N/A	0.078	0.205	0.260	2	FDA 1993
TUNA (FRESH/FROZEN, YELLOWFIN)	0.325	0.270	0.220	ND	1.079	87	FDA 2002-04
TUNA (FRESH/FROZEN, Species Unknown)	0.414	0.339	0.316	ND	1.300	100	FDA 1991-2004
WEAKFISH (SEA TROUT)	0.256	0.168	0.226	ND	0.744	39	FDA

Table 3. Mercury Levels of Other Fish and Shellfish [†]							
SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
							2002-04

Source of data: FDA 1990-2004, "National Marine Fisheries Service Survey of Trace Elements in the Fishery Resource" Report 1978,
 "The Occurrence of Mercury in the Fishery Resources of the Gulf of Mexico" Report 2000

Mercury was measured as Total Mercury except for species (*) when only Methylmercury was analyzed.

ND - mercury concentration below detection level (Level of Detection (LOD)=0.01ppm)
 N/A - data not available

[†]The following species have been removed from the tables:

- Bass (freshwater) – not commercial
- Pickerel – not commercial

‡ Standard deviation data generated for new data 2004 or later only.

¹Includes: Blue, King, Snow

²Includes: Flounder, Plaice, Sole

³Includes: Sea bass/ Striped Bass/ Rockfish

NOTE: On February 8, 2006, technical changes were made to the data that was posted on January 19, 2006. The changes corrected data or more properly characterized the species of fish or shellfish sampled.

ATTACHMENT 5:

CDC NHANES DATA ON MERCURY LEVELS EXCEEDING EPA RfD

found at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5343a5.htm>

November 5, 2004 / 53(43);1018-1020

Blood Mercury Levels in Young Children and Childbearing-Aged Women --- United States, 1999--2002

Exposure to high levels of mercury (Hg) can cause neurologic and kidney disorders (1--3). Because methylated Hg (methyl-Hg) in the aquatic environment accumulates in animal tissues up the food chain, persons in the United States can be exposed by eating freshwater fish, seafood, and shellfish. Exposure of childbearing-aged women is of particular concern because of the potential adverse neurologic effects of Hg in fetuses. To determine levels of total blood Hg in childbearing-aged women and in children aged 1--5 years in the United States, CDC's National Health and Nutrition Examination Survey (NHANES) began measuring blood Hg levels in these populations in 1999. This report summarizes NHANES results for 1999--2002 and updates previously published information (4,5). The findings confirmed that blood Hg levels in young children and women of childbearing age usually are below levels of concern. However, approximately 6% of childbearing-aged women had levels at or above a reference dose, an estimated level assumed to be without appreciable harm ($\geq 5.8 \mu\text{g/L}$). Women who are pregnant or who intend to become pregnant should follow federal and state advisories on consumption of fish.

NHANES is a continuous survey of the health and nutritional status of the civilian, noninstitutionalized U.S. population; data are released and reported in 2-year cycles (6). Each participant undergoes a household interview and a physical examination. During the physical examination, blood is collected by venipuncture from all persons aged ≥ 1 year. For this analysis, whole-blood specimens were analyzed for total and inorganic Hg for children aged 1--5 years and women aged 16--49 years by automated, cold-vapor atomic absorption spectrophotometry in CDC's inorganic toxicology laboratory. The analytic method detection limit was $0.14 \mu\text{g/L}$ (ppb) for total Hg and $0.4 \mu\text{g/L}$ (ppb) for inorganic Hg (7). Blood Hg levels less than the limit of detection were assigned a value equal to the detection limit divided by the square root of 2 for the calculation of geometric mean (GM) values.

During 1999--2002, the GMs of total blood Hg concentrations for all childbearing-aged women and for children aged 1--5 years were $0.92 \mu\text{g/L}$ and $0.33 \mu\text{g/L}$, respectively; the 95th percentiles of blood Hg for women and children were $6.04 \mu\text{g/L}$ and $2.21 \mu\text{g/L}$, respectively (Table 1). The percentage of all women aged 16--49 years with Hg levels $\geq 5.8 \mu\text{g/L}$ (the Environmental Protection Agency's [EPA] Reference Dose [RfD]) was 5.66%

(95% confidence interval [CI] = 4.04--7.95) ([Table 2](#)).

Among children aged 1--5 years, the estimated percentage who had blood Hg levels $\geq 5.8 \mu\text{g/L}$ during 1999--2002 could not be reported because the observed percentage was too low for the given sample size to calculate a statistically reliable national population estimate. Almost all inorganic blood Hg levels were undetectable, indicating that total blood Hg greater than or equal to the EPA RfD mostly reflected exposure to organic Hg (especially methyl-Hg).

Reported by: *RL Jones, PhD, T Sinks, PhD, SE Schober, PhD, M Pickett, MPH, National Center for Environmental Health; National Center for Health Statistics, CDC.*

Editorial Note:

This report updates NHANES 1999--2000 estimates of blood Hg levels (5), the first nationally representative estimates of U.S. women's and children's exposures to Hg based on biologic measures. The findings indicate that blood Hg levels in young children and childbearing-aged women usually are below levels of concern.

Among childbearing-aged women, for the 4-year period 1999--2002, estimates of the GM of blood Hg and the proportion with levels $\geq 5.8 \mu\text{g/L}$ were lower than estimates for the 2-year period 1999--2000, reflecting apparent declines in these values for the 2-year period 2001--2002. However, when these differences were evaluated by comparing estimates for the two 2-year periods, the declines were not statistically significant: the GM of blood Hg for 2001--2002 was $0.83 \mu\text{g/L}$ (CI = 0.73--0.93), compared with $1.02 \mu\text{g/L}$ (CI = 0.80--1.24) for 1999--2000, and the percentage of women with blood Hg levels $\geq 5.8 \mu\text{g/L}$ was 3.9% in 2001--2002 (CI = 2.40--6.43), compared with 7.8% in 1999--2000 (CI = 4.70--12.83). At least 2 more years of data are needed to best determine whether Hg exposure has declined among women of childbearing age in the United States.

Although NHANES data are released and often analyzed as 2-year periods, the estimates of blood Hg levels for 1999--2002 are the most reliable estimates of current exposure. The 4-year period provides greater geographic coverage, and estimates and sample errors are more stable, thus reducing variability caused by differing exposures to Hg across survey site locations. Accordingly, the National Center for Health Statistics advises users of these data that the most reliable estimates of current exposure are obtained when the 1999--2002 data are analyzed together (6).

The EPA RfD is based on measures of Hg in cord blood and is a level assumed to be without appreciable harm. The RfD was determined by applying an uncertainty factor of 10 to a dose ($58 \mu\text{g/L}$) that was the lower 95% confidence limit of a dose associated with an increased proportion of abnormal scores on the Boston Naming Test for children exposed in utero (2). All women and children in the 1999--2002 NHANES survey period had blood Hg levels below $58 \mu\text{g/L}$. The harm to a fetus from levels of exposure as measured by cord blood levels between $5.8 \mu\text{g/L}$ and $58 \mu\text{g/L}$ is uncertain.

The findings in this report are subject to at least two limitations. First, NHANES does not include an adequate sampling of women (e.g., sport fishers) who might eat large amounts of fish to characterize the distribution of total blood Hg in this group. Second, the ratio of Hg in cord to maternal blood (i.e., equivalent to NHANES measures) is uncertain (2,8). Therefore, NHANES values might not be directly comparable to the EPA RfD, which is based on cord blood Hg levels.

Fish are an important part of a diet, high in protein and nutrients and low in saturated fatty acids and cholesterol. The short-term strategy to reduce Hg exposure is to eat fish with low Hg levels and avoid or reduce consumption of fish with high Hg levels. Because exposure to methyl-Hg can harm fetuses, the Food and Drug Administration (FDA) advises that women who are or might become pregnant not eat shark, swordfish, king

mackerel, and tile fish (9). In addition, EPA and the Agency for Toxic Substances and Disease Registry have established daily consumption levels of Hg considered to be without harm (1). State-based fish advisories and bans identify fish species contaminated by Hg and their locations and provide safety advice (10). The NHANES program continues to collect Hg measurements in human tissue to monitor the effectiveness of efforts to reduce Hg exposure in the U.S. population.

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Table 1

TABLE 1. Geometric means (GMs) and selected percentiles of total blood mercury (Hg) concentrations ($\mu\text{g/L}$) for women aged 16–49 years and children aged 1–5 years, by selected variables — National Health and Nutrition Examination Survey, United States, 1999–2002

Variable	No.	GM	(95% CI) ^a	Selected percentile (95% CI)					
				5th	(95% CI)	10th	(95% CI)	25th	(95% CI)
Women									
Race/Ethnicity									
Mexican American	1,106	0.74	(0.64–0.84)	0.10	(0.08–0.15)	0.17	(0.12–0.23)	0.34	(0.27–0.45)
White, non-Hispanic	1,377	0.87	(0.76–0.99)	0.09	(0.08–0.10)	0.15	(0.13–0.18)	0.37	(0.34–0.45)
Black, non-Hispanic	794	1.18	(1.00–1.36)	0.17	(0.12–0.25)	0.30	(0.24–0.38)	0.60	(0.55–0.73)
Age group (yrs)									
16–29	2,004	0.68	(0.60–0.76)	0.08	(0.07–0.09)	0.11	(0.09–0.14)	0.29	(0.25–0.37)
30–49	1,633	1.10	(0.97–1.24)	0.13	(0.10–0.16)	0.24	(0.20–0.29)	0.52	(0.45–0.60)
Pregnancy status									
Pregnant	629	0.75	(0.60–0.90)	0.08	(...†–0.10)	0.10	(0.08–0.20)	0.32	(0.24–0.44)
Not pregnant	2,978	0.94	(0.84–1.04)	0.10	(0.09–0.11)	0.18	(0.15–0.21)	0.41	(0.38–0.47)
Total	3,637	0.92	(0.82–1.02)	0.09	(0.09–0.11)	0.17	(0.15–0.20)	0.40	(0.36–0.47)
Children									
Race/Ethnicity									
Mexican American	526	0.35	(0.30–0.40)	...		0.08	(...–0.09)	0.13	(0.10–0.16)
White, non-Hispanic	447	0.29	(0.24–0.33)	...		0.07	(...–0.08)	0.09	(0.09–0.10)
Black, non-Hispanic	424	0.50	(0.44–0.57)	0.08	(...–0.10)	0.10	(0.09–0.13)	0.22	(0.18–0.26)
Total	1,577	0.33	(0.30–0.37)	...		0.07	(...–0.08)	0.10	(0.09–0.12)

^a Confidence interval.

† Below the limits of detection.

TABLE 1. (Continued) Geometric means (GMs) and selected percentiles of total blood mercury (Hg) concentrations ($\mu\text{g/L}$) for women aged 16–49 years and children aged 1–5 years, by selected variables — National Health and Nutrition Examination Survey, United States, 1999–2002

Variable	Selected percentile (95% CI)							
	50th	(95% CI)	75th	(95% CI)	90th	(95% CI)	95th	(95% CI)
Women								
Race/Ethnicity								
Mexican American	0.73	(0.67–0.83)	1.27	(1.16–1.48)	2.38	(2.05–2.95)	3.60	(3.03–6.48)
White, non-Hispanic	0.81	(0.76–0.92)	1.69	(1.51–2.15)	3.73	(2.84–5.14)	6.17	(4.64–9.30)
Black, non-Hispanic	1.15	(1.05–1.41)	2.12	(1.86–2.70)	3.89	(3.24–5.03)	5.54	(4.27–11.08)
Age group (yrs)								
16–29	0.64	(0.55–0.77)	1.34	(1.24–1.54)	2.58	(2.28–3.13)	3.87	(3.32–7.80)
30–49	1.02	(0.91–1.19)	2.10	(1.79–2.69)	4.56	(3.74–5.76)	6.97	(5.73–11.62)
Pregnancy status								
Pregnant	0.73	(0.63–0.97)	1.50	(1.38–1.90)	3.11	(2.14–4.79)	4.86	(3.00–8.02)
Not pregnant	0.88	(0.80–1.00)	1.83	(1.65–2.11)	3.93	(3.26–4.93)	6.11	(5.12–10.90)
Total	0.86	(0.80–0.98)	1.81	(1.62–2.16)	3.89	(3.20–4.88)	6.04	(5.08–10.74)
Children								
Race/Ethnicity								
Mexican American	0.28	(0.24–0.33)	0.63	(0.56–0.81)	1.36	(1.05–1.57)	1.85	(1.60–2.66)
White, non-Hispanic	0.20	(0.17–0.25)	0.49	(0.38–0.63)	1.15	(0.80–1.49)	1.78	(1.18–2.69)
Black, non-Hispanic	0.47	(0.40–0.58)	0.88	(0.78–1.02)	1.54	(1.31–2.04)	2.37	(1.75–3.64)
Total	0.26	(0.23–0.29)	0.61	(0.56–0.70)	1.29	(1.08–1.69)	2.21	(1.80–3.66)

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Table 2

TABLE 2. Percentage of women aged 16–49 years with blood mercury (Hg) levels $\geq 5.8 \mu\text{g/L}$, by race/ethnicity — National Health and Nutrition Examination Survey, United States, 1999–2002

Race/Ethnicity	No.	% with Hg levels $\geq 5.8 \mu\text{g/L}$	(95% CI*)
Mexican American	1,106	1.70	(1.04–2.79)
White, non-Hispanic	1,377	5.77	(3.71–8.97)
Black, non-Hispanic	794	4.82	(2.55–9.11)
Total	3,637	5.66	(4.04–7.95)

* Confidence interval.

ATTACHMENT 6

REVIEW OF RECENT SCIENTIFIC STUDIES

The US EPA established the US Reference Dose for methylmercury in 1999, based on the best evidence then available, using data from a long-term epidemiological study in the Faeroe Islands carried out by researchers at Harvard and elsewhere. Research since then has sharpened scientific understanding of the benefits of maternal fish consumption for prenatal cognitive development, of the harm done by methylmercury to that cognitive development, and of improved research designs for separating the two effects. Several recent studies suggest more strongly than ever that public health concern over methylmercury exposure is completely justified, and that the effort to guide women to pick low-mercury fish must be expanded and improved.

In 2007, the Faeroe Islands research team reanalyzed their data to adjust for maternal fish intake, and determined that after adjusting for nutritional effects of fish consumption, cognitive deficits attributed to methylmercury were actually about twice as large as had originally been reported.¹ Similarly, a research team doing another long-term study, in the Seychelles Islands, which had previously reported no significant adverse effects of methylmercury on cognitive development, did a new analysis focused on measuring benefits of maternal fish consumption. In 2008, for the first time, the Seychelles researchers reported observing adverse mercury effects, which they concluded were probably masked by beneficial effects in their earlier analyses.²

Two US studies have shown that developmental benefits of fish intake and adverse effects of methylmercury occur in babies whose mothers consume average American amounts of fish. A study in Boston³ has assessed verbal development at the ages of six months and three years; high fish consumption during pregnancy improved scores, while higher mercury exposure (from the higher-mercury fish those women ate) reduced scores. The effects were of roughly comparable magnitude in the affected groups, about 5 points on a 100-point scale. A New York City study⁴ tested children's cognitive development at the ages of 12, 24, 36 and 48 months, using standard tests, and found similar results: High fish consumption enhanced performance, while elevated mercury exposure decreased performance on the same tests.

The populations in the Faeroes and Seychelles have high-fish diets, and the Faroese in fact get most of their methylmercury exposure from pilot whale meat. But the women in the Boston and New York studies had ordinary levels of fish consumption and mercury exposure. Only 7 percent of the Boston women ate two or more fish meals per week; about 5 percent of US women eat fish that often, according to CDC. The Boston research team classified a child as having high prenatal mercury exposure if his mother's hair mercury value was above the 90th percentile, which was 1.2 ppm in the study population. The 90th percentile hair NHANES mercury level is 1.1 ppm. Oken et al. did not measure blood mercury, but NHANES regional data show that the 90th percentile blood mercury level for women in New England is 5.2 µg/l.⁵ The New York study measured blood mercury, but not fish consumption. The geometric mean blood mercury level in the

women included in the study was 0.91 µg/l, while the geometric mean for the national NHANES sample was 0.92 µg/l.

Further research is needed to better document the complex relationships between fish intake during pregnancy and cognitive development. But the available evidence strongly suggests that methylmercury exposure can have adverse effects even at doses associated with just one or two fish meals per week. There is no evidence of a threshold for this toxic effect. Since women are advised to consume fish while pregnant, for the nutritional benefits, it seems vitally important that advice also be provided that helps women identify and buy low-mercury fish, so they (and their babies) can simultaneously enjoy the nutritional benefits and minimize their exposure to methylmercury.

- ¹ Budtz-Jorgensen, E., Grandjean, P., Weihe, P., 2007b. Separation of risks and benefits from fish consumption. *Environ. Health Perspect.* 115, 323-327.
- ² Davidson, P.W., Strain, J.J., Myers, G.J., Thurston, S.W., Bonham, M.P., Shamlaye, C.F., et al., 2008. Neurodevelopmental effects of maternal nutritional status and exposure to methylmercury from eating fish during pregnancy. *Neurotoxicol.* 29, 767-775.
- ³ Oken, E., Wright, R.O., Kleinman, K.P., Bellinger, D., Amarasiriwardena, C.J., Hu, H., et al., 2005. Maternal fish consumption, hair mercury, and infant cognition in a U.S. cohort. *Environ. Health Perspect.* 113, 1376-1380. Also, Oken, E., Radesky, J.S., Wright, R.O., Bellinger, D.C., Amarasiriwardena, C.J., Kleinman, K.P., et al., 2008. Maternal fish intake during pregnancy, blood mercury levels, and child cognition at age 3 years in a US cohort. *Am. J. Epidemiol.* 167, 1171-1181.
- ⁴ Lederman, S.A., Jones, R.L., Caldwell, K.L., Rauh, V., Sheets, S.E., Tang, D., et al., 2008. Relation between cord blood mercury levels and early childhood development in a World Trade Center cohort. *Environ. Health Perspect.* 116, 1085-1091.
- ⁵ Mahaffey, K.R., Clickner, R.P., Jeffries, R.A., 2009. Adult women's blood mercury concentrations vary regionally in the United States: Association with patterns of fish consumption (NHANES 1999-2004). *Environ. Health Perspect.* 117, 47-53; doi:10.1289/ehp.11674 [Online 25 August 2008].

FISH ADVISORY

Women Under Age 45 and Children

Seafood contains important nutrients, including Omega-3 fatty acids, but also contains mercury, which can be harmful to women and children.

DO NOT EAT
Swordfish - Shark - Tilefish - King Mackerel

Limit albacore tuna to one, 6-ounce serving a week, and eat no other fish that week.
Light canned tuna, however, may be eaten twice a week.

High (avoid)	Moderate (limit to one, 6-oz serving/week)*	Lower (12-ounces or 2 servings per week) (listed from lowest to highest levels)		
Fresh/Frozen Tuna and Sushi Tuna Spanish Mackerel Chilean Sea Bass Grouper Marlin Orange Roughy	Snapper Skate Freshwater Perch Monkfish Halibut Sablefish Sea Trout Sea Bass Bluefish American Lobster	Shrimp Sardines Tilapia Clams, Oysters, Scallops, Mussels Salmon Crayfish Freshw. Trout Ocean Perch/Mullet	Pollock Atl. Mackerel Anchovy/Herring Sole, Flounder Crab Pike Butterfish Catfish Squid	Atlantic Croaker Whitefish Pac. Mackerel/Chub Smelt Cod Canned Light Tuna Spiny Lobster

(1) * Women under age 45 and children who eat fish from the yellow category should eat no other fish that week.

(2) Fish are listed from lowest to highest mercury levels.

(3) For more information see www.epa.gov/mercury or www.fda.gov.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 006
Issue: 2010 II-035**

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

All information above the line is for conference use only.

Title:

Limiting Committee Member Numbers

Issue you would like the Conference to consider:

Reconsider direction that an unlimited number of members should be included on committees. This is not addressed in the Constitution and Bylaws or the Conference Procedures Manual under the Council Committees. Some committees specify representation from respective groups of regulatory, industry, academia or stakeholders. Committees having over 20 plus individuals find it difficult to achieve quorum, schedule mutually agreeable times for conference calls, and ensure that all present on conference calls had time to voice their opinions. A maximum limit of members should be established to facilitate consistent participation and progress on complex topic(s) that are given to committees to address.

Public Health Significance:

No public health significance is noted.

Recommended Solution: The Conference recommends...:

the Constitution and Bylaws Committee develop guidelines regarding committee structure, 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.

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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
2010 Issue Form**

**Internal Number: 007
Issue: 2010 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 - 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 seeks the Conference's acknowledgement of its Work Group Report.

Public Health Significance:

The Certification of Food Safety Regulation Professionals Work Group report submitted with this Issue as Attachment A provides a summary of the actions taken to address each of the following Conference charges:

- Review the 2006-2007 Assessment of Training Needs Pilot Project Report that resulted in the development of the current *CFP Field Training Manual* and Forms.
 - Work Group review and deliberations will assess whether additional revisions/updates are needed to the *CFP Field Training Manual* and forms. (See Charge #1 in Work Group report)
- Determine if an evaluation tool that mirrors the CFP Field Training process should be developed.
 - If such an evaluation tool is necessary, should it be incorporated into Standard #2 or left as a stand alone tool available from FDA's web site. For this initiative, the Work Group is charged to work in collaboration with FDA's Division of Human Resources Development. (See Charge #2 in Work Group report)
 - o Re-examine Step 4 of the current Program Standard 2 language as it relates to "standardization". Current language has raised some confusion among jurisdictions enrolled in the Standards as to what constitutes an acceptable standardization process. The Work Group will determine if the written criteria in Step 4 should be revised for clarification and, if so, submit a recommendation to the 2010 Biennial Meeting. (See Charge #3 in Work Group report)
- Review the criteria for *Standard 2 - Trained Regulatory Staff, FDA Draft Voluntary National Retail Food Regulatory Program Standards* to ensure it reflects the most up-to-date approach for training and standardizing Food Safety Inspection Officers (FSIOs) newly hired or assigned to regulatory retail food protection programs.

- Re-examine Program Standard #2 time lines established for new hires to attain the specific milestones for pre-requisite curriculum, completion of field training, through standardization (Steps 1 - 4 in Standard #2). (See Charge #4 in Work Group report)
- Charge transferred in 2008 from Council 3 - Assess the feasibility of incorporating an Allergen Management Course as part of the Standard 2 "Pre-Requisite Curriculum" and provide a recommendation to the 2010 Biennial Meeting. (See Charge #5 in Work Group report)
- Determine if there is a need to include the requirement of 25 joint field training inspections as a specific criterion within Step 2, Standard 2. (See Charge #6 in Work Group report)
- Assess the strengths/challenges associated with incorporating into Program Standard #2 curriculum requirements, courses related to Food Defense including National Incident Management Systems (NIMS) and Incident Command Systems (ICS) and provide a recommendation to the 2010 Biennial Meeting. (See Charge #7 in Work Group report)

In addition to this Issue requesting acknowledgement of the report, the CFP CFSRP Work Group has submitted 4 separate issues with recommended actions for the Conference to consider. A final issue with the recommendation for continuation of the CFP CFSRP Work Group and suggested 'charges' has also been submitted as a separate issue.

Recommended Solution: The Conference recommends...:

acknowledgement of the Conference for Food Protection, Certification of Food Safety Regulation Professionals - Work Group Report included as Attachment A with this Issue. The Conference further recommends that an expression of thanks be extended to all the CFSRP Work Group members who diligently dedicated their time over the past two years.

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Attachments:

- "Certification of Food Safety Regulation Professionals Work Group Report"

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

2010 Conference for Food Protection

Certification of Food Safety Regulation Professionals Work Group Report

Prepared and Submitted By the Work Group's Co-Chairs

John Marcello

Susan Kendrick

BACKGROUND

The Conference for Food Protection (CFP) has progressed through multiple stages in the development of a nationally recognized process for training and standardizing regulatory Food Safety Inspection Officers (FSIO) responsible for institutional foodservice, restaurant, and retail food safety inspections. The 2008-2010 CFP Certification of Food Safety Regulations Professionals (CFSRP) Work Group deliberations focused on:

- Obtaining feedback from jurisdictions using the CFP Field Training Manual and forms on their experiences with training newly hired or staff newly assigned to the regulatory retail food protection programs. The feedback from these jurisdictions was used to assess the need to enhance or revise the process and/or forms.
- Reviewing specific criteria in Standard 2, Trained Regulatory Staff, *FDA Program Standard (2009)*, that may be in need of clarification or revision.
- Assessing the need to include an audit process and tool that mirrors the CFP Field Training process as part of the *FDA Program Standards*.

A list of the members of the CFP Certification of Food Safety Regulations Professionals Work Group is included as Addendum A.

SUMMARY OF THE CONFERENCE CHARGES

The following tables provide a list of the Conference charges to the 2008-2010 CFP CFSRP Work Group. Following these tables, a short summary of the actions taken by the Work Group to address each of these charges is provided.

1. **Continue to review the results of the 2006-2007 Assessment of Training Needs Pilot Project that resulted in the development of the current *CFP Field Training Manual* and Forms. Consideration will be given as to whether additional revisions/updates are needed to the *CFP Field Training Manual* and Forms.**

2. Determine if an evaluation tool that mirrors the CFP Field Training process should be developed, and if so, should it be incorporated into Standard #2 or left as a stand alone tool available for FDA’s web site. For this initiative, the Work Group is charged to work in collaboration with FDA’s Division of Human Resources Development.

3. Re-examine Step 4 of the current Program Standard 2 language as it relates to “standardization”. Current language has raised some confusion among jurisdictions enrolled in the Standards as to what constitutes an acceptable process.

4. Re-examine the Program Standard 2 time lines established for new hires to attain the specific milestones for pre-requisite curriculum, completion of field training, through standardization.

5. Assess the feasibility of incorporating an Allergen Management Course as part of the Standard 2 “Pre-Requisite Curriculum”.

6. Re-examine the need to include the requirement of 25 joint field training inspections as a specific criteria within Step 2, Standard 2.

7. Assess the strengths/challenges associated with incorporating into the Program Standard 2 curriculum requirements, courses related to Food Defense including National Incident Management Systems (NIMS) and Incident Command Systems (ICS).

CFSRP WORK GROUP RESPONSE TO EACH CHARGE

RESPONSE – WORK GROUP CHARGE #1

1. Continue to review the results of the 2006-2007 Assessment of Training Needs Pilot Project that resulted in the development of the current CFP *Field Training Manual* and Forms. Consideration will be given as to whether additional revisions/updates are needed to the CFP *Field Training Manual* and Forms.

Follow-up interviews were conducted with Twenty-two (22) of the Twenty-nine (29) state/local/tribal jurisdictions that participated in the 2007 Assessment of Training Needs (ATN) pilot project. The interview tool developed by the Work Group as well as a summary of the responses from jurisdictions is included as Addendum B.

Jurisdictions using the CFP Field Training process and forms have indicated an overwhelmingly favorable experience. **The CFP CFSRP Work Group is not submitting any recommendations to the 2010 Conference for revisions to the CFP Field Training Manual or forms.** However, five areas of focus have been identified that the future Work Group should continue to review and update if necessary:

- In collaboration with FDA's Division of Human Resource Development, continue to review and revise, as needed, the Standard 2 classroom curriculum.
- Obtain feedback from state/local/tribal jurisdictions on the Standard 2 time frame for new hires or staff newly assigned the regulatory retail food protection program to complete Steps 1 through 4.
- Assess opportunities for enhancing the electronic versions of the CFP Field Training Manual and forms to minimize paperwork.
- Determine if the CFP Field Training Manual and forms have completely addressed all recommendations received as part of the 2007 ATN pilot project.
- Evaluate whether a performance audit should be included as part of the FDA Program Standards or made available via another mechanism.

The follow-up interviews did indicate the need for the Conference to enhance efforts to promote awareness of the *CFP Field Training Manual* and forms. The CFP CFSRP Work Group is recommending to the Conference that a new 2010-2012 charge be addressed to evaluate and determine the best approaches to promoting awareness and implementation of this national training model including use of websites, list serves, newsletters, testimonials, presentations, and training workshops, etc.

The responses obtain from the follow-up interviews with the ATN pilot jurisdictions served as an important resource for addressing several Conference charges related to the criteria in Standard 2 – Trained Regulatory Staff, *FDA Program Standards (2009)*.

RESPONSE – WORK GROUP CHARGE #2

2. Determine if an evaluation tool that mirrors the CFP Field Training process should be developed, and if so, should it be incorporated into Standard #2 or left as a stand alone tool available for FDA’s web site. For this initiative, the Work Group is charged to work in collaboration with FDA’s Division of Human Resources Development

Three points were identified as the primary steps needed to respond to the Work Group charge referenced above. These points are as follows:

- Is an audit tool needed?
- How would the audit tool be administered?
- Where would such an audit tool be housed (in Standard. 2, somewhere else in the Program Standards, or as a stand alone web document)?

Additional concerns were raised relative to the potential use of an FDA audit tool. Concerns included potential duplication between the FDA *Retail Food Level I Performance Audit* and its corresponding worksheet and the CFP *Field Training Manual* process; how the FDA *Audit* will fit with FDA *Standardization Procedures*; and, whether inclusion of an audit process into the CFP *Field Training Manual* would shift the focus from training assessment to performance competency and whether that would encompass disciplinary issues.

Results from the follow-up interviews with ATN pilot jurisdictions indicated support for the development of an audit tool that mirrored the CFP Field Training process. **The CFP CFSRP Work Group determined that there should be an audit tool available that mirrors the performance elements and competencies listed in the CFP Field Training Plan included as part of Appendix B-2, Standard 2, FDA Program Standards (2009).**

Subsequent Work Group deliberations addressed the feasibility of how such an audit tool would be administered and where it should be housed (whether in Standard 2, somewhere else in the Program Standards, or as a stand alone web document). The Work Group reached consensus that the audit process, whether included as part of Standard 2 or provided as a stand alone process, should be fully compatible with the *CFP Field Training Manual*.

The Work Group focused their review on four existing documents that contained guidance for, or related to, conducting training audits:

- *FDA Program Standards (2009)*, particularly Standard 4 – Uniform Inspection Program;

- The performance elements and competencies contained in the *CFP Field Training Manual*, Appendix B-2, Standard 2 – Trained Regulatory Staff, *FDA Program Standards (2009)*;
- *FDA Procedures for Standardization* (also referenced in Standard 2 – Trained Regulatory Staff); and
- *FDA Retail Food Level I Performance Audit* draft documents.

While there are distinct similarities between several of the reviewed programs, including a focus on inspection performance, quality and uniformity, there were significant concerns expressed relative to the relationship of the *FDA Retail Food Level I Performance Audit* tool to *Program Standard 2* as originally proposed by FDA in Issue 2008 II-052. If the *FDA Performance Audit* component is incorporated into *Standard 2*, along with the *CFP Field Training Manual* and *Standardization Procedures*, there will be three different yet similar types of verification tools within a single *Program Standard*.

The instructions and worksheets provided in the *CFP Field Training Manual* constitute a training process, ***not*** a certification or audit process. The *CFP Field Training Manual* is designed specifically for the newly hired or newly transferred FSIO and completion of that process represents program competency to initiate independent inspections. A “performance audit” is ***not*** a training function. It is designed to evaluate whether or not a candidate can successfully and repeatedly apply their knowledge and skills to the inspection environment in a manner that conforms to program requirements. “Standardization” is designed and intended for evaluation of FSIOs with a longer tenure as a field inspector with more varied experience conducting independent inspections and who will serve as training officers for other program inspection staff.

In order to eliminate potential program redundancies, the CFP CFSRP Work Group is recommending a new 2010-2012 charge to collaborate with FDA on clarifying whether “Standardization” is more appropriately housed within “Standard 2” as a training function, or whether it should be reorganized somewhere else within the *Standards*. The CFP CFSRP would explore with FDA the feasibility of either combining the “Performance Audit” functions with that of “Standardization”, or streamlining the duality of the processes to remove redundant or duplicative activities.

At this time, the program component with the greatest degree of compatibility for administration of the *FDA Retail Food Level I Performance Audit* is the *FDA Program Standards*, Standard 4 – Uniform Inspection Program. Use of the FDA “Performance Audit” as an application tool for the implementation of Standard 4 is relevant to the evaluation of a jurisdiction’s ongoing “quality assurance program.” Concurrently, the ten elements of competency derived from the *CFP Field Training Manual* and used for the “Performance Audit” criteria are well-suited to assess an FSIO’s knowledge, skills and abilities as related to inspection procedures. If accepted by FDA, modifications to the existing draft documents

for the *FDA Retail Food Level I Performance A* will be needed to incorporate the recommendations provided by the CFP CFSRP Work Group.

The CFP CSRP Work Group is recommending that a new 2010-2012 charge include conducting a pilot project 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. The proposed pilot project objectives and time line are included as Addendum C.

RESPONSE – WORK GROUP CHARGE #3

3. Re-examine Step 4 of the current Program Standard 2 language as it relates to “standardization”. Current language has raised some confusion among jurisdictions enrolled in the Standards as to what constitutes an acceptable process.

In 2006, the Conference unanimously approved a recommendation from the CFP CFSRP Work Group to revise the minimum number of inspections a FSIO must successfully complete as part of their Food Code standardization process. The minimum number of standardization inspections in Step 4, Standard 2, was reduced from 8 to 4 for FSIOs who would ***not*** be expected to serve as “Training Standards” responsible for standardizing other FSIOs. The standardization process must be similar to the “FDA Standardization Procedures” and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contributed to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP Principles;
4. Inspection equipment; and
5. Communication.

The FDA standardization procedures are based on a minimum of 8 inspections and include performance areas related to the development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP Plan. FDA standardizations are conducted with regulatory retail food protection personnel who would be ***expected to serve*** as “Training Standards” responsible for standardizing other FSIOs.

Jurisdictions participating in the *FDA Program Standards* have indicated that the Standard 2 criteria does not clearly address the differences in the standardization process needed to be a “Training Standard” versus standardization of FSIOs who will ***not*** conduct standardizations with other FSIOs.

The CFP CFSRP Work Group has submitted an Issue recommending that the definitions of “Trainer” and “Training Standard” contained in the *FDA Program Standards (2009)* be revised to clearly identify the requirements for each of these roles. In addition, the Work Group recommends that Step 4, Standard 2, be revised to include a reference to the requirements for conducting field standardizations of FSIOs as presented in the Work Group’s proposed “Training Standard” definition.

RESPONSE – WORK GROUP CHARGE #4

4. Re-examine the Standard 2 time line established for new hires to attain the specific milestones for pre-requisite curriculum, completion of field training, through standardization.

The Standard 2 – Trained Regulatory Staff criteria includes a time frame of 18 months for new hires or staff newly assigned to the regulatory retail food protection program to complete Steps 1-4.

Step 1 – Pre-requisite curriculum courses (prior to conducting independent inspections);

Step 2 – A minimum of 25 joint field training inspections with the jurisdiction’s trainer and completion of a field training process similar to that presented in the *CFP Field Training Manual*;

Step 3 – A minimum of 25 independent inspections; and

Step 4 – A standardization process, based on a minimum of 4 inspections that is similar to the *FDA Standardization Procedures*.

The CFP CFSRP Work Group recommends that **no change** be made to the **18 month time frame**. This consensus decision was based on internal Work Group deliberations and response from the follow-up interviews conducted with the ATN pilot project jurisdictions. The responses from the follow-up interviews were varied with 13 of the 22 respondents indicating that the 18 month time frame was appropriate.

RESPONSE – WORK GROUP CHARGE #5

5. Assess the feasibility of incorporating an Allergen Management Course as part of the Standard 2 “Pre-Requisite Curriculum”.

At the 2008 Biennial Meeting, the Voting Assembly of Delegates unanimously approved the Council III recommendation contained in Issue 2008 III-007, *Food Allergy Information for state/local regulatory officials*:

The CFP CFSRP Work Group has submitted an Issue recommending that a letter be sent to the FDA that food allergen resource information be included as part of the recommended curriculum in the FDA Voluntary National Retail Food Regulatory Program Standards, Standard #2, Trained Regulatory Staff and that a compendium of educational materials be made available to state/local/tribal regulators.

The Conference further recommends that the re-created Food Allergen Committee work with the FDA to develop an appropriate educational component regarding food allergen awareness.

The responses from the ATN pilot project jurisdictions indicated overwhelming support for inclusion of an Allergen Management Course as part of the Standard 2 – Trained Regulatory Staff curriculum.

Appendix B-1, Standard 2, contains a listing of the training curriculum expected to be completed by new hires or staff newly assigned to the regulatory retail food protection program. To be included in this listing, the subject matter must be in the form of a course with learning objectives. FDA's Division of Human Resource Development has developed several of the core elements for an Allergen Management Course. FDA's Center for Food Safety and Applied Nutrition is currently working on an Allergen Management guidance document. This document will include specific recommendations for the retail food industry. FDA is planning on collaborating with the CFP Food Allergen Committee to obtain feedback on the information contained in the Allergen Management guidance document. Once the document is finalized, FDA will incorporate specific allergen management guidance for foodservice and retail food operations into the Allergen Management course.

The CFP CFSRP Work Group has submitted a 2010 Issue recommending that the FDA Allergen Management Course be incorporated as part of the Standard 2 post curriculum upon its completion and review by the CFP Food Allergen Committee.

RESPONSE – WORK GROUP CHARGE #6

6. Re-examine the need to include the requirement of 25 joint field training inspections as a specific criteria within Step 2, Standard 2.

Feedback from the jurisdictions that participated in the 2007 ATN pilot project, administered through the Conference, indicated a wide variation in opinion as to the appropriate number of joint field training inspections needed to prepare new FSIOs for conducting independent inspections of foodservice and retail food facility types. A summary of the jurisdiction responses to appropriate number of joint field inspections is contained on pages 48 and 49 of the 2007 Assessment

of Training Needs Pilot Project Report which is available from the Conference for Food Protection web site: www.foodprotect.org

Sixty-five percent (65%) of the jurisdictions participating in the pilot project indicated that 25 joint field training inspections was the appropriate minimum number to include in Standard 2. Of the 10 that responded with a “no”, the number of joint field training inspections recommended ranged from 10 to 100, with an average of 75. From comments received from the pilot jurisdiction, the appropriate number of joint field training inspections is primarily based on an individual’s skill, capability and affinity for learning new tasks or accomplishment of certain skills. These learning characteristics will vary from one individual to another.

A recurring comment from ATN pilot project jurisdictions was that the number of joint field inspections was not the performance measure they used to determine a trainee’s readiness to conduct independent inspections. The ultimate performance measure is the trainee’s ability to successfully demonstrate all the competencies listed on the CFP Field Training Plan contained in Appendix B-2, Standard 2.

Many jurisdictions indicated that having a minimum of 25 joint field training inspections provided the jurisdiction’s trainer with expectations on time commitments/resources that should be devoted to the training process. It provides for a degree of quality assurance and expectation of the training process for both the candidate and trainer.

The CFP CFSRP Work Group is submitting an Issue recommending that the Conference retain the reference to the minimum of 25 joint field inspections in Step 2, Standard 2, but also include language that would allow a trainer to conduct a fewer number provided that the exception was supported by written documentation, such as completion of the CFP Field Training Plan included in Appendix B-2, Standard 2.

RESPONSE – WORK GROUP CHARGE #7

7. Assess the strengths/challenges associated with incorporating into the Standard 2 curriculum requirements, courses related to Food Defense including National Incident Management Systems (NIMS) and Incident Command Systems (ICS).

State/local/tribal regulatory retail food safety professionals are often the first responders to a food safety or food defense emergency. Frequently these incidents impact multiple jurisdictions and require an operational response and management to ensure maximum public health protection.

The Federal Emergency Management Agency (FEMA) offers a national model training curriculum for all public officials with emergency response and coordination responsibilities. FEMA's Emergency Management Institute provides many basic and advanced National Incident Management Systems and Incident Command Systems courses on-line for no cost. These courses which include final examinations and certificate of completions are available from the following web link: <http://training.fema.gov/IS/NIMS.asp>.

The CFP CFSRP Work Group has submitted an Issue recommending the inclusion of the following three FEMA courses as part of the “post curriculum” outlined on Appendix B-1, Standard 2.

IS-100.a, *Introduction to Incident Command System, ICS-100*

This course provides training and resources for personnel who require a basic understanding of the Incident Command System (ICS).

IS-200.a, *ICS for Single Resources and Initial Action Incidents, ICS-200*

This course provides training and resources for personnel who are likely to assume a supervisory position within the Incident Command System (ICS). The primary target audiences are response personnel at the supervisory level.

IS-700.a, *NIMS An Introduction, ICS 700*

This course provides training and resources for the National Incident Management System (NIMS). NIMS provide a consistent nationwide template to enable all government, private sector, and nongovernmental organizations to work together during domestic incidents.

2010-2012 Conference Charges for the Work Group

The Work Group issue titled, *Re-Create – Certification of Food Safety Regulation Professionals Work Group*, recommends that a new CFP CFSRP Work Group be re-created to address the following charges:

- 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.

- 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 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.

- 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.

- 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.
- Report back to the 2012 Biennial Meeting its findings regarding the above charges.

The last charge related to third party auditors presented above has been included as a new charge based on an increase in the number of independent third party auditors that have been contracted to conduct regulatory oversight inspections of institutional foodservice, restaurant, and retail food store facility types. Some areas of the country are beginning to disband the local regulatory retail food protection agency and contract the work to nongovernmental organizations. Currently, a national standard upon which to evaluate the

education and qualifications of independent third party auditors does not exist. Legislation has been introduced at the federal level that contains language that would recognize third party audits as a legitimate use of resources to enhance food safety. Since these issues are still not solidified at the time of submittal of the Work Group report to the 2010 Biennial Meeting, a closer look over the next two year cycle is in order.

**Summary of CFP CFSRP Work Group Issues
Submitted to the 2010 Conference**

(Work Group Issues are listed by titles. Conference assigned “Issue Numbers” were not available prior to submission.)

√ <u>Issue</u> Report – Certification of Food Safety Regulation Professionals Work Group <u>Attachment A</u> 2010 Conference for Food Protection Certification of Food Safety Regulation Professionals Work Group Report
√ <u>Issue</u> Emergency Management Course Additions to Appendix B-1, Standard 2
√ <u>Issue</u> Allergen Management Course Addition to Appendix B-1, Standard 2
√ <u>Issue</u> Clarifying Step 2, Standard 2 – Program Standards
√ <u>Issue</u> Clarifying Definitions for Step 4, Standard 2 – Program Standards
√ <u>Issue</u> Re-create – CFSRP Work Group <u>Attachment A</u> Performance Audit Tool Pilot Project Objectives and Time Line

CERTIFICATION OF FOOD SAFETY REGULATION PROFESSIONALS WORK GROUP

*(Part of the Conference for Food Protection (CFP)
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**CONFERENCE FOR FOOD PROTECTION (CFP)
MODEL FIELD TRAINING MANUAL AND PROGRAM FOR
REGULATORY RETAIL FOOD SAFETY INSPECTION OFFICERS (FSIO)
PILOT PROJECT JURISDICTION FOLLOW-UP FEEDBACK FORM**

(Please refer to the “CFP Field Training Manual” when responding to the following questions)

Name of Jurisdiction _____

Person Interviewed _____

Field Training Process Used:

CFP Field Training Manual **4** **or** **Assessment of Training Needs** **16**

Combination of Field Training Manual and ATN **2**

Comments on the Field Training Process:

- The municipal jurisdiction has not formally incorporated the use of the CFP Field Training Manual. All staff to date listed in Question #1 have been trained using the Assessment of Training Needs process and forms. The municipality’s training officer has reviewed the CFP Field Training Manual and prefers its design and format. The municipality plans to use the CFP Field Training process for when new hires begin training in the future.
- The State Department of Agriculture has developed a Training Plan that covers performance elements and competencies related to both retail food and manufactured foods. They are enrolled in both the FDA Manufactured Food and Retail Food Regulatory Program Standards. They also incorporate a Field Training Worksheet used to provide the new hire feedback. The worksheet is completed after every 5 inspections. The Field Training Worksheet basically follows the same format as the one provided in the CFP Field Training Manual. The training plan, however, is more aligned with the Assessment of Training Needs format. The State Department of Agriculture has a one year probationary period for new hires to determine whether or not the candidate is appropriate for state service. The Training Plan (ATN) process is used as documentation that a new hire has successfully completed all the performance elements and integrated into the agency’s probationary assessment.
- The county health department continues to use the Assessment of Training Needs because the tool met their training program needs. They have only made minor additions to the original tool. While aware of the revised version (CFP Field Training Manual), the need to move from the ATN process and forms has not been viewed as a priority. The county health agency is looking at the CFP Field Training Manual to assess whether it might better fit their training needs.
- The ATN was used by the county health department up to the point of the CFP Field Training Manual being released. No new employees have been hired since the Field

Training Manual was released. All training materials have been updated to replace the ATN and use the Field Training Manual. The county health department has computerized their inspection program and is in the process of developing a software package to support their training process. This software program will incorporate the use of all the forms contained in the CFP Field Training Manual. The county’s training officer indicated that once this project is complete, he would share the results with the CFP Work Group. Based on what is developed, CFP may consider looking into making such a software program available to other jurisdictions

- As one of the jurisdictions that participated in the ATN pilot project, city-county health department received a copy of the CFP Field Training Manual after it was approved at the 2008 Conference. The food program manager indicated the changes incorporated into the CFP Field Training Manual clarified with new hires that the framework was a training process not an evaluation process. The new forms provide useful tools in tracking how a new hire is progressing through the training process.
- The county health department continued use of the ATN tool instead of the CFP Field Training Manual appears to be the result of miscommunication within the agency. The training officer was aware that the Conference had revised the ATN process/forms and that the CFP Field Training document was available for use. He thought he had been using the updated version but came to realize during the interview that he had not as yet integrated the new CFP Field Training manual into County’s training program.
- The county health department has not hired any new staff since the release of the CFP Field Training Manual. When the next new hire comes on board they will use the CFP Field Training Manual and forms rather than the ATN material. The county thought the CFP Field Training Manual and forms provided a solid, targeted, FSIO training framework

1. How many FSIOS has the interviewee’s Jurisdiction trained using the field training process identified above? 162

2. Does the interviewee believe the FSIOs who have successfully completed the training program prescribed in the Model Field Training Manual or Assessment of Training Needs are properly prepared to conduct independent retail food and/or foodservice inspections at the conclusion of the training program?

Yes 19 **No 2** **Maybe 1**

If the interviewee said no, ask them to elaborate on what area(s) the FSIO is not properly prepared in to enable them to conduct independent inspections.

Comments Related to “No” Responses

Because we have only been able to do 8 inspections at the most. Independent inspections were not reviewed, lack of follow through on part of supervisors and trainers due to time constraints, priorities not well communicated and staff turnover/absences.

- Training on process HACCP approach to conduct risk-based inspections is not clearly identified in the training curriculum. This course is currently a classroom FDA ORA-U offering, not an online course.
- Public health risk communication is not well addressed by the online communications course.
- Complaint investigation training, especially foodborne illness investigation, requires a specific approach.

Maybe

They do initial training on HACCP, FBI investigations, specialized processing, etc. before having the trainee do the ORAU courses. They also focus more on Risk Based Inspections during the training process.

3. Does the interviewee believe the Glossary of Terms in the Manual was sufficient to understand and implement the training process in your jurisdiction? IF THE JURISDICTION YOU ARE SURVEYING USED THE ASSESSMENT OF TRAINING NEEDS INSTEAD OF THE CFP MODEL FIELD TRAINING MANUAL, SKIP TO QUESTION 4

- Yes **12** No **No Response 10**

If the interviewee said no, please specify what terms in the glossary he/she thought needed improvement or what terms they would like to see added to the glossary.

No additional terms were recommended

4. Did the jurisdiction’s FSIOs experience any problems with the Pre-Requisite Curriculum portion of the Program?

- Yes **5** No **17**

If the respondent said yes, ask them to specify what problem(s) were encountered. Please specify if the problems were related to the FDA ORA U Web-based training or the equivalent coursework.

Comments Related to “Yes” Responses

- Shockwave was required and had to be downloaded by IT to all computers (employees are not permitted to download ANY software).
- Getting signed in and finding the correct classes was a little difficult.
- Since they do training of staff prior to the ORA U curriculum it would be hard to answer this question. The health department is hiring inspectors without Bachelor’s degrees, much less environmental health degrees, so the trainees need additional training up front.

- Web-based training was helpful and covered basic principles of environmental health, but it was very time-consuming.
- ORA U courses were labor intensive because MFRPS courses were also added onto our curriculum. The criteria for completing these courses in the FDA specified time period did not correlate with our jurisdiction's "probationary" time period of one year. Our jurisdiction needs to complete the pre-training before the one year period, thus the liberal time frame FDA wants the courses completed puts our jurisdiction at a disadvantage because we must complete training (including standardization of each FSIO) within the first year of hire.
- A jurisdiction that has a set probationary period and must comply with basic course requirements during that probationary period may be a problem. I realize that having more time than the jurisdiction requires would in and of itself be a good thing. However, when there is nothing addressing this possibility an auditor (in our case a joint administrative procedures committee that works for the legislature) may have issues with what constitutes before you go out in the field and what you can do afterwards.
- Out of the four staff, only one has completed the FDA ORA U Web-based training. The rest have been given a deadline, July 2009 to complete all the training courses. The problem has not been the training material, but not making it a priority by the Environmental Health professional. Two of them have been in the field for at least 20 years, and they feel they have all the training they need; however, the problem has been addressed, and they should be finished with the online training by July.
- We did not have the 2 persons do all of the prerequisites before starting. We find it difficult to accomplish this, but so far we have had people with strong public health experience. A brand new person with no experience I think we would do it this way.
- We did not experience any problems using ORAU. Our new hires found the ORAU courses to be a review of concepts taught in their college courses.
- The communications course was not available (and I am still not finding it on ORAU) and this was confusing since it appears on the list of pre-requisite courses.
- Time wise it has been difficult to fit in all of the courses during our initial training period. We typically had inspectors ready to do independent inspections within 6 weeks of the hire date but sometimes it took 3-6 months for employees to complete the online courses due to the workload issue or computer/connection issues. Now the courses seem to be running smoothly compared to the past so the computer issues are no longer posing a problem. The workload issue is something we need to work on from a scheduling standpoint. Our trainees are often on travel status during training and it has been difficult to leave enough time during the training period for course completion.
- It would be a very helpful training tool to have the food code modules available or if they are now available I haven't been able to find them on ORAU.
- The number one problem that we have had is staff getting access to ORA-U once they are enrolled. That is an internal problem with our IT programs and we think we have it solved. The second problem is convincing new hires that they have to complete the coursework, because most of our newly hired staff has many years of experience in food safety. Again, this is an internal problem, and not a problem with the training itself.
- No problems were experienced related to the FDA ORA U web site, but using IE alternative web browsers (such as Mozilla Firefox) resulted in some functional problems. The problems were corrected by allowing pop-ups, and view this page in IE.

5. Does the interviewee believe the information provided in the Assessment of Training Needs or Section III of the Manual adequately describe the approach that is being recommended for identifying the training content, determining training needs, and tracking a FSIOs progress in demonstrating competencies specific to their job responsibilities?

Yes **22** No **0**

If the interviewee said no, identify those portions of the Assessment of Training Needs or CFP Field Training Manual that need improvement in the space below. Ask the interviewee to provide specific recommendation(s) for improving the content of the section of the ATN or Field Training Manual in the space provided below.

Additional Comments

- I really like how the CFP Field Training Manual is set up in this section for allowing flexibility.
- When the municipality did the pilot program they made some modifications in the program, which they have continued to use. So for the municipality, ORA U only supports the training, but most of the training is done as “one-on-one” classroom based training.
- The training officer liked the organization of the section.
- On page 7, include the definition of JFT in the table if this has not already been added.

6. The CFP Training Plan and Log or the Assessment of Training Needs are divided into six (6) inspection training areas and 23 “performance elements”. Does the interviewee believe these training areas and performance elements sufficiently address the knowledge and skills a FSIO needs to effectively conduct independent inspections of retail food and foodservice establishments?

Yes **18** No **3** In general **1**

If the interviewee said no, ask them to specify what improvements they believe should be made to the training areas or performance elements. This may include areas and elements they believe should be added or deleted.

Comments Related to “No” Responses

- Would like to see more focus on reviewing systems approach
 - Determining compliance with responsibilities of the person in charge (Food Code 2-103.??)
 - What are company policies→ example of policies for training employees on handwashing, how do they verify employees are following procedures?
Handwashing policy, handwashing training, handwashing verification.
- The program should add:

- State training
- FBI training
- HACCP
- Food Code training
- The ATN Field Training worksheet lists multiple items addressing aseptic sampling. These items should be deleted from the worksheet and offered in an addendum as optional performance elements. The focus on aseptic sampling (food and water) is too great for our food program.
- Elements of standardization should be included as part of a performance element. Our jurisdiction recently added a pre-standardization performance area to our check sheet which includes all HACCP exercises that the FSIO is required to complete for standardization. We found that after completing the training, these exercises were not included as part of training and the FSIO was not ready for the final evaluation of standardization. We also designed a performance element for all the training courses that were required throughout training. Each course was listed under the performance area and the tracking was beneficial to the evaluators.
- At the beginning of the pilot, the county added some optional items, like review file for repeated violation items, verify compliance with 410 IAC 7-22, review of HIPPA law, document repeat violations from previous inspection, refer report for enforcement action, complete a Risk Control Plan, Flow Chart. I believe some were incorporated into the final
- ATN form and some are jurisdiction-specific. All are addressed.
- We added specific computer-based inspection training: demonstrates ability to open a new establishment/inspection file, how to properly document risk factors, discussion with operators/employees; demonstrates ability to close an establishment file if needed.
- The State Department of Agriculture has identified a potential gap in the performance elements competencies contained in the CFP Field Training Plan and Worksheets. By the time the FSIO is scheduled to be standardized, all the performance elements and competencies related to the standardization process should have been addressed in the agency's training program. The State agency discovered that as their new hires proceeded through the process they had not been exposed to the competencies needed to complete the following exercises that are included as part of the FDA Standardization process:
 - Development of a Risk Control Plan
 - Development of HACCP Flow Charts for each of the three process food flows
 - Verification of a HACCP Plan

The State agency encourages the CFP Work Group to consider adding these areas as specific competencies in the existing field training plan/forms OR develop a specific performance element that address pre-standardization training that lists the above items as need competencies.

- The inspection training areas and performance elements sufficiently address the knowledge and skills a FSIO needs to effectively conduct independent inspections of retail foodservice establishments. One of the strengths of the Field Training Manual is the flexibility/customization that can be done and to meet the unique and specific needs of a program but providing a well defined structure for the basic knowledge and skills and FSIO needs.

- The county agency has included additional performance elements not included on the current CFP Field Training Worksheet based on their program needs. Additional performance elements include the FSIOs ability to use their computer based inspection system and training is provided to ensure a FSIO follows all the county’s procedures for determining if an establishment is in compliance with their smoke free environment ordinance. In addition, they included as a performance element area a FSIO’s ability to conduct a menu based review to determine food safety priorities during the inspection.

7. Has the interviewee experienced any problems when implementing the following steps that are integral to the field training process described in the Assessment of Training or Section IV of the Model Training Plan?

STEP 1 – Determine Performance Elements to be Included in Your Training Plan

STEP 2 – Determine Competencies for Each Selected Performance Element

STEP 3 – Determine Need for Additional Performance Elements and Competencies

STEP 4 – Determine Appropriate Training Method for Each Competency

Yes 2 **No 19** **No Response 1**

If the interviewee said yes, ask them to identify the step(s) that has/have caused a problem and describe the problem(s) they have encountered.

Comments Related to “Yes” Responses

- Our program has not been able to get organized on this process and has not been consistent in its use.
- The only real problem we have had has been that we have had to use multiple people to conduct the training and evaluations. I would prefer to have a single training officer do this, but this is not possible with our current structure.
- Not all of these elements have been incorporated in a formal manner into our training plan.

8. Based on your experience using the CFP Field Training Manual or the Assessment of Training Needs process, do you believe the 18 month timeline provided in the FDA Voluntary National Retail Food Regulatory Program Standard No. 2 - Trained Regulatory Staff for completing steps 1 through 4 in the training process is the proper amount of time?

Yes 13 **No 9**

If you said no, how many months do you believe are appropriate for completing steps 1 through 4 in the training process? _____

STEP 1 – Completion of curriculum courses designated as “Pre” in Appendix B-1 prior to conducting any independent routine inspections



STEP 2 – Completion of a minimum of 25 joint field training inspections,
AND
successful completion of the jurisdiction’s FSIO Field Training similar to the process outlined in Appendix B-2.



STEP 3 – Completion of a minimum of 25 independent inspections
AND
remaining course curriculum (designated as “post” courses) outlined in Appendix B-1.

STEP 4 - Completion of a standardization process similar to the FDA standardization procedures.

- 36 months – Inadequate staffing to do both training and standardization. We have been unable to standardize any employees as of yet.
- 18-24 months
- 6 months - ORAU courses were labor intensive because MFRPS courses were also added onto our curriculum. The criteria for completing these courses in the FDA specified time period did not correlate with our jurisdiction’s “probationary” time period of one year. Our jurisdiction needs to complete the pre-training before the one year period, thus the liberal timeframe FDA wants the course completed puts our jurisdiction at a disadvantage because we must complete training (including standardization of each FSIO) within the first year of hire.
- A jurisdiction that has a set probationary period and must comply with basic course requirements during that probationary period may be a problem. I realize that having more time than the jurisdiction requires would in and of itself be a good thing. However, when there is nothing addressing this possibility an auditor (in our case a joint administrative procedures committee that works for the legislature) may have issues with what constitutes before you go out in the field and what you can do afterwards.
- 24 months
- 24 months
- This is a difficult question to answer. Completing 25 joint inspections, 25 independent inspections and then completing a standardization process doesn’t seem feasible in an 18 month time frame. However, when we used the ATN process, we completed fewer than 25 joint inspections before proceeding to independent inspections. In such a case (less than 25 joint inspections) the 18 month time frame seems more realistic. We have not yet initiated step four due to limited resources.

- 24-36 months – We have not been able to standardize people due to economic and time resources. We hired 8 people all at once and this has been a drain on the system but we have performed follow-up field inspections with these individuals to ensure they are on track.
- 36 months.
- 24 months.
- The municipality does not have a large staff. Staff assigned to the food program is, for the most part, “specialized” concentrating the bulk of their work time to the food program. The training officer indicated that they have not experience a problem with the 18 month time frame for completing Standard 2 Steps 1 through 4. They standardize staff using the FDA process of 8 inspections including the exercises. They have had a problem with staff completing the post curriculum course in a timely manner. The training officer attributed this problem to the agency’s lack of quality assurance oversight to ensure completion of the post curriculum courses. Staff has been concentrating on completing their required number of inspections and not viewing the completion of the coursework as an integral part of their work plan responsibilities.
- The State agency must complete all their training and standardizations within the first 12 months due to the probationary assessment that must be conducted of all their new hires. The shorten time frame places significant stress on their agency’s ability to fit in all the required training, especially since they are also enrolled in the Manufactured Food Regulatory Program Standards that contain additional coursework requirements.
- Though the county marked YES to this question indicating that an 18 month time frame was appropriate for a new hire to complete Steps 1 through 4, it is important to note that they do not include (Standardization – Step 4) as part of the training process. The county’s training program consists of Steps 1 through 3. The training officer did indicate, however, that she is familiar with the FDA Standardization process and if it were included as part of the training program she still thinks the 18 month time frame is appropriate for all 4 Steps described in Standard 2.
- 25 joint field training inspections provide a good baseline for new hires. Some require less, some more. The Standard needs to maintain a minimum number of joint inspections otherwise time pressure related to having new hires contribute productively too the program will compromise the training process. In addition trainers have work load pressures as well and may not allocate the appropriate amount of time (number of inspections) to really ensure that the new hire is effectively trained and proficient in all performance element areas.
- The food program manager indicated that the 18 month Standard 2 time frame was appropriate for completion of Steps 1 through 3 but more time is needed for new hires to complete Standardization (Step 4). The county’s staff isare, for the most part, Specialists not Generalists. Even with that said, the training officer encourages the Work Group to extend the time frame for completion of Steps 1 – 4 to 24 months. Staff needs some time in the field to assimilate the basic training prior to standardization. Generally the standardization process begins around 15-18 months into the new hire employment. Additional training, especially in risk based inspections, is needed to fully prepare the candidate for standardization.

9. The Assessment of Training Needs or Sections V and VI of the CFP Field Training Plan describe steps to follow when preparing for and conducting joint field training inspections. Has the interviewee experienced any problems when implementing these steps as part of their program?

Yes 5 **No 16** **No Response 1**

If the interviewee said yes, please have them identify which step(s) posed a problem for your jurisdiction and what they have done or what they believe should be done to correct this problem(s).

- It is a lot of paperwork to maintain. We would like to print all of the forms that will be filled out for the full process for each candidate (FSIO) into a comb binder. The FSIO will be responsible for making sure that the binder forms are filled out and maintained. A copy of this will be kept at the central office after completion.
- Initially (first 2-3 inspectors) we discovered that having more than one trainer was problematic. Once all joint inspections were done by the same standardizing officer the process has been much less confusing to the trainee.
- We created our own form based on the CFP Field Training Plan, condensed the format and limited the amount of times the form was required to be used. Evaluators fill out a joint inspection form only once, after they have completed at least 5 inspections in the session with that evaluator.
- On the first one we had to adopt it to the wholesale inspection, but it worked well.
- Our jurisdiction does not require new inspectors to become Registered Sanitarians or to have experience in food safety. We feel that 25 inspections were not enough for them to be trained and to start doing solo inspections. On average, it took around 40-45 inspections for them to obtain the information and to feel comfortable doing the inspections on their own.
- These areas have not been implemented into the State’s Agriculture training program.
- Although we have not been able to hire inspectors with processing or retail inspection experience, we found that we needed a classroom review session after the inspectors had been in the field because of the complexities of navigating the policies and procedures, laws and regulations, processing of paperwork and navigation of the computerized inspection program. We incorporated this classroom training into a modified version of the face-to-face Applications Course.

10. Do you believe the 25 joint inspections that are required in the CFP Field Training Manual or the Assessment of Training Needs process are too many, too few or just the right number?

 4 Too many; 2 Too few; 15 Just right number;
 1 None of these options

If you said too many or too few, how many joint inspections would you recommend that a FSIO be required to complete as part of the training process? _____

- 8
- 8-10
- 10 inspections, consistent with the standardization process, FDA
- 40-45
- New inspectors learn at different levels and have had different experience prior to hire. Staff that had some food regulatory experience prior to hire were ready to move into independent inspections before completing the 25 joint inspections. The trainer is in a better position to determine readiness to move into independent inspections rather than requiring a person ready to conduct independent inspections to continue to conduct joint inspections until 25 are completed.
- In our use of the ATN process, there was no predetermined number of joint inspections. The process was continued until a consistent, acceptable level of competency in all areas of the ATN had been demonstrated.
- During the interview, Dawn indicated that the Standard should not reference a specific number of joint inspections that needed to be completed. She said that the Standard should be reworded to reflect that a sufficient number of joint inspections should be conducted until such time as the Trainer determines that the Trainee can successfully perform all the competencies listed on the CFP Field Training Worksheet.
- We have made adjustments up or down depending on the trainee's level of experience coming in to the job.
- 50 or more should be required because it takes more than 25 inspections to see all types of facilities in a jurisdiction and also to allow enough time for an inspector to feel comfortable doing these inspections solo.
- The training officer echoes the comments submitted by many of the jurisdictions I have interviewed that 25 joint inspections was the right minimum number. There is an understanding conceptually that the reasoning behind removing a minimum number and focusing on the use of the Training Plan as the determiner as to how many joint inspections are needed. The number of inspections should be based on how many it takes to ensure that a new hire can perform all the competencies. The municipality could live with either approach but if they had to make a choice they support retaining the minimum number of 25 joint inspections. A specified number of inspections provide a degree of quality assurance and expectation to the training process for both the candidate and trainer.
- The State agency does many more joint field training inspections that the minimum 25 contained in the Standard 2 criteria. They recommend that the CFP Work Group retain the reference to a minimum of 25 joint field training inspections.
- Conceptually the county would not have an issue with removing a reference to a specified number of joint field training inspections in the Standard 2 criteria and simply stating that the new hire would have to successful demonstration the performance elements in the CFP Field Training Manual before conducting independent inspections. The training officer did indicate, however, that having a minimum baseline number of 25 would assist jurisdictions with expectations on time commitments/resources that should be devoted to

the training process. For the county 25 joint field training inspections was considered a minimum number and for most new hires many more joint inspections are conducted.

- Our experience is 25 joint inspections is the right number. We have had individuals who were ready prior to completing all 25, but it provides the opportunity for additional observations of the FSIO, as well as opportunities for the FSIO to observe special circumstances that may not be observed in a setting with fewer joint inspections.
- The training officer echoed the same concerns for not having a minimum number of joint field training inspections stipulated in Standard 2. He stated that this is a quality assurance issue. If a minimum number of inspections are not stipulated, pressure exists to get new hires into the field to conduct inspections. While the training officer agreed that conceptually it really isn't the number of joint training inspections that is the ultimate measurement rather it is the FSIO's ability to demonstrate the performance elements and competencies, he stated that the county would retain a minimum of 25 joint field training inspections as a requirement in their own program should this criteria be removed from the Standard.
- A new hire to the food program will generally be able to assimilate the technical aspects of food inspections (knowing the code; observing violations; filling out reports, etc.) within the current 18 month period of time. Thirty-six (36) months, however, are necessary for the new hire to become proficient in the inter-communication skills that are key to behavior changes related to active managerial control of foodborne illness risk factors. If the goal of the Standard and standardization is simply to assess Food Code application and knowledge then the 18 month time frame is appropriate. If, however, the goal of Standard 2 is to train FSIOs to facilitate behavior changes within the inspection framework, then inter-communication skills are an essential piece and require experience in the field to acquire. The Standardization process should begin sometime the beginning of a candidates third year, therefore, I would recommend that the Standard provide a 36 month period of time from hire to successful completion of standardization.
- Echoing the comments received from other jurisdictions I have interviewed, the county's training officer who thought that a minimum of 25 joint field training inspections was the appropriate number to include in the Standards. Conceptually the training officer understands the rationale for the Work Group's consideration of possibly removing any reference to a specific number of inspections and focusing on conducting a sufficient number to ensure the new hire can perform all the competencies contained in the agencies training plan. Keeping a minimum number within the Standard, however, provides a quality assurance check for an agency's training program. The training officer recommends that the CFP Work Group retain the reference to a minimum of 25 joint field training inspections.

11. Does the information presented in the Assessment of Training Needs or Section VII of the Model Training Plan provide the information the interviewee needs for their jurisdiction to develop an effective system to track a FSIO's training progress and accomplishments?

Yes **21**

No **1**

If the interviewee said no, ask them to identify the step(s) that has caused a problem and describe the problem(s) they have encountered.

- The logs are helpful, especially in the CFP Manual
- Using only the field training worksheet
- The ATN Field Training worksheet and separate documentation of successful completion do not provide an effective system to track an individual FSIO’s training needs and observed improvements as the FSIO progresses through training. A single document merging these two ATN components with entry of notes/comments is recommended.

12. Do you have an audit process or tool that you use as part of your training program to assure that a FSIO is properly trained before he/she is released into the field to conduct independent inspections?

Yes **14** No **8**

If you said no, do you think it would be beneficial to have an audit process or tool to use to assure that FSIOs are properly trained before they are allowed to conduct independent inspections?

- This tool – We don’t have an audit process separate from this.
- I say yes, but the tool is very informal
- The municipality standardizes their trainees to assure they are ready. (The training officer is FDA standardized)
- The training officer is not only the “trainer” but the “auditor” for the training.
- Yes, and it is in the developing stages. We hope we would have completed standard 2 of the FDA by the end of this fiscal year, including a verification tool.
- The audit process the food program manager used involved the review of all written reports; 3-4 joint field inspections with each staff and impromptu staff meetings to discuss new things.
- Yes. However, the training manual could serve in this capacity, but one more finely tuned as an audit tool would be beneficial. We need some way to monitor ongoing effective of field work by existing FSIO’s.
- No
- We have used the documents to conduct an evaluation, but only conduct a formal evaluation one time; we currently do not have the staff to do more frequent evaluations.
- During the interview, the training officer indicated that the county does not have a separate and distinct audit process for new hires. Currently they use the CFP Field Training Process and forms for both training and a final assessment by the Trainer. But it is done as one process. There is not a distinct “evaluation” component to their program. The training officer did indicate, however, that an audit tool should be added and based off the field training manual. In addition, such an evaluation process would be better positioned as a component of Standard 4 – Uniform Inspection Program than Standard 2 because it is a quality assurance issue rather than a training issue.

- We have a 6 month probationary period and it would be nice to have some sort of document that could be filled out by a supervisor to verify that the candidate is performing their job correctly. If used prior to the end of the probationary period, this document would likely help determine whether to keep a candidate or terminate them so this might be beyond the scope of an audit form.
- The Training officer indicated a preference for having an audit tool incorporated as part of Standard 2 not Standard 4. The audit tool would be a value added part of the training process that ensured the FSIO is ready to conduct independent inspections. The training officer's preference was to have the audit process conducted before releasing the FSIO for independent inspections.
- We do not have a formal audit process. We have used the completion of the ATN/Joint Field Training Worksheet to determine whether the FSIO is ready to be released for independent inspections. After completion of the joint field inspections a supervisor observes the FSIO in the field and gives the final release. If an FSIO is not ready then the joint field training exercises would be extended. Yes, an audit process or tool would be beneficial.
- I feel that the ATN process assures that all necessary technical matters are discussed before an FSIO is approved to conduct independent inspections. No training process can be 100% complete and the ATN provides a reasonable foundation for a field inspector. Many questions will still come up during subsequent field work and our standardized training officer is always available for consultation.
- If an audit tool is included as part of the process, it should be included as part of Standard 4 quality assurance rather than Standard 2. Currently Standard 4 requires that 2 inspections be conducted with each Food Safety Inspection Officer to assess the QA elements contained in Standard 4. While this Standard specifies the number of QA inspections and broad based criteria, it does not provide a protocol for a consistent assessment of the candidate during the 2 QA inspections. An audit tool would provide a consistent approach to assessing whether a candidate in the field is performing to expectations and what gaps might exist in the jurisdiction's training program.
- If not included in Standard 4, an audit tool might be considered as an intermediate step between the end of the field training process and standardization.
- Yes, having some ability to assure that a FSIO is properly trained before being released into the field to conduct independent inspections would be beneficial. Current format used includes discussion with trainee and trainer(s) to assess competency and comfort level for establishments in each risk level prior to conducting independent inspections in the corresponding risk levels.
- The training officer included in the survey response that they have an audit tool but it is an informal process. The municipality uses the Assessment of Training Needs first and foremost as a method for structuring their training and ensuring exposure to all the performance elements and competencies. The ATN worksheets are used more as an assessment tool. The municipality's training officer questioned the need for an audit tool – not sure what value it brought to the program. After some discussion they indicated they would have to wait to review what the audit tool looked like and where it was positioned in the Standard. They indicated that they had not worked much with Standard 4 so they were not in a position to comment as to whether the audit tool would be more appropriately positioned as part of Standard 2 or 4.

- The State agency using the ATN as a framework for creating their training plan. Though not the intention of the CFP Work Group, the state agency not only uses this training plan to assess the progress of a candidate through the training process but the information also is used to assess a new hire through the probationary period.
- Though YES is marked on the questionnaire, the county does not implement a formal audit/evaluation process for inspectors in the field. The YES is marked as a reference that the ATN is used by training staff as an assessment tool as well as a training tool. The training officer indicated that the direction the county would like to take is to have staff supervisors conduct and audit/assessment of trained staff once they have been cleared to conduct independent inspections using a tool that mirrors the ATN, if not the ATN field training worksheet itself. Given that the county would prefer the supervisor’s conduct the audit/evaluation, should the CFP Work Group develop an audit process and forms, the training officer indicated that the audit/evaluation process should be included as a component of Standard 4 rather than Standard 2.
- The food program manager would find an audit tool a value-added addition to the training process. If such a tool is added it should be incorporated as part of the QA process in Standard 4 rather than the training process in Standard 2. The training officer noted that the CFP Work Group had revised the original ATN to remove any reference to it being an evaluation/audit process. This was done to position the entire structure as a training process. If an audit tool is developed and incorporated into Standard 2 isn’t the CFP Work Group reverting back to incorporating elements of an evaluation?

13. The Assessment of Training Needs or Section VIII of the Model Training Plan describes additional food safety related courses and a modified standardization process that an FSIO should complete after she/he has started to conduct independent inspections. Have these requirements presented any problems for your jurisdiction or the FSIOs who are participating in the program?

Yes **5** No **17** Yes and No **1**

If the interviewee said yes, please identify what problems they have encountered.

- It hasn’t been a problem to standardize staff, but we have not been able to do the additional course work. Once staff are “cut loose” to do field work it’s harder to find time to keep them in the office doing online training.
- Standardization has not yet been completed. Because of workload and limited resources, State DOH has been unable to schedule standardization exercised with the County. This is still a priority and hopefully will be accomplished in 2009.
- This related to jurisdictions such as ours that have to meet both the retail and manufacturers program standards at the same time which can relate to a burdensome task when both programs require their own separate agenda and must be met within the same time frame.
- We do not use the modified standardization process. Therefore, we cannot truly evaluate how effective using this modified structure would be.

- “Application of the Basics of Inspection/Investigation Course FD170” through ORA-U . I checked the AFDO website and Indiana had no trainer available. I did not pursue obtaining the CD. It was implied that a “Train-the-Trainer” status was required to teach the course. I was unable to locate this course on ORA-U at the end of the pilot.
- Attendance at state environmental health sponsored training should always be encouraged and funding is a problem.
- Other meeting such as the State’s Food Safety and Defense Task Force, Symposium and other professional meetings are included in this.
- We have not completed the standardization process due to our perception of limited value with the current process. A primary concern is that doing eight standardization inspections is probably not always necessary, and is very time consuming. The standardization process should be complete when the requirements of standardization can be met through performance criteria rather than requiring that 8 standardization inspections be conducted.
- FDA’s standardization process does provide a good framework that we would like to build upon in order to better meet our standardization needs. However, we have lacked the resources to pursue this as quickly as we would like to. Below is some feedback from my standardization experience in 2005. While completing the standardization process some areas for improvement were identified. Below is a list of examples where the standardization marking instructions created limitations in adequately documenting food safety risk factors:
 1. During one inspection the operator revealed that his salesman delivered food products to the restaurant by car. This was a concern identified by discussion. Following the standardization inspection report marking instructions, item 4.0D (receiving) was marked IN even though concerns were identified via discussion.
 2. Two operators were able to discuss appropriate quick cooling methods. Discussion revealed that cooling had not been verified to meet food code requirements. Because no cooling was taking place at the time of inspection, item 5.3A was marked NO even though the operator hadn’t developed a system to monitor cooling (PIC responsibility 2-103.11 G)
 3. One operator described cooling of roasted meats. One step in the process was described as leaving the roast out on the counter at room temp until it was 120 °F. The operator could not relay how long the roast was on the counter or how long it then took to cool to 70 °F and then to 41 °F. Following the standardization inspection report marking instructions, item 5.3A (cooling) was marked NO (no cooling occurring during inspection) even though discussion revealed questionable cooling practices. Operator was marked IN for item 1.0A (demonstration of knowledge) because there were many good food safety systems in place.
 4. The standardization inspection report and CFP instructions do not address how to assess handwashing after restroom use. Handwashing in the restroom will rarely if ever be able to be assessed by sanitarian observation. However, discussion with operators can reveal how well the handwashing policy is followed by employees and how the operator monitors for appropriate employee behavior.

5. There were multiple instances where NO was marked, but discussion could have been an effective means of risk factor identification. For example:
- * Discussion with operators can reveal what temperature each type of meat usually reaches when temps are taken or what the goal temp is for each product.
 - * Having the operator describe reheating and cooling processes and how these are monitored can help to identify potential problems even if the processes aren't occurring during the inspection.
- Discussion can cover more topics (high risk processes and behaviors) while observation will be limited to what is happening at inspection time. Discussion helps to identify gaps in monitoring or knowledge. This creates a teaching moment.
 - Whenever possible, observation should be used to confirm what the operator says.
 - The value of discussion to supplement observations in risk identification needs to be emphasized. This is especially important in identifying factors that contribute to foodborne illness. The State's experience in outbreak investigations and what we know about norovirus has shown that employee health, employee behaviors and food handling practices are risk identification and risk reduction focus areas. These risks are often difficult to see. Failure to recognize the importance of discussion and building an inspection process that doesn't promote and capitalize on sanitarian ability to use a variety of methods in risk identification is a missed opportunity. Now is the time to thoroughly evaluate the standardization process and make adjustments that take what the FDA has provided and make it even better. This type of continuous improvement approach will maximize what the standardization process and the CFP form can do to support reduction and prevention of foodborne illness.
 - The current marking instructions for the Standardization Inspection Report and the Conference of Food Protection Form require making broad judgments about operator compliance in demonstration of knowledge and employee health. This is challenging, because management of these areas is multi-faceted.
 - Our field work has been so far behind due to budget and the limits this has placed upon us being fully staffed that so far we have not had any candidates complete all of the post requisite courses. For the same reasons, we have also not standardized any of our new employees, however, we have had trainers work with the new employees twice per month for their first 6 months in the field and once per month for the next 6 months so that we can ensure we are following up and keeping the new employees on track. However, this follow up training includes time in manufacturing as well as retail inspections.

14. It has been suggested that a course on allergens be added to the training curriculum in the CFP Training Manual. Would you recommend that this course be added as part of the pre-inspection curriculum or the post-inspection curriculum, or does it matter?

 8 Pre-inspection 11 Post-inspection 3 Doesn't matter

Comments:

- The training officer agrees that an allergen course should be part of the Standard 2 curriculum and is best positioned as a pre-requisite course.
- The municipality’s training staff did view the allergen management course as a “value added” component to the Standard 2 curriculum. They did not, however, view it as an essential course for determining whether a new hire would be ready to conduct an independent inspection. Viewed the allergen course as an enhancement of existing food safety knowledge and better positioned within the post curriculum segment of Standard 2.
- The state agency views the allergen management course as a “value added” part for Standard 2 and has developed an allergen management course for the training of their new hires. They support incorporation of the allergen management course into Standard 2 as a pre-requisite course.
- Allergen management course does provide value added to the training process but the food program manager does not considered an essential element to conducting basic inspection work. Though it is an emerging issue, the existing pre-requisite courses provide the needed information to get staff ready for independent inspections. Much like HACCP is positioned as a post curriculum course, the allergen management course will provide useful information but directed at a very specific process/procedure or set of circumstances.

15. It has been suggested that one or more courses on Food Defense [National Incident Management System (NIMS) or Incident Command System (ICS)] be added to the training curriculum in the CFP Training Manual. Would you recommend that this course be added as part of the pre-inspection curriculum or the post-inspection curriculum, or does it matter?

 1 Pre-inspection 18 Post-inspection 3 Doesn’t matter

Comments:

- The training officer agrees that an NIMS/ICS course should be part of the Standard 2 curriculum and is best positioned as a post curriculum course.
- The county has already included NIMS and ICS training into their new hire program. The training officer was not sure whether they course material provided was consistent with the EPA course offered on line.
- I am still studying this question. Many of the smaller jurisdictions do not use an incident command system, so the courses might not be useful. On the other hand, fire departments across the country use the ICS and many of the state jurisdictions are now using ICS on outbreaks, so just the understanding of the concept would be helpful.
- The municipality’s training staff also viewed the NIMS and ICS courses as “value-added” pieces of the Standard 2 curriculum as long as they remained basic for new hires. They specifically mentioned that the scope of the courses should mirror the 100, 200, and 700 series course available on line. They definitely thought that these courses should be part of the Standard 2 post curriculum.
- The state agency views NIMS and ICS training as “value added” course to the Standard 2 curriculum. FL Ag already delivers NIMS and ICS training for its new hires. They support incorporation of these courses into Standard 2 as part of the post curriculum.

- Both the allergen management and ICS courses are viewed as value-added training by the county. The training officer supports their incorporation into the Standard 2 criteria. The county is already looking into incorporating the web based NIMS and ICS courses in their training of new hires.
- The food program manager questioned whether NIMS and ICS are an appropriate addition to a “Retail Food Safety” curriculum. The manager recognized the value of training in these areas but think these courses should be part of an agencies overall training program for new employees rather than part of the Standard 2 curriculum. It was pointed out that NIMS and ICS are not food specific but can be related to any type of emergency management situations.

16. Is there is any relevant information the interviewee would like to share about the Assessment of Training Needs or CFP Field Training Process that has not been addressed in the first 10 items of this survey? If so, please provide this information in the space below.

Comments:

- It would be great if a bound “field book” could be printed to provide to each FSIO when starting the training process. It would include all of the forms that need to be completed during the process. The trainee could provide the workbook to the trainer during each inspection. At the end there would be a complete record of training available AND/OR Develop an electronic database for recording all of the training information into.
- They are both great tools for ensuring all aspects of our food inspection program are covered. It is so easy to miss something if you are simply conducting joint inspections and not purposely looking for specific skill/knowledge areas.
- I also really like the abbreviated field training worksheet. The only thing I would change/modify would be along the lines of “signing off” on an aspect of it once it has sufficiently been shown to be mastered...ex: Professionalism.
- The ability to sign off that a new hire has performed a specific task is incorporated into the CFP Field Training Plan. Once the trainer determines that a new hire can perform a specific competency, the trainer does not need to continue to assess an area that the new hire can perform, rather they can concentrate on new areas or competencies the new hire is having difficulty with.
- I would like to hear how other jurisdictions are proceeding with this training program as well as communication from FDA on a more regular basis. Thank you for your support.
- The interviewee felt that this training is great.
- I believe the process is sound, but when there is not one dedicated trainer for all new trainees it presents problems for consistency within a program. Even amongst FDA standardized individuals there are still differences of interpretation of findings. I am not sure if this can ever be overcome.
- Our current plan resembles the CFP Training manual, but it not exactly the same and some of the forms used are different, but equivalent. Additionally, it should be noted that the state agency has responsibilities for retail food and manufactured food and our plan combines training requirements from both retail and manufactured Program Standard 2. We began development of this training plan in 2006 and continue to make

modifications to the plan with each new group of trainees. For an organization such as ours that has both programs, it is impractical to separate the two training plans; while generally, staff start with one or the other track (retail OR manufacturing), there is obviously overlap between the two and depending on staff and trainer resources, there may be cross training between the two at any one time (especially on field training). Because we are conducting the retail and manufactured foods training either consecutively or concurrently, this impacts our time for completion – especially to achieve Step 4 (standardization); not achieved within 18 months.

CFP Certification of Food Safety Regulation Professionals Work Group

Proposed Performance Audit Pilot Project Objectives and Time Line

Objectives of Pilot Project

1. Evaluate the FDA *Retail Food Level I Performance Audit* (Audit) documents [i.e., Guide to the Performance Audit Process for State, Local & Tribal Food Safety Inspection Officers (hereafter FSIO), Retail Food Level I Performance Audit Criteria for FSIO, Audit Failure Reference Guide, Level I FSIO Audit Results Summary Form, Level I FSIO Audit Worksheet, Level I FSIO Auditor Feedback Form]
 - Review the performance elements and criteria for omissions, additions, and items not applicable.
 - Determine the strengths and weaknesses of the documents.
 - Verify ease of use of the documents, including instructions and format. Are jurisdictions able to utilize documents independently without direct supervision or oversight?
 - Determine length of time required to use the documents and complete the Audit process.
2. Assess the use of the Audit process
 - Verify that the Audit process is appropriate to assess the FSIO's knowledge, skills and ability when applying the competencies required during a field inspection.
 - Verify the appropriate placement of the Audit process application tool; as a stand-alone document or within the Voluntary National Retail Food Regulatory Program Standards as part of the training process (Standard 2 – Trained Regulatory Staff) or as part of the ongoing quality assurance program (Program Standard 4 – Uniform Inspection Program).
3. Gather and analyze data from the pilot study and prepare a Pilot Project Report for the Conference for Food Protection Certification of Food Safety Regulation Professionals Work Group (Work Group) at the 2012 biennial meeting of the Conference for Food Protection (Conference).

Pilot Project Timeline

March 2010	Begin development of Pilot Project packages / Fact Sheet (web-based, paper, etc.)
April 2010	Solicitation of interested jurisdictions during the 2010 biennial meeting of the Conference
May 2010	Selection of jurisdictions for Pilot Project (Minimum of 8 jurisdictions desired)
June 2010	Send out Pilot Project packages to selected jurisdictions and notify jurisdictions not selected
July 2010	Conference call with selected jurisdictions (Overview of Pilot Project objectives, goals, methodology, data collection, etc.)
January 2011	Interim data collection from jurisdictions (Data may be received through CFP website)
February 2011	Interim conference call with jurisdictions (Review of data received to date, overview of progress, solicitation of questions, reminder of deadlines, etc.)
July 2011	Completion of field component of Pilot Project and collection of completed data reports from jurisdictions
August 2011	Convene conference call focus group of jurisdiction representatives to review Pilot Project outcomes
Sept / Oct 2011	CFP Work Group review, analysis, summary and development of Pilot Project results into Conference report and issue.
December 2011	Submit final Work Group report and any Issues for consideration at the 2012 biennial meeting of the Conference.

Methodology

Selection of jurisdictional participants: Criteria for participation in the Audit Pilot Project is as follows:

- Jurisdictions MUST be enrolled in Program Standards to participate.
- Jurisdictions must agree to follow the training criteria specified in Program Standard 2, Steps 1 – 3 (includes use of a field training process and documentation similar to that contained in the CFP Field Training Manual and forms, Appendix B-2) with newly hired FSIOs while a participant in the Pilot Project.
- Jurisdictions must have a sufficient number of FSIOs that have successfully completed Standard 2, Steps 1-3 .
- Jurisdictions must make a commitment to meet the Pilot Project timelines, reporting protocols. and participate in conference calls.
- Jurisdictions must agree to publication of their participation in Pilot Project Report (note: individual responses will remain confidential).
- Any jurisdictions not selected will be notified.

Distribution of Pilot Project Package: All selected jurisdictions will receive an Electronic Pilot Project Package containing the following materials:

- Copy of newly revised Standard 2 – Trained Regulatory Staff(as approved by the 2010 biennial meeting of the Conference) and Standard #4 – Uniform Inspection Program
- Copy of the FDA Retail Food Level I Performance Audit process documents including instructions.
- Copy of the *CFP Field Training Manual*.
- Performance Audit Pilot Project protocol and timeline.
- Contact information for Performance Audit Pilot Project Director.

Launch of Pilot Project: Pilot Project will be initiated with a conference call of all participating jurisdictions. The purpose of the conference call will be to provide an overview of the Pilot Project objectives, goals, timeline, methodology, participant expectations, data collection, and other reporting criteria.

Interim Progress Review of Pilot Project: Participating jurisdictions will submit reporting documents completed to date to Pilot Project Director. Data will be analyzed and summarized to identify any potential challenges, omissions, or errors that would hinder completion of the project. Additionally, a conference call will be conducted with participating jurisdictions for additional verbal feedback and clarification.

Data Collection and Reporting: The design of the Data Collection and Reporting Instrument will incorporate the following:

- A questionnaire designed to solicit information.
- Demographical information

- Focus Group(s) designed to solicit additional anecdotal information and recommendations.

Roles and Responsibilities

The following roles and responsibilities are integral to this Pilot Project:

Role	Responsibility
Conference for Food Protection Certification of Food Safety Regulation Professionals Work Group	Staff all Pilot Project Activities, review the Pilot Project outcomes and make further recommendations to the Conference.
Pilot Project Subgroup	Prepare Pilot Project Package, prepare Fact Sheet, solicit jurisdictional participation, select participants, distribute Pilot Project Package, receive Pilot Project data from the Pilot Project Director, tabulate and analyze data, summarize the results of the Pilot Project and prepare the Pilot Project Report (including recommendations) for presentation to the 2012 biennial meeting of the Conference.
Pilot Project Director	Serve as the central point of contact for the Pilot Project, collect data and forward to the Pilot Project Subgroup, coordinate focus group meetings, and present Pilot Project findings to the Conference.
Jurisdictional Participants	Carry out the activities of the Pilot Project including following the criteria specified in <i>Retail Food Level I Performance Audit</i> documents. Jurisdictions must be active participants in the FDA Program Standards and will have met the requirements of Standard 2, Steps 1 – 3, relative to use of the <i>CFP Field Training Manual</i> ; must also be able to assess the feasibility of using the Audit documents with newly hired or existing FSIOs relative to applicability to Standard 4; completing the data reporting instruments; participating in focus group calls; agreeing to publication of Pilot Project participation; and providing feedback to the Pilot Project Subgroup.
Conference for Food Protection	Provide assistance as requested by the Work Group to disseminate and collect information.
FDA	Will collaborate with the Pilot Project Subgroup in the design and format of the Pilot Project, analysis of data, and subsequent recommendations for use and placement of the Audit documents and/or process.

Analysis of Data

The Pilot Project Subgroup will analyze the data by tabulating and summarizing all responses to the questionnaire and the focus group meetings. Based on the results of the Pilot Project, the Work Group will determine necessary or recommended changes that need to be made to the training/Audit documents and/or process.

Preparation of Pilot Project Report

A report of the results of the Pilot Project will be created. The report will include a summary of the results of the data tabulation (including participant list, demographics, and questionnaire results), a list of recommended changes to the Audit documents and a list of recommended changes to the Voluntary National Retail Food Regulatory Program Standards (Standard #2 and/or Standard #4). This report will be submitted to the 2012 biennial meeting of the Conference for Food Protection.

Additionally, Pilot Project results and recommendations will be developed in collaboration with FDA's Division of Human Resource Development to assist in the development of a performance assessment specific to the responsibilities of state, local and tribal retail food safety inspection officers.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 008
Issue: 2010 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:

Emergency Management Course Additions to Appendix B-1, Standard 2

Issue you would like the Conference to consider:

The CFP Certification of Food Safety Regulation Professionals (CFSRP) Work Group is recommending that the basic Federal Emergency Management Agency (FEMA) courses related to National Incident Management Systems (NIMS) and Incident Command Systems (ICS) be included as part of the required "post curriculum" contained in Appendix B-1, Standard 2, of the *FDA National Voluntary Retail Food Regulatory Program Standards (2009)*.

Public Health Significance:

State/local/tribal regulatory retail food safety professionals are often the first responders to a food safety or food defense emergency. Frequently these incidents impact multiple jurisdictions and require an operational response and management to ensure maximum public health protection.

The Federal Emergency Management Agency (FEMA) offers a national model training curriculum for all public officials with emergency response and coordination responsibilities. FEMA's Emergency Management Institute provides many basic and advance National Incident Management Systems and Incident Command Systems courses on-line for no cost. These courses which include final examinations and certificate of completions are available from the following web link: <http://training.fema.gov/IS/NIMS.asp>.

Three basic NIMS and ICS courses are being recommended by the CFP CFSRP work group for inclusion as part of the post curriculum outlined on Appendix B-1, Standard 2.

IS-100.a, *Introduction to Incident Command System*, ICS-100

This course provides training and resources for personnel who require a basic understanding of the Incident Command System (ICS).

IS-200.a, *ICS for Single Resources and Initial Action Incidents*, ICS-200

This course provides training and resources for personnel who are likely to assume a supervisory position within the Incident Command System (ICS). The primary target audiences are response personnel at the supervisory level.

IS-700.a, *NIMS An Introduction*, ICS 700

This course provides training and resources for the National Incident Management System (NIMS). NIMS provides a consistent nationwide template to enable all government, private sector, and nongovernmental organizations to work together during domestic incidents. Each of these courses is three hours (total of nine hours).

Successful completion of the learning objectives contained in these three courses establishes a solid foundation for preparing regulatory retail food protection staff to prevent, respond to, recover from, and mitigate the effects of incidents regardless of cause, size, location and complexity in order to reduce the loss of life, property damage, and harm to the environment.

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:

- include the following three Federal Emergency Management Agency (FEMA) courses as part of the post curriculum retail food protection training program as contained in Attachment A with this Issue (changes are noted with shaded background)
 - IS-100.a, *Introduction to Incident Command System*, ICS-100
 - IS-200.a, *ICS for Single Resources and Initial Action Incidents*, ICS 200
 - IS-700.a, *NIMS an Introduction*, ICS-700; and
- update the post curriculum courses and total training hours listed in Appendix B-1 to reflect the additional 9 hours needed to complete the three FEMA courses. Any references to these training hours in other parts of the FDA Program Standards are to be updated to ensure consistency.

Submitter Information:

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Attachments:

- "Program Standard 2 - Appendix B-1 Curriculum for Regulatory Retail Food Saf"

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.

APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

For state, local & tribal regulators to register on-line for free access to web courses, go to:
<http://www.fda.gov/ora/training/>

Pre-requisite (“Pre”) curriculum courses

(to be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

PUBLIC HEALTH PRINCIPLES

Public Health Principles (90) FDA36

MICROBIOLOGY

Food Microbiological Control (series):

1. Overview of Microbiology (60) MIC01
- 2A. Gram-Negative Rods (60) MIC02
- 2B. Gram-Positive Rods & Cocci (90) MIC03
3. Foodborne Viruses (60) MIC04
4. Foodborne Parasites (90) MIC05
Mid-Series Exam (30) MIC16
5. Controlling Growth Factors (90) MIC06
6. Control by Refrigeration & Freezing (60) MIC07
- 7A. Control by Thermal Processing (90) MIC08
- 7B. Control by Pasteurization (90) MIC09
10. Aseptic Sampling (90) MIC13
12. Cleaning & Sanitizing (90) MIC15

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Basic Food Law for State Regulators (60) FDA35

Basics of Inspection:

Beginning an Inspection (90) FDA38

Issues & Observations (90) FDA39

An Introduction to Food Security Awareness (60) FD251
(ORA U internet site)

2005 Food Code*

NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction

COMMUNICATION SKILLS

Communication Skills for Regulators*

Curriculum (“Post”) courses

(to be completed anytime prior to Food Code Standardization AND within 18 months of hire or assignment to the regulatory retail food program)

MICROBIOLOGY

Food Microbiological Control (series):

- 7C. Control by Retorting (90) MIC10
8. Technology-Based Food Processes (120) MIC11
9. Natural Toxins (90) MIC12

HACCP

Basics of HACCP (series):

1. Overview of HACCP (60) FDA16
2. Prerequisite Programs & Preliminary Steps (60) FDA17
3. The Principles (60) FDA18

EPIDEMIOLOGY

Foodborne Illness Investigations (series):

1. Collecting Surveillance Data (90) FI01
2. Beginning the Investigation (90) FI02
3. Expanding the Investigation (90) FI03
4. Conducting a Food Hazard Review (90) FI04
5. Epidemiological Statistics (90) FI05
6. Final Report (30) FI06

EMERGENCY MANAGEMENT

FEMA – Incident Command System and National Incident Management System: Course available from FEMA web link. – <http://training.fema.gov/IS/NIMS.asp>

1. IS-100.a, Introduction to Incident Command System, ICS-100
 2. IS-200.a, ICS for Single Resources and Initial Action Incidents, ICS-200
 3. IS-700.a, NIMS an Introduction, ICS 700
-

() Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

Estimated total hours for “Pre” courses are 42 hours.

Estimated total hours for “Post” courses are 22 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 64 hours

Program Standard #2

APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

“Application” Courses and “Hands-On” Training

To provide application and transfer of web instruction to the FSIO’s work environment, a jurisdiction’s training program (inclusive of both classroom instruction *and* field training inspections) for staff newly hired or newly assigned to the retail food protection program must include a minimum of eighty percent (80%) of the learning objectives contained in the ORA U *Application of Basics of Inspection/Investigation Course* (FD170). A jurisdiction may use any one of the following options to address learning objectives not covered in their existing training programs.

1. **Classroom Course: Application of the Basics of Inspection/Investigation FD170** (available at www.afdo.org/ or course contents are available on CD through FDA’s Division of Human Resource Development’s lending library).
2. **Courses and or field training exercises developed by State/local regulatory jurisdictions or other entities** containing learning objectives and exercises equivalent to Option 1 above.
3. **Discussions Questions & Exercises *** (Conducted in the office or during the 25 joint inspections)

* Under construction

The learning objectives for the ORA U Application of the Basics of Inspection/Investigation course (FD170) are included below:

APPLICATION OF THE BASICS OF INVESTIGATION/INSPECTION – FD170

Applying Knowledge and Principles to the Real World of Inspection and Investigation of Food Establishments

Learning Objectives: Upon completion of this course, participants will be able to:

1. Demonstrate their knowledge of relevant food laws and regulations and how to apply them properly during inspections.
2. Demonstrate hands-on competency in the use of equipment and instruments used during food establishment inspections.
3. Successfully perform a hands-on exercise of aseptic sampling with sterile sampling containers using deli-style food samples.
4. Identify biological, physical, and chemical hazards and risks associated with foods and the operation of food establishments and will apply this knowledge to determine if a food establishment is in compliance.
5. Identify good basic inspection and communication techniques used in food processing, storage, and retail facilities.
6. Demonstrate their ability to identify the causes and symptoms of food borne illness, to identify implicated foods, to select proper foods for sampling, to determine individuals to interview, to identify the likely causative organism(s), and to recommend procedures that would prevent further outbreaks.
7. Demonstrate their ability to document quantitative observations, to distinguish fact from opinion, to gather, synthesize and document all facts, to avoid ambiguity, and to distinguish relevant from irrelevant facts.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 009
Issue: 2010 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:

Allergen Management Course Addition to Appendix B-1, Standard 2

Issue you would like the Conference to consider:

The CFP Certification of Food Safety Regulation Professionals (CFSRP) Work Group is recommending that the Allergen Management course currently under development within FDA's Division of Human Resources Development be included as part of the required "post curriculum" contained in Appendix B-1, Standard 2, of the *FDA National Voluntary Retail Food Regulatory Program Standards (2009)* upon completion and review by the CFP Food Allergen Committee.

Public Health Significance:

At the 2008 Biennial Meeting, the Voting Assembly of Delegates unanimously approved the Council III recommendation contained in Issue 2008 III-007, *Food Allergy Information for state/local regulatory officials*, stating:

The Conference recommends that the Food Allergen Committee be reestablished and that a letter be sent to the FDA recommending that food allergen resource information be included as part of the recommended curriculum in the FDA Voluntary National Retail Food Regulatory Program Standards, Standard #2, Trained Regulatory Staff and that a compendium of educational materials be made available to state/local regulators.

The Conference further recommends that the Food Allergen Committee work with the FDA to develop an appropriate educational component regarding food allergen awareness.

The Executive Board of the Conference charged the CFP CFSRP Work Group with incorporating Food Allergen resource information as part of the recommended curriculum in Standard #2, Trained Regulatory Staff, FDA Program Standards (2009). The CFP CFSRP Work Group conducted follow-up interviews with State/local/tribal jurisdictions that participated in the CFP Assessment of Training Needs Pilot Project in 2007. One of the objectives of this pilot project was to assess the appropriateness of the Standard #2 curriculum. The feedback received indicated overwhelming support for inclusion of an Allergen Management Course as part of the Standard #2 curriculum.

Appendix B-1 of Standard #2 contains a listing of the training curriculum expected to be completed by new hires or staff newly assigned to the regulatory retail food protection program. To be included in this listing, the subject matter must be in the form of a course with learning objectives. FDA's Division of Human Resource Development has developed

several of the core elements for an Allergen Management Course. FDA's Center for Food Safety and Applied Nutrition is currently working on an Allergen Management guidance document. This document will include specific recommendations for the retail food industry. FDA is planning on collaborating with the CFP Food Allergen Committee to obtain feedback on the information contained in the Allergen Management guidance document. Once the document is finalized, FDA will include specific allergen management guidance for foodservice and retail food operations in the Allergen Management course.

The CFP CFSRP Work Group is recommending that the FDA Allergen Management course be incorporated as part of the Standard #2 post curriculum upon its completion and review by the CFP Food Allergen Committee. This course is not likely to be ready for posting by the 2010 Biennial Meeting but may be ready shortly thereafter. Rather than waiting another 2 years to deliberate the inclusion of this course into the Standard #2 post curriculum at the 2012 Biennial Meeting, the CFP CFSRP thinks it is prudent for the Conference to send a letter to FDA recommending that upon its full completion, the Allergen Management Course be included as part of the Standard #2 post curriculum when FDA revises the Standards document to reflect the recommended changes and/or revisions approved at the 2010 Biennial Meeting.

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.
- the inclusion of the finalized Allergen Management Course as part of the "post curriculum" training in Appendix, B-1, Standard 2 - Trained Regulatory Staff, FDA Draft Voluntary National Retail Food Regulatory Program Standards when the next subsequent version is drafted. Moreover, at the time the Allergen Management Course is ready for inclusion as part of Appendix B-1, the total post curriculum hours and total Standard 2 training hours should be revised accordingly.

Submitter Information:

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Attachments:

- "Program Standard 2 Appendix B-1"

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.

Program Standard #2
APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers
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<http://www.fda.gov/ora/training/>

Pre-requisite (“Pre”) curriculum courses

(to be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

PUBLIC HEALTH PRINCIPLES

Public Health Principles (90) FDA36

MICROBIOLOGY

Food Microbiological Control (series):

1. Overview of Microbiology (60) MIC01
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NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction

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Communication Skills for Regulators*

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(to be completed anytime prior to Food Code Standardization AND within 18 months of hire or assignment to the regulatory retail food program)

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3. Expanding the Investigation (90) FI03
4. Conducting a Food Hazard Review (90) FI04
5. Epidemiological Statistics (90) FI05
6. Final Report (30) FI06

ALLERGEN MANAGEMENT

NOTE: Upon completion by FDA’s DHRD and review by the CFP Allergen Committee – the Allergen Management Course will be listed as a post-curriculum course in Standard 2

() Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

Estimated total hours for “Pre” courses are 42 hours.

Estimated total hours for “Post” courses are 22 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 64 hours

Program Standard #2

APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

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2. **Courses and or field training exercises developed by State/local regulatory jurisdictions or other entities** containing learning objectives and exercises equivalent to Option 1 above.
3. **Discussions Questions & Exercises *** (Conducted in the office or during the 25 joint inspections)

* Under construction

The learning objectives for the ORA U Application of the Basics of Inspection/Investigation course (FD170) are included below:

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3. Successfully perform a hands-on exercise of aseptic sampling with sterile sampling containers using deli-style food samples.
4. Identify biological, physical, and chemical hazards and risks associated with foods and the operation of food establishments and will apply this knowledge to determine if a food establishment is in compliance.
5. Identify good basic inspection and communication techniques used in food processing, storage, and retail facilities.
6. Demonstrate their ability to identify the causes and symptoms of food borne illness, to identify implicated foods, to select proper foods for sampling, to determine individuals to interview, to identify the likely causative organism(s), and to recommend procedures that would prevent further outbreaks.
7. Demonstrate their ability to document quantitative observations, to distinguish fact from opinion, to gather, synthesize and document all facts, to avoid ambiguity, and to distinguish relevant from irrelevant facts.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 010
Issue: 2010 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:

Clarifying language for Step 2, Standard 2 - Program Standards

Issue you would like the Conference to consider:

Revise Step 2, Standard 2 - Trained Regulatory Staff, FDA Voluntary National Retail Food Regulatory Program Standards (2009)

Public Health Significance:

The CFP Certification of Food Safety Regulation Professionals (CFSRP) Work Group received a charge from the 2008 Biennial Meeting to re-examine the Standard 2 criteria requiring new hires or staff newly assigned to the retail food protection program to conduct a minimum of 25 joint field inspections with the jurisdiction's designated trainer. Feedback from the jurisdictions that participated in the 2007 Assessment of Training Needs (ATN) pilot project, administered through the Conference, indicated a wide variation in opinion as to the appropriate number of joint field training inspections needed to prepare new Food Safety Inspection Officers (FSIO) for conducting independent inspections of foodservice and retail food facility types. A summary of the jurisdiction responses to appropriate number of joint field inspections is contained on pages 48 and 49 of the 2007 Assessment of Training Needs Pilot Project Report which is available from the Conference for Food Protection web site.

Sixty-five percent (65%) of the jurisdictions participating in the pilot project indicated that 25 joint field training inspections was the appropriate minimum number to include in Standard 2. Of the 10 that responded with a "no", the number of joint field training inspections recommended ranged from 10 to 100, with an average of 75. From comments received from the pilot jurisdictions, the appropriate number of joint field training inspections is primarily based on an individual's skill, capability and affinity for learning new tasks or accomplishment of certain skills. These learning characteristics will vary from one individual to another.

In 2009, the CFP CFSRP Work Group conducted follow-up interviews with the jurisdictions that participated in the pilot project to assess their experiences with the continued use of the CFP Field Training Manual and forms. Twenty-two jurisdictions were canvassed, fifteen (68%) indicated a minimum of 25 joint field inspections was the appropriate number. A recurring comment from these jurisdictions was that the number of joint field inspections was not the performance measure they used to determine a trainee's readiness to conduct

independent inspections. The ultimate performance measure is the trainee's ability to successfully demonstrate all the competencies listed on the CFP Field Training Plan contained in Appendix B-2, Standard 2.

Many jurisdictions indicated that having a minimum of 25 joint field training inspections specifically referenced in Standard 2, provided the jurisdiction's trainer with expectations on time commitments/resources that should be devoted to the training process. It provides for a degree of quality assurance and expectation of the training process for both the candidate and trainer.

The CFP CFSRP Work Group has deliberated the information received from jurisdictions that have implemented the Standard 2 training process. Based on this research, the CFP CFSRP Work Group is recommending that the Conference retain the reference to the minimum of 25 joint field inspections in Step 2, Standard 2, but also include language that would allow a trainer to conduct a fewer number provided that exception was supported by written documentation, such as completion of the CFP Field Training Plan included in Appendix B-2, Standard 2.

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:

Note, in the context below:

-- FSIO is a "Food Safety Inspection Officer" and the acronym is spelled out and defined earlier in the Standard.

-- wording to be inserted is indicated with underline format; wording to be deleted is with strike through.

REQUIREMENT SUMMARY

STEP 2 - Completion of a minimum of 25 joint field training inspections or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments.

AND

successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in Appendix B-2.

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer ~~or the jurisdiction's designated staff member,~~ who has successfully completed all training elements (Steps 1 - 3) ~~required by~~ of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "FSIO-led" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction. If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Demonstration inspections are those in which the jurisdiction's trainer ~~and/or designated staff person~~ takes the lead and the FSIO observes the inspection process. FSIO-led inspections are those in which the candidate takes the lead and demonstrates competencies identified in the jurisdiction's retail food program training plan. The jurisdiction's trainer is responsible for determining the appropriate combination of demonstration and FSIO-led inspections based on the FSIO's food safety knowledge and performance during the joint field training inspections.

The joint inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of this Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

NOTE: The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.

- *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*

- *Regulatory jurisdictions are NOT to use the CFP Field Training Manual for administrative purposes including but not limited to, job classifications, promotions, or disciplinary actions up to and including termination.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2005 FDA Food Code). The jurisdiction's trainer/food program manager can make a determination as to the FSIO's readiness to conduct independent inspections of risk category 1 establishments as defined in Appendix B-3 at any time during the training process.

NOTE: The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections

- *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*

- *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Reference:

APPENDIX B-2: CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers, Standard #2 - Trained Regulatory Staff, *FDA Voluntary National Retail Food Regulatory Program Standards*, referenced in this Issue is available from the following CFP web link:

www.foodprotect.org/media/guide/CFPFieldTrainingManual-1-7-08.pdf

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 011
Issue: 2010 II-012**

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

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Title:

Clarifying Definitions for Step 4, Standard 2 - Program Standards

Issue you would like the Conference to consider:

Revise the definitions for "Trainer" and "Training Standard" to clarify the differences in performance responsibilities and qualifications. In addition, revise Step 4, Standard 2 - Trained Regulatory Staff, FDA Voluntary National Retail Food Regulatory Program Standards (2009) to include a reference to the "Training Standard" qualifications listed in the definition section of the FDA Program Standards document.

Public Health Significance:

In 2006, the Conference unanimously approved a recommendation from the CFP Certification of Food Safety Regulation Professionals (CFSRP) work group to revise the minimum number of inspections a Food Safety Inspection Officer (FSIO) must successfully complete as part of their Food Code standardization process. The minimum number of standardization inspections in Step 4, Standard 2, was reduced from 8 to 4 for FSIOs who would NOT be expected to serve as "Training Standards" responsible for standardizing other FSIOs. The standardization process must be similar to the "FDA Standardization Procedures" and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contributed to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP Principles;
4. Inspection equipment; and
5. Communication.

The FDA standardization procedures are based on a minimum of 8 inspections and include performance areas related to the development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP Plan. FDA standardizations are conducted with regulatory retail food protection personnel who would be expected to serve as "Training Standards" responsible for standardizing other FSIOs.

Jurisdictions participating in the FDA Program Standards have indicated that the Standard 2 criteria does not clearly address the differences in the standardization process needed to be a "Training Standard" versus standardization of FSIOs who will NOT conduct standardizations with other FSIOs.

The CFP CFSRP work group is recommending that the definitions of "Trainer" and "Training Standard" contained in the FDA Program Standards (2009) be revised to clearly identify the requirements for each of these roles. In addition, the work group recommends that Step 4, Standard 2, be revised to include a reference to the requirements for conducting field standardization of FSIOs as presented in the work group's proposed "Training Standard" definition.

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.

Note: new language is underlined; language to be deleted is with strike through.

DEFINITIONS

The following definitions apply in the interpretation and application of these Standards.

24) Trainer - an individual who has successfully completed the training elements as outlined in Steps 1-3, Standard 2, and is recognized by the program manager as having field experience and communication skills necessary to train new employees.

1. Satisfactory completion of the prerequisite curriculum;
2. Completion of a field training process similar to that contained in Appendix B-2, and
3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum.

25) Training Standard - a trainer who has successfully completed the following training ~~AND~~ and standardization elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train and standardize new employees. The training and standardization elements include:

1. Satisfactory completion of the prerequisite curriculum;
2. Completion of a field training process similar to that contained in Appendix B-2;
3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum; and
4. Successful completion of a standardization process based on a minimum of eight inspections that includes development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP Plan, similar to the FDA Standardization Procedures.

Step 4 - Food Safety Inspection Officer - Field Standardization

Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section for these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;

2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

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**Conference for Food Protection
2010 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:

Re-create - CFSRP 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 2010-2012 CFP Certification of Food Safety Regulations Professional (CFSRP) Work Group should be re-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 all regulatory retail food safety professionals - including third party independent auditors - 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 all 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.

Results from the follow-up interviews with Assessment of Training Needs ATN pilot jurisdictions indicated support for the development of an audit tool that mirrored the CFP Field Training process. The Work Group reached consensus that the audit process, whether included as part of Standard 2 or provided as a stand alone process, should be fully compatible with the CFP *Field Training Plan* included as part of Appendix B-2, Standard 2, *FDA Program Standards (2009)*.

In order to eliminate potential program redundancies, the CFP CFSRP Work Group is recommending a new 2010-2012 charge to collaborate with FDA 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 to prevent any unnecessary redundancies in the creation of work products or assignment of tasks/responsibilities. This collaborative effort will include an assessment of the need and potential structure for incorporating Food Safety Inspection Officer "Performance Audits" as a component of the Program Standards.

In addition, a new charge for this Work Group is proposed based on an increase in the number of independent third party auditors contracted to conduct regulatory oversight inspections of institutional foodservice, restaurant, and retail food store facilities. Some areas of the country are beginning to disband the local regulatory retail food protection agency and contract the work to nongovernmental organizations. Currently, a national standard upon which to evaluate the education and qualifications of independent third party auditors does not exist. Legislation has been introduced at the federal level that contains language that would recognize third party audits as a legitimate use of resources to enhance food safety. Since these issues are not solidified at the time of submittal of the Work Group report to the Conference of Food Protection, a closer look over the next two year cycle is in order.

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 opportunitite 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.

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Attachments:

- "Proposed Performance Audit Pilot Project Objectives and Time Line"

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CFP Certification of Food Safety Regulation Professionals Work Group

Proposed Performance Audit Pilot Project Objectives and Time Line

Objectives of Pilot Project

1. Evaluate the FDA *Retail Food Level I Performance Audit* (Audit) documents [i.e., Guide to the Performance Audit Process for State, Local & Tribal Food Safety Inspection Officers (hereafter FSIO), Retail Food Level I Performance Audit Criteria for FSIO, Audit Failure Reference Guide, Level I FSIO Audit Results Summary Form, Level I FSIO Audit Worksheet, Level I FSIO Auditor Feedback Form]
 - Review the performance elements and criteria for omissions, additions, and items not applicable.
 - Determine the strengths and weaknesses of the documents.
 - Verify ease of use of the documents, including instructions and format. Are jurisdictions able to utilize documents independently without direct supervision or oversight?
 - Determine length of time required to use the documents and complete the Audit process.
2. Assess the use of the Audit process
 - Verify that the Audit process is appropriate to assess the FSIO's knowledge, skills and ability when applying the competencies required during a field inspection.
 - Verify the appropriate placement of the Audit process application tool; as a stand-alone document or within the Voluntary National Retail Food Regulatory Program Standards as part of the training process (Standard 2 – Trained Regulatory Staff) or as part of the ongoing quality assurance program (Program Standard 4 – Uniform Inspection Program).
3. Gather and analyze data from the pilot study and prepare a Pilot Project Report for the Conference for Food Protection Certification of Food Safety Regulation Professionals Work Group (Work Group) at the 2012 biennial meeting of the Conference for Food Protection (Conference).

Pilot Project Timeline

March 2010	Begin development of Pilot Project packages / Fact Sheet (web-based, paper, etc.)
April 2010	Solicitation of interested jurisdictions during the 2010 biennial meeting of the Conference
May 2010	Selection of jurisdictions for Pilot Project (Minimum of 8 jurisdictions desired)
June 2010	Send out Pilot Project packages to selected jurisdictions and notify jurisdictions not selected
July 2010	Conference call with selected jurisdictions (Overview of Pilot Project objectives, goals, methodology, data collection, etc.)
January 2011	Interim data collection from jurisdictions (Data may be received through CFP website)
February 2011	Interim conference call with jurisdictions (Review of data received to date, overview of progress, solicitation of questions, reminder of deadlines, etc.)
July 2011	Completion of field component of Pilot Project and collection of completed data reports from jurisdictions
August 2011	Convene conference call focus group of jurisdiction representatives to review Pilot Project outcomes
Sept / Oct 2011	CFP Work Group review, analysis, summary and development of Pilot Project results into Conference report and issue.
December 2011	Submit final Work Group report and any Issues for consideration at the 2012 biennial meeting of the Conference.

Methodology

Selection of jurisdictional participants: Criteria for participation in the Audit Pilot Project is as follows:

- Jurisdictions MUST be enrolled in Program Standards to participate.
- Jurisdictions must agree to follow the training criteria specified in Program Standard 2, Steps 1 – 3 (includes use of a field training process and documentation similar to that contained in the CFP Field Training Manual and forms, Appendix B-2) with newly hired FSIOs while a participant in the Pilot Project.
- Jurisdictions must have a sufficient number of FSIOs that have successfully completed Standard 2, Steps 1-3 .
- Jurisdictions must make a commitment to meet the Pilot Project timelines, reporting protocols. and participate in conference calls.
- Jurisdictions must agree to publication of their participation in Pilot Project Report (note: individual responses will remain confidential).
- Any jurisdictions not selected will be notified.

Distribution of Pilot Project Package: All selected jurisdictions will receive an Electronic Pilot Project Package containing the following materials:

- Copy of newly revised Standard 2 – Trained Regulatory Staff(as approved by the 2010 biennial meeting of the Conference) and Standard #4 – Uniform Inspection Program
- Copy of the FDA Retail Food Level I Performance Audit process documents including instructions.
- Copy of the *CFP Field Training Manual*.
- Performance Audit Pilot Project protocol and timeline.
- Contact information for Performance Audit Pilot Project Director.

Launch of Pilot Project: Pilot Project will be initiated with a conference call of all participating jurisdictions. The purpose of the conference call will be to provide an overview of the Pilot Project objectives, goals, timeline, methodology, participant expectations, data collection, and other reporting criteria.

Interim Progress Review of Pilot Project: Participating jurisdictions will submit reporting documents completed to date to Pilot Project Director. Data will be analyzed and summarized to identify any potential challenges, omissions, or errors that would hinder completion of the project. Additionally, a conference call will be conducted with participating jurisdictions for additional verbal feedback and clarification.

Data Collection and Reporting: The design of the Data Collection and Reporting Instrument will incorporate the following:

- A questionnaire designed to solicit information.
- Demographical information
- Focus Group(s) designed to solicit additional anecdotal information and recommendations.

Roles and Responsibilities

The following roles and responsibilities are integral to this Pilot Project:

Role	Responsibility
Conference for Food Protection Certification of Food Safety Regulation Professionals Work Group	Staff all Pilot Project Activities, review the Pilot Project outcomes and make further recommendations to the Conference.
Pilot Project Subgroup	Prepare Pilot Project Package, prepare Fact Sheet, solicit jurisdictional participation, select participants, distribute Pilot Project Package, receive Pilot Project data from the Pilot Project Director, tabulate and analyze data, summarize the results of the Pilot Project and prepare the Pilot Project Report (including recommendations) for presentation to the 2012 biennial meeting of the Conference.
Pilot Project Director	Serve as the central point of contact for the Pilot Project, collect data and forward to the Pilot Project Subgroup, coordinate focus group meetings, and present Pilot Project findings to the Conference.
Jurisdictional Participants	Carry out the activities of the Pilot Project including following the criteria specified in <i>Retail Food Level I Performance Audit</i> documents. Jurisdictions must be active participants in the FDA Program Standards and will have met the requirements of Standard 2, Steps 1 – 3, relative to use of the <i>CFP Field Training Manual</i> ; must also be able to assess the feasibility of using the Audit documents with newly hired or existing FSIOs relative to applicability to Standard 4; completing the data reporting instruments; participating in focus group calls; agreeing to publication of Pilot Project participation; and providing feedback to the Pilot Project Subgroup.
Conference for Food Protection	Provide assistance as requested by the Work Group to disseminate and collect information.
FDA	Will collaborate with the Pilot Project Subgroup in the design and format of the Pilot Project, analysis of data, and subsequent recommendations for use and placement of the Audit documents and/or process.

Analysis of Data

The Pilot Project Subgroup will analyze the data by tabulating and summarizing all responses to the questionnaire and the focus group meetings. Based on the results of the Pilot Project, the Work Group will determine necessary or recommended changes that need to be made to the training/Audit documents and/or process.

Preparation of Pilot Project Report

A report of the results of the Pilot Project will be created. The report will include a summary of the results of the data tabulation (including participant list, demographics, and questionnaire results), a list of recommended changes to the Audit documents and a list of recommended changes to the Voluntary National Retail Food Regulatory Program Standards (Standard #2 and/or Standard #4). This report will be submitted to the 2012 biennial meeting of the Conference for Food Protection.

Additionally, Pilot Project results and recommendations will be developed in collaboration with FDA's Division of Human Resource Development to assist in the development of a performance assessment specific to the responsibilities of state, local and tribal retail food safety inspection officers.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 029
Issue: 2010 II-022**

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 for Food Protection (CFP) Program Standards Committee 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 and management of a retail food program in our continued goal of reducing foodborne illnesses and the promotion of active managerial control of all factors that may cause foodborne illness. This committee was formed to work with the FDA Clearinghouse Committee to clarify and address language issues currently found in the Standards.

Over the past two years, the Committee has worked with the FDA Clearinghouse Committee and the attached report outlines the process and culmination of their work.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the CFP Program Standards Committee Report;
2. Thanking the Committee members; and,
3. 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

Submitter Information:

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Attachments:

- "2008-2010 Program Standards Committee Final Report"
- "2008-2010 Program Standards Committee Roster"

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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: November 25, 2009

SUBMITTED BY: Liza Frias

COMMITTEE CHARGE(S):

1. Serve as a stakeholder group to provide input to an FDA internal working group which will be considering administrative functions such as:
 - A. The frequency of revision of the Program Standards document
 - B. Dissemination of changes to the Program Standards document and supporting tools and training materials
 - C. Effective dates/timeframes for meeting new requirements of the Standards
 - D. Mechanisms for encouraging timely self-assessments and audits by enrolled jurisdictions
 - E. Mechanisms for making changes to the PS documents
2. Formulate resolutions to issues brought before the Committee for language changes to the Program Standards prior to the 2010 CFP Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The 2008-2010 Program Standards Committee has met on a regular basis by conference call to discuss the issues brought forth by the FDA Clearinghouse Committee as identified in the committee charge.

Charge 1A – The frequency of revision to the Program Standards document

- The committee recommends that changes to the Program Standards be published every 2 years; however, the effective date for compliance by a jurisdiction would be every 5 years at their next self assessment. These changes have been included as part of the amendments to Standard 9 as attached (submitted as Issue titled: Amendment to Standard No. 9 Program Assessment).

Charge 1B - Dissemination of changes to the Program Standards document and its supporting tools and materials

- The committee recommends that FDA continue to send the Retail Resource Disk to all enrolled jurisdictions and a hard copy only if requested by an enrolled jurisdiction.
- The committee requests that the following documents be available on the FDA website:
 - Summary of Changes from 2007 and 2009
 - Two most current versions of the Program Standards (i.e. 2007, 2009)
 - Supplemental Tools and Materials
 - FDA Data Collection Manual

Charge 1C - Effective dates/timeframes for meeting new requirements to the Standards

The committee spent the majority of the two years working on Standard No. 9 to help clarify the parameters for both the self-assessment and verification audit. Through this review, the committee is recommending the addition of a new definition Self-Assessment Update (submitted as Issue titled: Proposed New

Definition for Voluntary Retail Food Regulatory Program Standards) and also amending Standard No. 9 (submitted as Issue titled: Amendment to Standard No. 9 Program Assessment).

Charge 1D - Mechanisms for encouraging timely self assessments (SAs) and audits by enrolled jurisdictions

The committee discussed how to encourage jurisdictions to participate in the Program Standards. The concern raised among the committee members was the financial commitment that is required and in these days where budgets are being reduced, the lack of adequate resources available to jurisdictions. The committee recommends that an issue be submitted requesting that the Conference send a letter 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 Regulatory Retail Program Standards to build the necessary infrastructure to assess, implement and audit program efforts to attain standards (submitted as Issue titled: Financial Support for Voluntary Retail Food Regulatory Program Standards).

Charge 1E -Need for additional changes or improvement to the Standards

The FDA Clearinghouse is working on changes to Standard No. 6. These changes were discussed by the Program Standards committee and will be submitted to the conference by the FDA Clearinghouse committee.

The NVEAIS Committee provided the Program Standards committee an update on July 23, 2009 regarding their proposed issue submission to amend Standard 5, FBI and Food Security Preparedness and Response to incorporate a recommendation to the outcome section of this standard that would encourage jurisdictions participation in the CDC National Voluntary Environmental Assessment Information System (NVEAIS). The Program Standards committee supported their recommendation.

Recommendation(s) for future charge:

The Committee recommends that the following charges be made to a re-instituted Program Standards Committee following the CFP 2010 Conference (submitted as Issue titled: Re-Create Program Standards Committee):

1. Serve as a stakeholder group to provide input to an FDA internal working group which will be considering administrative functions such as:
 - a. Criteria for verification auditors
 - b. Recommending additional changes or improvements to the Program Standards
2. Formulate resolutions to issues brought before the committee and report back to Conference at the 2012 CFP Biennial Meeting.

REQUESTED ACTION:

The Program Standards committee will submit five (5) issues at the 2010 Conference based on the recommendations of the committee. The issues are:

- Report – Program Standards Committee
- Proposed New Definition for Voluntary Retail Food Regulatory Program Standards;
- Amendment to Standard No. 9 Program Assessment; and
- Financial Support for Voluntary Retail Food Regulatory Program Standards
- Re-Create Program Standards Committee

ATTACHMENTS:

- Proposed New Definition for Voluntary Retail Food Regulatory Program Standards
- Proposed Amendment to Standard No. 9 Program Assessment
- Financial Support for Voluntary Retail Food Regulatory Program Standards
- Re-Create Program Standards Committee
- 2008-2010 Program Standard Committee Roster

Committee Name: Program Standards Committee 2010

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 031
Issue: 2010 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:

New Definition for Voluntary Retail Food Regulatory Program Standards

Issue you would like the Conference to consider:

The Program Standards Committee in collaboration with the FDA Clearinghouse Committee would like to add a new definition for "Self-Assessment Update" to the Program Standards in an effort to provide further clarification to the Program Standards.

Public Health Significance:

The definitions provided in the beginning of the Program Standards assist with the interpretation and application of the standards. The proposed changes will ensure that the Program Standards are more uniformly followed and applied.

Recommended Solution: The Conference recommends...:

that the Conference Chair send a letter to the FDA Commissioner requesting:

1. that the Definitions in the Program Standards be amended to include designation in numerical order, and
2. 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.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 032
Issue: 2010 II-024**

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

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Title:

Amendments to Program Standard No. 9 - Program Assessment

Issue you would like the Conference to consider:

Amend Program Standard No. 9 to provide jurisdictions with clarification on what a regulatory agency must achieve to be listed as an active participant of the Voluntary National Retail Food Regulatory Program Standards and how to meet and achieve Standard No 9.

Public Health Significance:

The committee was charged with looking at an effective way of meeting the needs of state, local, and tribal jurisdictions with respect to the FDA's current approach to establishing timelines with meeting new Program Standards and self assessments.

Currently, a jurisdiction that has not yet completed its self assessment must meet any new requirements in a revised Standard in order to achieve conformance with that Standard. Jurisdictions that already meet a certain Standard before the changes go into effect have a specific deadline to meet the requirements to continue meeting the standard. For instance, changes to Standard No. 2 were approved at the 2006 CFP Biennial Meeting. The effective date of these changes was January 1, 2007. Jurisdictions that previously met Standard 2 had to implement the changes for any new staff hired after January 1, 2007 in order to continue meeting the Standard.

Due to the current language included in Standard No. 9, a jurisdiction would not be encouraged to participate in the Voluntary National Retail Food Regulatory Program Standards due to the complex and often inability to complete the required self assessments in a two year time period.

The proposed language as submitted by the Program Standards Committee not only provides clarity on what a jurisdiction must complete to be listed as an active participant of the Program Standards, but also provides for flexibility and continued enhancement of a jurisdiction's food safety program within a reasonable time period.

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*.

Submitter Information:

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Attachments:

- "Proposed Amendments to Standard No. 9 Program Assessment"

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.

Proposed Amendments to Standard No. 9 – Program Assessment

Due to the amount of formatting and editing changes made and to allow for ease of reading, the language proposed below does not include underline/strike-out format. A full text of the existing language contained in Standard No. 9 can be found beginning on page 6 of this document.

STANDARD NO. 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 that:

- 1 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,
- 1 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,
- 1 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 an update to a SELF-ASSESSMENT and following any VERIFICATION AUDIT.

To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must assure that:

- 1 1. A RISK FACTOR STUDY (SURVEY) 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,
- 1 2. An analysis is made of the data collected and a report on the outcomes and conclusions of the RISK FACTOR STUDY (SURVEY) 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:

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 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, requests 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)*, is 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 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 assure that:

- A. A RISK FACTOR STUDY (SURVEY) and report on the occurrence of foodborne illness risk factors is completed. A RISK FACTOR STUDY (SURVEY) 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 (SURVEY) includes all facility types under regulation by the jurisdiction.

It is recommended that a jurisdiction's first RISK FACTOR STUDY (SURVEY) 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 (SURVEY) 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:

- 1 ○ Institutions – 1) Hospitals; 2) Nursing Homes; 3) Elementary Schools (K-5)
- 2 ○ Restaurants – 4) Full Service; 5) Fast Food
- 3 ○ 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.)

- D.** A jurisdiction may use routine inspection data or may conduct a separate data collection in completing a Risk Factor Study (Survey). 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.** 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 1. The completed Appendices (worksheets) for each Standard and supporting records,
- 2 2. Written reports on the occurrence of RISK FACTOR STUDIES (SURVEYS),
- 3 3. VERIFICATION AUDIT reports,
- 4 4. FDA National Registry Report (FDA Form 3519), and
- 5 5. Affidavit of Permission to Publish (FDA Form 3520).

Existing language

STANDARD NO. 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

1. For listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure:
 - A. That the program manager conducts an initial *self-assessment* within 12 months of the date of enrollment in the National Registry and every 36 months thereafter; and,
 - B. That a *verification audit* is conducted within 36 months of the initial *self-assessment*. Subsequent verification audits are conducted every 36 months thereafter.
2. For achievement of Standard 9, a jurisdiction must assure:
 - A. That a survey and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit; and
 - B. A survey on the occurrence of foodborne illness risk factors and *Food Code* interventions is conducted at least once every five years thereafter to measure trends specific to the occurrence of the risk factors and interventions.
3. Reporting by means of the FDA National Registry Report form.

Description of Requirement

For Listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that:

1. Self-Assessment

The program manager, or a designated representative, conducts an initial *self-assessment* of the retail food safety program within 12 months of the date of enrollment in the National Registry and every 36 months thereafter. The *self-assessment* will determine:

- A. The compliance status with each of the National Standards by completing the Appendix documents (hereafter referred to as the worksheets) or documents containing equivalent summary information for each Standard, and
- B. 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 are incomplete or provide inadequate information upon which to make a determination or to enable a verification audit, that standard is not met.

2. Verification Audit

The first *verification audit* is conducted within 36 months the initial *self-assessment*. An individual as defined in the definitions shall complete the verification audit. Subsequent verification audits are conducted every 36 months thereafter. Verification audits confirm and report on the accuracy of the *self-assessment* and the occurrence of risk factors and *Food Code* interventions survey reports. During the *verification audit*, the auditor will:

- A. Review the *quality records* and confirm that the *self-assessment* accurately reflects the current program compliance status in each of the program elements, and
- B. Confirm that the occurrence of risk factors survey collection procedures and survey tools similar to Appendix J have been used and that the conclusions are supported by the data.

3. Achievement of Standard 9

A jurisdiction must assure that a survey and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit. The survey information is updated at least once in every 5 years to measure trends specific to the occurrence of the risk factors and *Food Code* interventions. The subsequent surveys and reports will determine whether there has been a net change in the occurrence of the risk factors and use *Food Code* interventions.

A data collection instrument similar to the FDA model form referenced in 2.B., 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 study or with data from other jurisdictions.

4. Reporting

The FDA National Registry Report (Appendix I) will be completed and submitted to the appropriate FDA Regional office within 30 days following completion of the self-assessment, survey report on the occurrence of foodborne illness risk factors and *Food Code* interventions, verification audits, and/or survey of risk factor occurrence updates. The FDA National Registry listing will be updated using data contained in this report. A current Release and Permission to Publish Form must accompany each FDA National Registry Report.

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. Verification audit reports,
4. FDA National Registry Report, and
5. Affidavit of Permission to Publish.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 033
Issue: 2010 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:

Financial Support for Voluntary Retail Food Regulatory Program Standards

Issue you would like the Conference to consider:

Request financial support from the U.S. Food and Drug Administration for State, Territorial, Tribal, and Local Food Safety Agency adoption, assessment and implementation of the Voluntary National Retail Food Regulatory Program Standards.

Public Health Significance:

On July 7, 2009 the multi-agency Food Safety Working Group established by President Obama recommended a new public health focused approach to food safety based upon three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. An effective food safety system requires an integrated approach where the U.S. Food and Drug Administration (FDA) relies on the more than 3,000 state, territorial, tribal, and local food safety agencies to conduct food safety inspections across the food supply chain, monitor the safety of the food supply through sampling and testing, and conduct foodborne illness surveillance, response and recovery actions.

The Voluntary National Retail Food Regulatory Program Standards have been established by the FDA in collaboration with the Conference for Food Protection to establish a uniform foundation for the design and management of federal, state, territorial, tribal, and local food programs. The standards specify best practices and requirements for high quality food safety programs. The development and implementation of these programs are hampered by insufficient funding for non-federal food safety agency partners to develop the basic infrastructures necessary to implement uniform, protective, and effective food safety programs. The Voluntary National Retail Food Regulatory Program Standards effort also lack infrastructure and resources for conducting timely verification audits of program assessments.

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.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 040
Issue: 2010 II-034**

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

All information above the line is for conference use only.

Title:

Support & 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 Model Food Code. The cooperation and input of various stakeholders-including consumer, industry, and regulatory representatives-is crucial to the development of this important public health guidance document. Currently, consumer participation in the Conference is anemic, in part because of the financial cost of attending the Conference. Without adequate consumer participation, both the credibility and the substance of the Model 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 CFP, with a goal toward increasing consumer participation each cycle. Scholarships should be adequate to cover the cost of transportation to and from the conference, conference 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.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 046
Issue: 2010 II-004**

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

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Title:

Report - Inspection Form Scoring Committee

Issue you would like the Conference to consider:

The Inspection Form Scoring Committee seeks Council II's acknowledgement of its committee report.

Public Health Significance:

A model scoring system will provide a uniform method to communicate food establishment inspection scores to regulators, the public, and the regulated industry throughout the country. A uniform system will also assist regulators and the regulated industry in redirecting resources so they are prioritized on improving food employee behaviors and food preparation practices that minimize the risk of foodborne illness.

Recommended Solution: The Conference recommends...:

acknowledgement of the work of the Inspection Form Scoring Committee and to thank the committee for their hard work and dedication.

Submitter Information:

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Attachments:

- "Inspection Form Scoring Committee Final Report"

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2010 Conference for Food Protection Committee Final Report

COMMITTEE NAME: Inspection Form Scoring Committee

COUNCIL II

DATE OF REPORT: 11-20-09

SUBMITTED BY: Chuck Catlin, Liz Pozzebon

COMMITTEE CHARGE(S):

At the 2008 Biennial Meeting, CFP recommended the creation of the Inspection Form Scoring Committee after the Inspection Form Committee completed their charge. The new Inspection Form Scoring Committee was charged with the following:

- Develop a research proposal to:
 - Determine the most effective foodservice establishment scoring system, including the most effective way to communicate food establishment inspection scores to the general public, in advance of them choosing where to dine.
 - Identify possible funding sources and researchers to conduct the research. .
 - Report the committee's findings back to the conference at the 2010 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

This committee originally found a researcher in early March 2009 from Loma Linda University. However, due to the downturn in the economy, the Loma Linda team withdrew their draft research proposal since they would no longer be able to commit resources to the project as previously anticipated. A literature review was conducted by committee members to identify other potential researchers and the Inspection Form Committee Work Plan was developed. After the literature review, three potential researchers were identified.

1. Dr. Craig Hedberg of the University Of Minnesota School Of Public Health is a recognized foodborne disease epidemiologist and an accomplished researcher. Dr. Hedberg has assigned a graduate student to assist in developing the research proposal that will accomplish the objectives of the committee.
2. Dr. Douglas Powell, Associate Professor from Kansas State University, is a recognized food safety professor, proactive food safety information communicator, and an accomplished researcher. Dr. Powell has a graduate student who is working on a similar project in New Zealand and will assist in developing the research proposal that will accomplish the objectives of the committee.
3. Dr. Ben Chapman, Assistant Professor Food Safety Extension Specialist from North Carolina State University, is an accomplished researcher. Dr. Chapman has students in the University Extension courses that study food safety and can actively participate in research that will accomplish the objectives of the committee.

After numerous conference calls and other correspondence with the three researchers and graduate student from the University of Minnesota, it became apparent that the committee charge was so broad in scope that the researchers and the committee agreed that it is advantageous for the team of researchers to work together. The research team (the three researchers and graduate student) is in the process of developing a comprehensive grant application for the Fiscal Year 2010 National Institute of Food and Agriculture (NIFA) Integrated Research, Education, and Extension Competitive Grants Program--National Integrated Food Safety Initiative. The deadline for submission is during January 2010. The CFP Inspection Forms Scoring Committee prepared a letter of recommendation for the research team to support their application; this letter was reviewed and approved by the CFP Executive Director. The Project Title is: Using Restaurant Inspection as a tool for Improving Food Safety. If the application is successful, the grant has the potential to fund the entire research project. With the diversity of representation from across the country and the support of the Inspection Form Scoring Committee, the research proposal is not only more representative of public opinion, but also a much stronger contender for the coveted research grant funding.

OUTCOMES (for charges assigned to re-created committee):

1. By 2012, develop a scoring system for the FDA Model Food Establishment Inspection Report Form.
2. By 2012, develop a method to post inspection scores so the public has access to the information in advance of choosing where to dine and purchase food items.

The Scoring Committee developed a work plan and through a literature review, was successful in finding groups from three universities willing to conduct research in the areas identified in the committee objectives. The researchers are in the process of applying for grant funding through NIFA. If their grant application is not successful, alternate sources of funding will be pursued. The researchers are planning to begin their research during 2010 and 2011. With the results of the research in hand, the committee expects to complete it's objectives before February 2012.

REQUESTED ACTION

CFP recommends re-creating the Inspection Form Scoring Committee during 2010-2012 to:

1. Continue working with academic researchers to:
 - a. 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.
 - b. 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 them choosing where to dine and purchase food items.
 - c. Identify funding sources to conduct their research and provide a letter of support for funding already identified.
2. Report the committee's findings back to the conference at the 2012 Biennial Meeting.

Conference for Food Protection Scoring Committee Members

<u>Last Name</u>	<u>First Name</u>	<u>Position</u>	<u>Constituency</u>	<u>Telephone</u>
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Pozzebon	Liz	Co Chair	Regulatory - Local	(619) 338-2298
Brania	Jonathan	Member	Standards & Compliance	(916) 549-1766
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Davis	Douglas	Member	Industry-Food Service	(301) 380-5736
Ferko	Frank	Member	Industry-Food Service	(847) 232-5896
Gibson	Arian	Member	Regulatory – State	(202) 535-2346
Gilliam	A. Scott	Member	Industry-Food Service	(317)233-7360
Girard	Loma	Member	Regulatory – State	(651) 201-6591
Hardister	Bill	Member	Regulatory – Local	(704) 336-5533
Hargrave	Cheryn	Member	Industry-Retail Food Stores	(806) 791-0220
Huffman	Troy	Member	Industry-Food Service	(402) 471-0387
Lane	Janet	Member	Regulatory – Local	(713) 439-6267
Lawrence	Michael David	Member	Regulatory – Local	(703) 246-8435
Leever	Jeff	Member	Industry-Food Service	(407) 245-5861
LeMaster	Lori	Member	Regulatory – State	(615) 741-7206
Lorca	Tatiana	Member	Industry-Food Service	(540) 381-7968
Luebkekmann	Geoff	Member	Industry-Restaurant Association	((850) 879-2581
Mathis	Ric	Member	Other-Software Technology	(850) 245-4277
McGuffey	Charles E.	Member	Industry-Food Service	(972) 828-6844
Miles	Pamela	Member	Regulatory – State	(804) 786-0412
Morris	Sheri L.	Member	Regulatory – State	(717) 787-4315
Nesel	Nancy	Member	Industry-Food Service	(502) 874-8493
Paulus	Colleen	Member	Regulatory – State	(651) 201-4507
Penland	Cindy	Member	Regulatory – State	(828) 524-0415
Pippert	Eric	Member	Industry-Food Service	(971) 673-0453

Plante	Andrew	Member	Industry-Food Service	(972) 770-1778
Schnipke	Jill	Member	Industry-Food Service	
Sestak	Mark	Member	Regulatory – State	(334) 206-5375
Sharp	Roxanne	Member	Regulatory – Local	(417) 864-1426
Sherratt	Grant	Member	Other-Software Technology	(435) 656-5655
Stryker	Kimberly	Member	Regulatory – State	(907) 269-7628
Vergne	Sue	Member	Industry-Food Service	(858) 571-2171
Wagner	Kimberly	Member	Industry-Retail Food Stores	(508) 207-5769
Wallace	Susan M.	Member	Regulatory – State	(401) 598-1706
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Leong	Mary	Member	Regulatory – Federal	(718) 662-5536
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-

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 048
Issue: 2010 II-005**

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

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Title:

Re-create - Inspection Form Scoring Committee

Issue you would like the Conference to consider:

The Conference recommends re-creating the Inspection Form Scoring Committee during 2010-2012 to further develop a model scoring system as outlined in the charges below.

Public Health Significance:

A model scoring system will provide a uniform method to communicate food establishment inspection scores to regulators, the public, and the regulated industry throughout the country. A uniform system will also assist regulators and the regulated industry in redirecting resources so they are prioritized on improving food employee behaviors and food preparation practices that minimize the risk of foodborne illness.

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.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 049
Issue: 2010 II-030**

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

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Title:

Expand archive & posting capabilities of CFP approved documents

Issue you would like the Conference to consider:

To expand archive and posting capabilities to include Portable Document Format (PDF) and the original editable format of all Conference approved documents, guides and presentations; and modifications of documents or attachments that occur after Issue packets are posted, including changes made during and after Council deliberations at the Biennial Meetings.

Public Health Significance:

Conference committees made up of all stakeholders have produced excellent educational products through various guidelines, documents and presentations throughout the years. Unfortunately, because of the complexity of the review, deliberation, and approval process, many of those very tools have been under utilized because the Conference has only captured information as a PDF file. Presentations are difficult to use in PDF format and speaker notes are lost completely leaving the user to either re-create the presentation and notes that may fail to capture the intent of the original; or users spend valuable time trying to track down the original creators of the presentation or document in question. For example: original authors (e.g., committee chairs) may no longer be involved with the Conference and the original editable or readily usable presentation or document can no longer be located.

It is important to be able to capture not only Conference approved guidance documents in both PDF and an editable format (e.g., Word), but to also capture and archive the final version of documents modified during and after deliberation at the Biennial Meetings. It is often confusing after the Biennial Meeting as to what the final outcome was of a particular document.

The process currently does not accommodate revisions made to documents after issues have been submitted to Council. For example, if an attachment is revised during a Committee meeting immediately preceding the Biennial Meeting, the revised documents are NOT formally captured anywhere by the Conference. Currently, the ONLY documentation retained from the deliberation process is the final wording within an "Issue Recommendation" and does not include attachments referenced in that recommendation.

Because the revised documents do not currently become part of the CFP archives, confusion results when revisions have been made to Issue content attachments.

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.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 051
Issue: 2010 II-006**

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

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Title:

Report - Electronic Reporting Committee

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Electronic Reporting Committee seeks Council II to acknowledge the committee report and thank the committee for completed work.

Public Health Significance:

The 2008 CFP Biennial Meeting created a new committee - Electronic Reporting Committee and gave the following charges (2008 II-036):

Charge 1: Consider options to make the results of the "Best Practices and Lessons Learned" as identified in the 2006-2008 Electronic Data Capture and Reporting Committee Survey 2 available to jurisdictions considering an electronic data capture system.

Charge 2: Conduct research into the feasibility of providing an anonymous, central electronic database for the collection of electronic data from jurisdictions across the country.

Charge 3: Work with jurisdictions to create a pilot project for collection of inspection data and include it in an anonymous test database and identify any challenges associated with such database development.

The 2008-2010 committee felt very strongly that 2006-2008 Electronic Data Capture and Reporting Committee Survey be made available from the CFP website in an easier way by placing a more prominent link. Creating an anonymous database will be very valuable to participating agencies and the food service industry. Data collection and analysis has important values within any regulatory program that are currently collecting their food inspection data electronically. Due to the current economic status of many agencies, the committee feels that CFP should wait for Food and Drug Administration (FDA) to determine the results of the next phase of baseline survey based on Center for Disease Control (CDC) contributing factors to foodborne illness. After FDA formulates their plan, CFP should pursue charges 2 and 3 through the continued committee.

Recommended Solution: The Conference recommends...:

1. acknowledgement of the Electronic Reporting Committee final report,
2. thanking the committee members for completed work; and

3. that a more prominent link be provided on the CFP web site to the 2006-2008 Electronic Data Capture and Reporting Committee Survey.

Submitter Information:

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Attachments:

- "Electronic Reporting Committee Final Report"
- "Committee Roster"

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**Conference for Food Protection
FINAL REPORT
Electronic Reporting Committee**

2008-2010 Electronic Reporting Committee.

Council II

DATE OF REPORT: December 1, 2009

**SUBMITTED BY:
Chirag H. Bhatt, RS
Electronic Reporting Committee Chair**

**Kim Stryker
Electronic Reporting Committee Co-Chair**

COMMITTEE CHARGES:

Charge 1: Consider options to make the results of the "Best Practices and Lessons Learned" as identified in the 2006-2008 Electronic Data Capture and Reporting Committee Survey 2 available to jurisdictions considering an electronic data capture system.

Charge 2: Conduct research into the feasibility of providing an anonymous, central electronic database for the collection of electronic data from jurisdictions across the country.

Charge 3: Work with jurisdictions to create a pilot project for collection of inspection data and include it in an anonymous test database and identify any challenges associated with such database development.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The 2006 Biennial Meeting recognized that after the creation of the standardized FDA Food Inspection Report Form the next step was to make it available electronically. Conference further recognized that regulatory agencies may be interested in capturing inspection data in an electronic format, and that this information could then be compiled into an anonymous national database for the purpose of research.

This committee was created to compile information regarding the software packages currently in use, development and implementation of these programs, costs, elements for incorporation into a single uniform electronic database to benefit all regulatory agencies, etc. Surveys of regulatory agencies were compiled in the 2006 – 2008 *Electronic Data Capture and Reporting Committee Final Report*.

The 2008 Conference created a new committee – Electronic Reporting Committee and gave the charges as described above (2008 II-036).

The committee met via conference calls 6 times. The calls were conducted during October 2008, January 2009, February 2009, May 2009, July 2009 and October 2009. A Google group site was also created and used by the members to post messages, files, web-links. Additionally, a draft request for proposal for database development was initiated and will be shared with the re-created committee.

The 2008-2010 committee felt very strongly that 2006-2008 Electronic Data Capture and Reporting Committee Survey be made available from the CFP website in an easier way by placing a more prominent link. The 2008-2010 Committee feels that creating such an anonymous database will be very valuable to participating agencies and the food service industry. Data collection and analysis has important values within any regulatory program that are currently collecting their food inspection data electronically. Due to the current economic status of many

agencies, the committee feels that Conference wait for Food and Drug Administration (FDA) to determine next phase of conducting baseline survey (based on CDC contributing factors to foodborne illness).

The committee recommends that Charge #1 be addressed by providing a more prominent link on the CFP web site to the 2006-2008 Electronic Data Capture and Reporting Committee Survey; and that charge #2 and #3 be pursued after FDA formulates their plan.

REQUESTED ACTION:

The committee will submit the following issues at the 2010 Conference.

- 1) Acknowledgement of the committee report and thank the committee for completed work. (*see Issue titled: Report – Electronic Reporting Committee*)
- 2) Continue the Electronic Reporting Committee to work with Conference and others to discuss the benefits of creating an anonymous data base and maintaining it. (*see Issue titled: Re-Create – Electronic Reporting Committee*)

COMMITTEE MEMBER ROSTER:

Attached

Committee Name:
Electronic Reporting Committee

Last Name	First Name	Position	Constituency	Employer	Address	City	State	Zip	Telephone	Email
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Juarez	Padraic	Member	Local	Florida Dept of Health	48 Oak Street	Crawfordville	FL	32327	(850) 926-2558	padraic_Juarez@doh.state.fl.us
Yamnik	Dale	Member	Ind (FS)	Yum Brands	542 Eaglestone Drive	Castle Rock	CO	80104	(303) 708-1536	dale.yamnik@yum.com
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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 053
Issue: 2010 II-007**

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

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Title:

Re-create - Electronic Reporting Committee

Issue you would like the Conference to consider:

Re-create the Electronic Reporting Committee to work with Conference on the Request for Proposal for an anonymous database and continue in order to complete all charges issued to this committee and secure consensus among all committee members.

Public Health Significance:

The 2006 CFP Biennial Meeting recognized that after the creation of the standardized Inspection Report Form the next step was to make it available electronically. Conference further recognized that regulatory agencies may be interested in capturing inspection data in an electronic format, and that this information could then be compiled into an anonymous national database for the purpose of research. This committee was originally created to compile information regarding the software packages currently in use, development and implementation of these programs, costs, elements for incorporation into a single uniform electronic database to benefit all regulatory agencies, etc. Surveys of regulatory agencies were compiled in the 2006 - 2008 Electronic Data Capture and Reporting Committee Final Report.

The 2008 CFP Biennial Meeting created a new committee - Electronic Reporting Committee and gave 3 charges:

Charge 1: Consider options to make the results of the "Best Practices and Lessons Learned" as identified in the 2006-2008 Electronic Data Capture and Reporting Committee Survey 2 available to jurisdictions considering an electronic data capture system.

Charge 2: Conduct research into the feasibility of providing an anonymous, central electronic database for the collection of electronic data from jurisdictions across the country.

Charge 3: Work with jurisdictions to create a pilot project for collection of inspection data and include it in an anonymous test database and identify any challenges associated with such database development.

The 2008-2010 committee felt very strongly that 2006-2008 Electronic Data Capture and Reporting Committee Survey be made available from the CFP website in an easier way by placing a more prominent link. Creating an anonymous database will be very valuable to participating agencies and the food service industry. Data collection and analysis has

important values within any regulatory program that are currently collecting their food inspection data electronically. Due to the current economic status of many agencies, the committee feels that CFP should wait for Food and Drug Administration (FDA) to determine the results of the next phase of baseline survey based on Center for Disease Control (CDC) contributing factors to foodborne illness. After FDA formulates their plan, CFP should pursue charges 2 and 3 through the continued committee.

Recommended Solution: The Conference recommends...:

To re-create the Electronic Reporting Committee to work and develop a Request for Proposal for an anonymous data base after Food and Drug Administration (FDA) formulates future baseline survey plans and that the following charges then be pursued:

- Conduct research into the feasibility of providing an anonymous, central electronic database for the collection of electronic data from jurisdictions across the country.
- Work with jurisdictions to create a pilot project for collection of inspection data and include it in an anonymous test database and identify any challenges associated with such database development.
- Report back to the 2012 Biennial Meeting.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 055
Issue: 2010 II-031**

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

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Title:

Coordination of the two current FDA food program standards

Issue you would like the Conference to consider:

Harmonization of the 1) FDA Voluntary National Retail Food Regulatory Program Standards and the 2) FDA Manufactured Food Regulatory Program Standards.

Public Health Significance:

The goal in setting program standards is to provide a "standard" where all regulatory jurisdictions throughout the nation have the opportunity to enroll in a program that follows a structure, promotes uniformity, and provides best practice principles in food safety.

Currently, the FDA has created two sets of program standards: one for retail food programs and one for manufactured foods. While, each set of standards are designed for a specific segment of the food chain and there are differences integral to each process; there are areas that can be coordinated. There are jurisdictions that regulate both retail and manufacturing within the same inspection framework. For those jurisdictions, complying with and maintaining two distinct and separate sets of standards is proving to be labor intensive and not cost effective. There are components in each set of standards that can benefit the other and there are components in each set of standards that can be captured in the same format.

Although the Conference for Food Protection has placed emphasis in the retail arena, the Conference recognizes the need to promote food safety and food safety programs throughout the food chain. There already is recognition and inclusion within the CFP governing documents of food processing and manufacturing and the impact manufacturing has on retail food.

The Constitution and By-laws of the Conference for Food Protection state the following:

"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;...."

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;

Article IV Composition of Organizational Components and Eligibility Requirements for Service in Official Capacities

Six (6) members from the food industry with at least one (1) each representing food processing, food service, retail food stores and food vending;

Recommended Solution: The Conference recommends...:

that a work group be created within the Program Standards Committee to:

1. Work with the FDA and the Association of Food and Drug Officials Manufactured Food Regulatory Program Standards Workgroup to study the differences and likenesses of both the Retail Food Regulatory Program Standards and the Manufactured Food Regulatory Program Standards,
2. identify areas where harmonization can be achieved,
3. make recommendations based on their findings, and
4. report back to the 2012 Biennial Meeting.

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Attachments:

- "A - Manufactured Food Regulatory Program Standards"
- "B. Part 1 Voluntary National Retail Food Regulatory Program Standards"
- "B. Part 2 Voluntary National Retail Food Regulatory Program Standards"
- "B. Part 3 Voluntary National Retail Food Regulatory Program Standards"

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Manufactured Food Regulatory Program Standards



The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and has been assigned OMB control number 0910-0601.

The document can be viewed at:

http://www.fda.gov/ora/fed_state/default.htm

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U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

May 2007

INTRODUCTION

The Manufactured Food Regulatory Program Standards (program standards) establish a uniform foundation for the design and management of State programs¹ responsible for the regulation of food plants. The elements of the program standards describe best practices of a high-quality regulatory program. Achieving conformance with them will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation.

The program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets and certain standards have supplemental worksheets and forms for determining a level of conformance with such standards. The State program is not required to use the forms and worksheets contained herein; however, alternate forms should be comparable to the forms and worksheets for program standards. These program standards do not address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

FDA will use the program standards as a tool to improve contracts with States. The program standards will assist both FDA and the States in fulfilling their regulatory obligations. The implementation of the program standards will be negotiated as an option for payment under the State contract. States that are awarded this option will be expected to implement the program standards to evaluate and improve their manufactured food program. FDA recognizes that full use and implementation of the program standards by those States will take several years. Such States will, however, be expected to implement improvement plans to demonstrate that they are moving toward full implementation.

The goal is to implement a risk-based food safety program by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help Federal and State programs better direct their regulatory activities at reducing foodborne illness hazards in food plants. Consequently, the safety and security of the United States food supply will improve.

The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and has been assigned OMB control number 0910-0601.

BACKGROUND

The food safety regulatory system in the United States is a tiered system that involves Federal, State, and local governments. The Food and Drug Administration (FDA) is responsible for ensuring that all foods moving in interstate commerce, except those under United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies conduct inspection and regulatory activities that help ensure that safe food is produced, processed, or sold within their jurisdictions. Many State agencies also conduct food plant inspections under contract with the FDA. These inspections are performed under the States' laws and authorities or the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or both. To maximize

¹ Program defined as an operational unit(s) that is responsible for the regulatory oversight of food plants.

the use of resources among the FDA and the State governments, particularly when their jurisdictions overlap, their inspection programs should be equivalent in effect.

In June 2000, the Department of Health and Human Services' Office of the Inspector General (OIG) released a report of FDA's oversight of State contracts. In this report, the OIG recommended that [FDA] take steps to promote "equivalency among Federal and State food safety standards, inspection programs, and enforcement practices."² In response to their findings, FDA established a committee to develop a set of quality standards for manufactured food regulatory programs. The committee was comprised of officials from FDA and from State agencies responsible for the regulation and inspection of food plants³.

² Office of Inspector General, *FDA Oversight of State Food Firm Inspections: OEI-01-98-00400* (Department of Health and Human Services, 2000), p. 5.

³ A building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food as defined by 21 CFR Part 110.3 (k) .

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STANDARD No. 1 Regulatory Foundation

1.1 Purpose

This standard describes the elements of the regulatory foundation⁴ used by a State program to regulate food plants.

1.2 Requirement Summary

The State program has the legal authority and regulatory provisions to perform inspections and investigations, gather evidence, collect samples, and take enforcement actions under Federal and State laws.

1.3 Program Elements

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⁴ Laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of a food plant or manufacturing establishment.

- a. The State program has the legal authority to inspect food plants, gather evidence, collect and analyze samples, and take enforcement actions for adulteration or misbranding of foods equivalent in effect to sections of the FD&C Act specified in appendix 1.
- b. The State program enforces regulatory provisions equivalent in effect to the corresponding Federal regulations specified in appendix 1. In the absence of a corresponding law or regulation, the State program will explain how equivalent regulatory authority is met in appendix 1.
- c. The State program uses its laws and regulations to broaden its scope of regulatory authority.

1.4 Outcome

The State program has the legal authority and regulatory provisions to protect the public health by ensuring the safety and security of the food supply.

1.5 Documentation

The State program maintains the records listed here.

- Appendix 1 Self-assessment worksheet
- The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the operation of food plants, (2) delegate authority to the State agency, and (3) stipulate the process by which the State agency establishes its authority, for example, the administrative rulemaking process

STANDARD No. 2 Training Program

2.1 Purpose

This standard defines the essential elements of a training program for inspectors.

2.2 Requirement Summary

The State program has a training plan that ensures all inspectors receive training required to adequately perform their work assignments. The plan provides for basic and advanced food inspection training as well as continued training for professional development in the field of food processing.

2.3 Program Elements

The State program maintains a history of the training provided to all inspectors. Appendix 2.1 may be used to document all training provided to inspectors. Or, the training history may be recorded and retained electronically.

The State program provides, or otherwise makes available, inspection training for all inspectors. A training record similar to appendix 2.2 is maintained.

a. Basic Food Inspection Training

The State program requires that each inspector complete a basic food inspection training curriculum that consists of coursework and field training described here.

Coursework

The State program requires each inspector to complete coursework in the following areas within 24 months of his or her start date with the State program.

- Prevailing statutes, regulations, and ordinances
- Public health principles
- Food defense awareness training
- Communications skills
- Microbiology
- Epidemiology
- Basics of HACCP
- Basic labeling
- Control of allergens

Coursework is obtained from sources listed here.

- In-house training provided by a government agency
- Distance learning, for example, satellite downlinks or web-based training⁵
- Colleges, schools, and research centers

Field training

The State program requires that each inspector participate in a minimum of ten joint inspections with a qualified trainer and receive a minimum of two acceptable evaluations from the trainer. Joint inspections are conducted in firms that are representative of the food plants in the State program's establishment inventory. Each inspector will complete the minimum field training requirements within 18 months of his or her start date with the State program and prior to conducting independent inspections.

b. Advanced Food Inspection Training

The State program requires each inspector who will conduct specialized food inspections to complete an advanced inspection training curriculum that consists of relevant coursework and field training as described here.

Coursework

The State program requires each inspector who will perform specialized food inspections to complete coursework listed here for such inspections.

- Applications of epidemiology & foodborne illness investigations
- Traceback investigations
- Nutrition labeling
- Acidified foods
- Low acid canned foods
- Principles of juice HACCP
- Principles of seafood HACCP

Field training

The State program requires that each inspector who will conduct specialized food inspections participate in three joint inspections with a qualified trainer and receive a minimum of two acceptable evaluations from the trainer. The joint inspections are conducted in food plants representative of the specialty area. The inspector will complete the minimum field training requirements prior to performing independent inspections.

c. Continuing education

The State program requires that each inspector participate in continuing education that includes coursework and inspections. Every 36-month interval, each inspector is required to receive 36 contact hours of classroom training and participate in at least two joint inspections with a qualified trainer. These joint inspections are

⁵ FDA/ORU classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html

intended to assist the inspector with applying what was learned in the classroom to what should be covered during an inspection.

[Note: The 36-month continuing education interval starts when the basic training cycle is complete -- 24 months after the employee's start date.]

One contact hour is earned for each hour of participation in the continuing education activities from sources described in Section 2.3a.

2.4 Outcome

The State program has trained inspectors with the knowledge, skills, and abilities to competently inspect food plants.

2.5 Documentation

The State program maintains the records listed here.

- Appendix 2.1 Self-assessment worksheet
- Appendix 2.2 Individual training record
- Documents verifying successful completion of required courses
- Course description, if necessary
- Field training and evaluations
- Continuing education certificates

STANDARD No. 3

Inspection Program

3.1 Purpose

This standard describes the elements of an effective inspection program for food plants.

3.2 Requirement Summary

The State program has an inspection system. This system provides the foundation for inspection of food plants to determine compliance with the laws administered by Federal, State, and local governments. In addition, the State program has: (1) an established recall system, (2) a system to respond appropriately to consumer complaints, (3) a system to resolve industry complaints about inspections, and (4) a recordkeeping system for all elements of the inspection program.

3.3 Program Elements

a. Risk-based inspection program

The State program maintains an accurate inventory of its food plants. The inventory is categorized by the degree of risk associated with the likelihood that a food safety or defense incident will occur. Inspections are prioritized, frequencies assigned, and resources allocated based on risk categories assigned to a food plant or product, the manufacturing processes, and the inspection history of the food plant. Appendix 3.2 contains examples of factors that may be considered in defining risk categories.

b. Inspection protocol

The State program has written policies and procedures for inspecting food plants that require the inspectors to:

1. Review the previous inspection report and consumer complaints
2. Have appropriate equipment⁶ and forms needed to conduct inspections
3. Establish [FDA] jurisdiction
4. Select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the plant is producing
5. Assess employee activities critical to the safe and sanitary production and storage of food
6. Properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded
7. Recognize significant violative conditions or practices if present and record findings consistent with State program procedures
8. Distinguish between significant and insignificant observations, and isolated incidents versus trends
9. Review and evaluate the appropriate records and procedures for the establishment's operation and effectively apply the information obtained from this review [during the inspection]
10. Collect adequate evidence and documentation to support inspection observations in accordance with State program procedures
11. Verify correction of deficiencies identified during the previous inspection
12. Behave professionally and demonstrate proper sanitary practices during the inspection

⁶ Standard number 8, appendix 8.3 Inspection Equipment

As appropriate for seafood and juice processors subject to HACCP regulations:

13. Use the *Fish and Fishery Products Hazards and Controls Guide* or the *Juice HACCP Hazards and Controls Guide*, when and as appropriate, to identify and evaluate the hazards associated with the product and process
 14. Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation
 15. Review the firm's HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring verification and corrective action records, including those related to sanitation
 16. Recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations
17. Make appropriate introductions, and explain the purpose and scope of the inspection
 18. Use suitable interviewing techniques
 19. Explain findings clearly and adequately throughout the inspection
 20. Alert the firm's person in charge when an immediate corrective action is necessary
 21. Answer questions and provide information in an appropriate manner
 22. Write findings accurately, clearly, and concisely on the State document and provide a copy to the firm's person in charge

c. Food recalls

The State program has a food recall system.

The State program has written recall procedures for:

1. Sharing information about recalls with affected government agencies
2. Promptly removing recalled food products from the market
3. Performing recall audit checks
4. Identifying and maintaining records about essential recall information

d. Consumer complaints

The State program has a system for handling consumer complaints. The system contains written procedures for receiving, tracking, evaluating, answering, closing, and maintaining records of consumer complaints.

e. Food industry inspection complaints

The State program has a system to resolve industry complaints about inspections. The system contains written procedures for receiving, evaluating, answering, and maintaining records of industry complaints about inspections.

3.4 Outcome

The State program has an inspection program that reduces the occurrence of foodborne illness, injury, or allergic reaction by:

1. Focusing inspection resources on high risk plants, products, and processes
2. Obtaining immediate corrections and long-term improvements by manufactured food processors
3. Responding efficiently to prevent unsafe products from reaching consumers or to remove unsafe food from the human food system

3.5 Documentation

The State program maintains the records listed here.

- Appendix 3.1 Self-assessment worksheet
- An official establishment inventory of food plants
- Written procedures and rationale used for grouping establishments based on food safety risk, including the inspection frequency assigned to each defined risk-based establishment category
- Inspection policies and procedures including guidelines for performing inspections that require immediate corrective action and re-inspection
- Written procedures for food recalls, consumer complaints, and industry complaints about inspections
- Records for the three previous years, including inspection reports and reports pertaining to food recalls and follow-up activities, consumer complaints, and industry complaints about inspections

STANDARD No. 4

Inspection Audit Program

4.1 Purpose

This standard describes the basic quality assurance reviews necessary to: (1) evaluate the effectiveness of the inspection program, (2) recognize trends in inspectional coverage, and (3) identify best practices used to achieve quality inspections and sample collections.

4.2 Requirement Summary

The State program conducts quality assurance reviews to assess the effectiveness of its inspections and sample collections. The data used to determine such performance is obtained from observing an inspector conducting an inspection and the inspector's written reports. This standard is not intended, however, to evaluate individual performance.

4.3 Program Elements

The State program implements a quality assurance program (QAP) that identifies elements of its inspection and sample collection processes that need improvement. The QAP has two components: (1) a field audit component, which is an on-site performance evaluation of inspections and (2) a desk audit component, which is a performance review of the written reports of inspections and sample collections. Worksheets 4.2, 4.3, and 4.4 will be used to: (1) calculate an overall audit rating for each review (field inspection performance and written reports of inspections and samples collections) and (2) evaluate ratings for a single performance factor. Managers use the ratings to identify specific aspects of its inspection program that need improvement. Performance ratings that fall below 80 percent indicate a need for improvement and require corrective action.

The State program compiles and summarizes the results of the field and desk audits annually and determines an overall performance rating, which is reported on the self-assessment worksheet (appendix 4.1). The results of the audits are evaluated every 36 months to: (1) determine the effectiveness of the food inspection program, (2) recognize trends in inspectional coverage, and (3) identify best practices used to achieve quality inspections and sample collections.

The worksheets in appendices 4.1-4.8 are used to record and summarize audit findings. Or, the State program may use comparable worksheets to record audit findings.

a. Field Inspection Audit

Supervisory inspector, senior inspector, or team leader conducts field inspection audits to verify that inspections are consistently performed according to the established policies and procedures. The quality of each inspection is audited using the performance factors identified on appendix 4.5. An overall rating for field inspection performance is calculated using worksheet 4.2.

Frequency The QAP requires a minimum of two field inspection audits of each inspector be conducted every 36 months. Inspections selected for audit should include high-risk food firms such as seafood facilities, juice processors, and low-acid canned food operations.

Performance Documentation Appendices 4.5 and 4.2 (including worksheet 4.2)

Performance Factors Inspection procedures and policies described in standard number 3 and appendix 4.5

b. Inspection Report Audit

The QAP requires periodic review of inspection reports to verify that inspectional findings are obtained and reported according to established procedures and policies. The quality of each inspection report is audited using the performance factors listed in appendix 4.6. An overall inspection report rating is calculated using worksheet 4.3.

Frequency The State program determines the number of reports for review based on its inventory of food plants and the number of inspections completed in the past 12 months. At least 75 reports are randomly selected across inspectors and supervisors, and geographical locations. If less than 75 inspections were conducted, all inspection reports will be reviewed.

Performance Documentation Appendices 4.6 and 4.3 (including worksheet 4.3)

Performance Factors Performance factors listed on appendix 4.6, and policies and procedures established by the State program.

c. Sample Report Audit

The QAP requires periodic review of sample reports to verify that samples were properly collected, identified, and submitted according to established procedures and policies and that appropriate information was recorded. The quality of each sample report is audited using the performance factors listed in appendix 4.7. An overall sample report rating is calculated using worksheet 4.4.

Frequency	The State program determines the number of reports for review based on the number of samples collected in the past 12 months. At least 75 reports are randomly selected across inspectors and supervisors, and according to sample type, for example, microbiology, aflatoxin, or low-acid canned foods. If less than 75 samples were collected, all reports will be reviewed.
Performance Documentation	Appendices 4.7 and 4.4 (including worksheet 4.4)
Performance Factors	Performance factors listed in appendix 4.7, and policies and procedures established by the State program.

d. Corrective Action Plan

A corrective action plan is required when an overall audit rating or the rating for an individual performance factor falls below 80 percent. Appendix 4.8 is used to document how the deficiency was corrected.

4.4 Outcome

The State program systematically evaluates and improves its inspection and sample collection systems to ensure that activities and information are accurate, complete, and comply with the jurisdiction's procedures and policies.

4.5 Documentation

The State program maintains the records listed here.

- Written procedures that describe the quality assurance program
- Appendix 4.1 Self-assessment worksheet
- Appendix 4.2 Summary of field inspection audit findings (includes worksheet 4.2)
- Appendix 4.3 Summary of inspection report audit findings (includes worksheet 4.3)

- Appendix 4.4 Summary of sample report audit findings (includes worksheet 4.4)
- Appendix 4.5 Contract Audit - FDA Form 3610
- Appendix 4.5a Guidance for completing contract audit form
- Appendix 4.6 Inspection report audit form
- Appendix 4.7 Sample report audit form
- Appendix 4.8 Corrective action plan (includes table 4.8)

STANDARD No. 5
Food-related Illness and Outbreaks
And
Food Defense Preparedness and Response

5.1 Purpose

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate that may result in illness, injury, and outbreaks. It also applies to the collection, analysis, and dissemination of information that may prevent their recurrence.

5.2 Requirement Summary

The State program establishes systems to:

- a. Use epidemiological information supplied by local, State, or Federal agencies to detect incidents or outbreaks of foodborne illness or injury
- b. Investigate reports of illness, injury, and suspected outbreaks
- c. Correlate and analyze data
- d. Disseminate public information
- e. Distribute outbreak reports and surveillance summaries to relevant agencies
- f. Disseminate current guidance to industry on food defense
- g. Provide guidance for immediate notification of law enforcement agencies when intentional food contamination or terrorism is suspected or threatened
- h. Collaborate as necessary with FDA and other Federal authorities under conditions of increased threat of intentional contamination

5.3 Program Elements

A State program complies with this standard either by performing all of the required elements or by contracting (or signing a memorandum of understanding) with another State agency to perform, coordinate, and/or communicate foodborne illness support activities.

If a State program contracts for support of foodborne illness or injury investigations, it will:

- a. Develop and coordinate the operation of written support service agreements between the food program and the epidemiology support program.
- b. Ensure the support service contract or agreement identifies and describes the roles, duties, and responsibilities of each program for: (1) receiving reports of foodborne illness or injury, (2) performing investigational activities to identify the source of the problem, (3) reporting and recording the results of the investigations, (4) containing or mitigating the incident, and (5) preventing recurrence.

Whether foodborne illness support activities are performed by the State program or under a contractual agreement, it must have [or contract for] a system to:

- a. Conduct illness or injury investigations and collect information using established epidemiology procedures similar to those found in the “*International Association for Food Protection Procedures to Investigate a Foodborne Illnesses, Fifth Edition*”
- b. Provide laboratory support⁷ for investigations of illness, injury, or outbreaks
- c. Maintain a current list of relevant agencies and emergency contacts
- d. Coordinate the traceback and trace-forward of food implicated in an illness, injury, or outbreak
- e. Identify contributing factors for reports of illness, injury, or incidents implicating food
- f. Maintain investigational findings
- g. Distribute the final report of illness or injury implicating food to relevant agencies, e.g. the State epidemiologist and Centers for Disease Control
- h. Immediately notify all relevant agencies if intentional contamination is suspected or threatened, e.g. tampering or terrorism
- i. Establish criteria for releasing information to the public (includes identifying a media person and developing guidelines for coordinating media information with other jurisdictions)
- j. Mitigate and contain food-related illness and injury using enforcement activities and public awareness programs
- k. Provide guidance to prevent or reduce the incidence of food-related illness, injury, and intentional contamination, e.g. tampering or terrorism
- l. Collaborate as necessary with FDA and other Federal authorities under conditions of increased threat or intentional contamination

5.4 Outcome

The State program has a system for surveillance, investigation, response, documentation, analysis, and communication of alleged food-related illnesses, injuries, and unintentional or deliberate food contamination.

5.5 Documentation

The program maintains the records listed here.

- Appendix 5.1 Self-assessment worksheet
- A written description of epidemiology support available or an agreement⁸ that outlines epidemiology support
- A complaint log or database
- Current emergency contact list for communicating with all relevant agencies
- Procedure and contact person for releasing information to the public
- Documented timeframes for responding to complaints
- The illness, injury, or outbreak response procedures and the data collection forms
- Policies and procedures for handling incidents and threats of deliberate contamination and for collaborations with FDA and other Federal authorities under conditions of increased threat or intentional contamination

⁷ Specific requirements for laboratory support are contained in standard number 10.

⁸ Appendix 5.2 is an example of an agreement for epidemiology support between a State department of agriculture and the State health department.

- Written agreements that identify and describe sources of supplemental laboratory capacity and expertise including laboratory support⁹ to detect contaminants not normally found in food
- Investigation reports and summaries

⁹ Standard number 10 describes the elements of laboratory support for a manufactured food regulatory program.

STANDARD No. 6

Compliance and Enforcement Program

6.1 Purpose

This standard describes the State agency's strategies, procedures, and actions to enforce the laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program.

6.2 Requirement Summary

The State program has a compliance and enforcement program, which describes its compliance strategy and procedures. It also audits its conformance to established compliance procedures and identifies areas that need improvement and may require procedural changes.

6.3 Program Elements

The State program has a compliance and enforcement program that: (1) contains enforcement strategies, (2) tracks critical and chronic violations and violators, (3) uses a risk-based system to determine when a directed investigation, follow-up, or re-inspection is needed, (4) establishes a timeline for progressive actions, and (5) has a system to communicate verbal and written policy and guidance to managerial and non-managerial staff. Appendix 6.1 is used to describe the compliance and enforcement program.

The State program conducts a performance review of enforcement actions. A summary of enforcement actions¹⁰ is compiled and an overall rating is calculated using worksheet 6.2. Performance ratings that fall below 80 percent indicate a need for improvement and require corrective action.

Frequency

The audit is conducted every 12 months. The results of the audit will be included in the 36 month overall assessment of the State program's performance vis-à-vis the program standards.

10

1

Actions in the enforcement strategy may include, but are not limited to:

- Preventive actions such as promoting voluntary compliance through education program and consultation;
- Field actions such as verbal warnings, documented warnings, re-inspections, and product embargos;
- Supervisory/management actions such as warning letters or informal hearings;
- Administrative actions such as complaints and evidentiary hearings to suspend or revoke a business license; and
- Civil or criminal sanctions.

Performance Documentation

Appendix 6.2 (including worksheet 6.2) or equivalent form.

Performance Factors

Performance factors listed in appendix 6.1 and policies and procedures established by the State program.

6.4 Outcome

The State program has a compliance and enforcement program that provides procedures to ensure that compliance actions are supported by sound judgment, adequate evidence, and appropriate documentation that is submitted in program-prescribed formats and timeframes.

6.5 Documentation

The State program maintains the records listed here.

- Appendix 6.1 Self-assessment worksheet
- Appendix 6.2 Summary of compliance and enforcement activities (includes worksheet 6.2)
- Applicable laws, regulations, and guidance documents referenced in standard number 1
- Written procedures that describe the compliance and enforcement program
- Written enforcement strategy and/or procedures

STANDARD No. 7

Industry and Community Relations

7.1 Purpose

This standard describes the elements of industry and community outreach activities developed and accomplished by the State program.

7.2 Requirement Summary

The State program participates in activities that foster communication and information exchange among the regulators, industry, academia, and consumer representatives.

The State program coordinates or participates in outreach activities that provide educational information on food safety and defense issues.

7.3 Program Elements

The State program interacts with industry and consumers by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees. Topics at such outreach efforts may include food defense, investigation strategies, and regulatory requirements. Representatives from affected food industries, consumers, academia, and other Federal, State, and local food protection agencies are invited to these meetings.

Outreach efforts are tailored to a target population and may include dissemination of information using electronic sources and traditional methods such as mailings.

7.4 Outcome

The State program uses outreach activities to inform varied populations about food-related issues.

7.5 Documentation

The State program maintains the records listed here.

- Appendix 7 Self-assessment worksheet
- Meeting summaries, agendas, or other records documenting interaction with food industries and consumers

STANDARD No. 8

Program Resources

8.1 Purpose

This standard describes the elements for assessing the adequacy of the resources (staff, equipment, and funding) needed to support a manufactured food regulatory program.

8.2 Requirement Summary

Staff, equipment, and funding are managed to accomplish the elements detailed in these standards.

8.3 Program Elements

Staffing

a. General Administration and Management

The State program has adequate staff to provide the direction, support, and oversight needed to achieve conformance with the program standards. These activities include program management and direction, general administration, clerical support, office services, and coordination with laboratories.

b. Training Program (standard number 2)

The State program has adequate staff to coordinate a training curriculum and ensure it is properly delivered and tracked.

c. Inspection Program (standard number 3)

The State program has adequate staff to inspect all food plants in its establishment inventory at an adequate frequency that is based on the plant's risk classification and the necessary inspection and travel time. Appendix 8.2 provides formulas for calculating an adequate number of inspection staff.

d. Inspection Audit Program (standard number 4)

The State program has adequate staff to administer and monitor its inspection quality assurance program.

e. Food-related Illness and Outbreaks and Food Defense Preparedness and Response (standard number 5)

The State program has adequate staff to prepare for and respond to emergency situations.

f. Compliance and Enforcement Program (standard number 6)

The State program has adequate staff to implement compliance and enforcement strategies.

g. Industry and Community Relations (standard number 7)

The State program has adequate staff to participate in outreach and education activities.

h. Program Assessment (standard number 9)

The State program has adequate staff to conduct self-assessments of the manufactured food regulatory program.

Equipment

a. Program administration and recordkeeping

The State program has computers, software, and equipment necessary to maintain and secure records.

b. Communication systems and equipment

The State program has equipment needed for routine and emergency communications.

c. Inspections

The State program provides inspectors with equipment needed to conduct quality inspections. Appendix 8.3 is a list of inspection equipment.

Program funding

The State program is adequately funded to cover the following expenses:

- a. Salary and benefits
- b. Training costs
- c. Travel-related expenses
- d. Equipment and supplies
- e. Industry and community outreach expenses
- f. Laboratory expenses
- g. Legal services fees
- h. Indirect costs
- i. Overhead costs

8.4 Outcome

The State program has the resources needed to support a manufactured food regulatory program.

8.5 Documentation

The State program maintains the records listed here.

- Appendix 8.1 Self-assessment worksheet
- Document showing the calculations used to determine an adequate number of inspectors such as appendix 8.2
- Inventory of assigned and available inspection equipment similar to appendix 8.3
- Document containing the number and function of administrative support staff

STANDARD No. 9

Program Assessment

9.1 Purpose

This standard describes the process a State program uses to assess and demonstrate its conformance with each of the program standards.

9.2 Requirement Summary

Managers conduct periodic self-assessments of its manufactured food regulatory program against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the State program by determining the level of conformance with the program standards. Self-assessments are independently verified using an audit process.

The results of the self-assessments are used to determine areas or functions of the State program that need improvement. The results of the initial self-assessments are used to develop an improvement plan that moves the State program toward conformance with each of the program standards and establishes timeframes for making improvements. Subsequent self-assessments are used to track progress toward meeting and maintaining conformance with the program standards.

9.3 Program Elements

- a. The State program conducts an initial self-assessment of its conformity with each standard. A subsequent self-assessment is conducted every 36 months or less after completion of the initial self-assessment.
- b. When conducting a self-assessment, the State program uses worksheets comparable to those contained in the appendices of each standard.
- c. The State program uses the results of its self-assessments to develop or update an improvement plan. If the elements of the standard are not met, the improvement plan contains specific strategies and timeframes for achieving conformance and maintaining an acceptable level of performance. The improvement plan also contains reviews of the State program's progress in implementing the plan.

- d. The State program arranges for a verification audit to confirm and validate the accuracy of each self-assessment. During the verification audit, an auditor reviews the records required by each standard to determine if the self-assessment accurately reflects the State program's level of conformance with each of the standards. Verification audits are conducted within six months of completion of the self-assessment. Audits conducted by FDA for contract purposes satisfy this requirement.
- e. The State program maintains the records required by each standard and records of all self-assessments, improvement plans, and verification audits until superseded.

9.4. Outcome

The State program conforms to the program standards through well-defined evaluation activities and a process for continuous improvement.

9.5. Documentation

The State program maintains the records listed here.

- Worksheet 9 Self-worksheet assessment and improvement tracking
- Completed appendices 1, 2.1-6.1, 7, 8.1, 10
- Supporting operational documents required for each standard
- Verification audit report
- Program improvement plan

STANDARD No. 10 Laboratory Support

10.1 Purpose

This standard describes the elements of laboratory support for a manufactured food regulatory program.

10.2 Requirement Summary

The State program has access to the laboratory services needed to support program functions and documents its laboratory capabilities including agreements with external laboratories.

10.3 Program Elements

- a. The State program has access to a laboratory that is capable of analyzing a variety of samples including food, environmental, and clinical samples.
- b. The State program maintains a record of services for routine and non-routine analyses such as biological hazard determinations.
- c. The State program has a contract or written agreement with its servicing laboratories.
- d. The State program utilizes laboratories that are accredited or certified or that have a written QAP. The QAP will require:
 - Calibration, verification, and maintenance of equipment
 - Documentation of analytical results
 - Control and maintenance of documents
 - Sample accountability
 - Sample integrity and chain of custody
 - Qualifications and training of analysts
 - Audit procedures such as scheduled performance reviews of staff and instrument checks

10.4 Outcome

The State program has access to laboratory services described in this standard.

10.5 Documentation

The State program maintains records listed here.

- Appendix 10 Self-assessment worksheet
- A list of servicing laboratories used by the State program
- Contracts or written agreements with servicing laboratories

Appendix 1**Self-Assessment Worksheet**

The State program describes how equivalency is accomplished when it lacks authority to enforce the sections of the FD&C Act and the parts of the CFR listed in the following tables.

For example, the State program may comply with standard number 1 either by identifying its equivalent State authorities or by describing how equivalency is attained through alternative procedures or agreements.

a. Federal Food, Drug, and Cosmetic Act (FD&C Act)

The State law must be equivalent in effect to the sections of the FD&C Act. The language used does not have to be identical if the same outcome is achieved.

Section	Title	State equivalent or alternate provision	“✓” if full intent is met
201	Definitions (f), (k), (m), and (ff)		
301	Prohibited acts (a), (b), (c), (d), (e), (f), (k), and (v)		
303*	Penalties		
304**	Seizure		
401	Definitions and standards for food		
402	Adulterated food		
403	Misbranded food (a)-(s)		
413	New dietary ingredients		
701	Regulations and hearings		
703***	Records of interstate shipments		
704	Factory inspection		

*Penalties may vary from Federal statute.

**Seizure authority is not required under this standard. The agency, however, should have legal authority to stop adulterated and misbranded products from moving in commerce, for example, detention, stop-sale orders, and embargoes.

***This section covers records in interstate commerce. State law should include intrastate records.

b. Code of Federal Regulations (CFR)

The State regulation must be equivalent in effect to the sections listed in the CFR. The language used does not have to be identical if the same outcome is achieved. States may have more stringent regulations unless preempted.

Part	Title	State equivalent or alternate provision	“✓” if full intent is met
1	General enforcement regulations (ONLY § 1.20-1.24)		
7	Enforcement policy (ONLY § 7.1-7.13 and § 7.40-7.59)		
70	Color additives (ONLY § 70.20-70.25)		
Part	Title	State equivalent or alternate provision	“✓” if full intent is met
73	Listing of colors exempt from certification (ONLY § 73.1- § 73.615)		

74	Listing of color additives subject to certification (ONLY § 74.101-706)		
82	Listing of certified provisionally listed colors and specifications (ONLY § 82.3- § 82.706)		
100	General (ONLY § 100.155 and § 101.100)		
101	Food labeling (EXCEPT § 101.69 and § 101.108)		
102	Common or usual name for nonstandardized foods (EXCEPT § 102.19)		
104	Nutritional quality guidelines for foods		
105	Foods for special dietary use		
106	Infant formula quality control procedures (EXCEPT § 106.120)		
107	Infant formula (EXCEPT § 107.200- § 107.280)		
108	Emergency permit control (ONLY § 108.25- § 108.35)		
109	Unavoidable contaminants in food for human consumption and food-packaging materials		
110	Current good manufacturing practice in manufacturing, packing, or holding human food		
111	Current good manufacturing practice for dietary supplements		
113	Thermally processed low-acid foods packaged in hermetically sealed containers		
114	Acidified foods		
115	Shell eggs		
120	Hazard Analysis and Critical Control Point (HACCP) systems		
123	Fish and fishery products		
129	Processing and bottling of bottled drinking water		
130	Food standards: general (EXCEPT § 130.5-6 and § 130.17)		
131	Milk and cream		
133	Cheeses and related cheese products		
135	Frozen desserts		
136	Bakery products		
Part	Title	State equivalent or alternate provision	“✓” if full intent is met
137	Cereal flours and related products		
139	Macaroni and noodle products		
145	Canned fruits		

146	Canned fruit juices		
150	Fruit butters, jellies, preserves, and related products		
152	Fruit pies		
155	Canned vegetables		
156	Vegetable juices		
158	Frozen vegetables		
160	Eggs and egg products		
161	Fish and shellfish		
163	Cacao products		
164	Tree nut and peanut products		
165	Beverages		
166	Margarine		
168	Sweeteners and table syrups		
169	Food dressings and flavorings		
170	Food additives (EXCEPT § 170.6, § 170.15, and § 170.17)		
172	Food additives permitted for direct addition to food for human consumption		
173	Secondary direct food additives permitted in food for human consumption		
174	Indirect food additives: general		
175	Indirect food additives: adhesives and components of coatings		
176	Indirect food additives: paper and paperboard components		
177	Indirect food additives: polymers		
178	Indirect food additives: adjuvants, production aids, and sanitizers		
180	Food additives permitted in food or in contact with food on an interim basis pending additional study		
181	Prior-sanctioned food ingredients		
182	Substances generally recognized as safe		
184	Direct food substances affirmed as generally recognized as safe		
186	Indirect food substances affirmed as generally recognized as safe		
189	Substances prohibited from use in human food		
190	Dietary supplements		

c. State law and regulations

State laws and regulations used by the program to broaden its scope of regulatory authority are listed below.

**Appendix 2.1
Self-Assessment Worksheet**

State agency: _____ State program:
 _____ Year _____

Instructions: Record the name of the employee and the completion date for each training component. additional sheets as needed.

Employee name	Start Date	Basic Food Inspection Curriculum		Advanced Food Inspection Curriculum			Continuing Education	
		Course work	Field work	Area of specialty	Course work	Field work	Course work	Field work

Name/title of auditor: _____

Signature: _____ Date: _____

Appendix 2.2
Individual Training Record

State agency _____

Name of inspector _____ Inspector's start date _____

Basic Food Inspection Curriculum Coursework			
Please provide the course name and location for the subject areas listed here.	Completion Date	Inspector's Initials	Supervisor's Initials
Prevailing statutes, regulations, and ordinances			
Public health principles			
Communication skills			
Microbiology			
Epidemiology			
Basics of HACCP			
Control of allergens			
Basic food labeling			

Basic Food Inspection Curriculum Fieldwork				
Joint Inspections		Completion Date	Inspector's Initials	Supervisor's Initials
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
Evaluations				
1.				
2.				

Advanced Food Inspection Curriculum Coursework			
Please provide the name and location of the course. Note: <u>Only</u> the juice and seafood HACCP courses listed on this form will meet the training requirement.	Completion Date	Inspector's Initials	Supervisor's Initials
Applications of foodborne illness investigations			
Traceback investigations			
Nutrition labeling			
Acidified foods			
Low acid canned foods			
Principles of Juice HACCP			
Juice HACCP Alliance Training			
<i>Or</i> comparable training			
Juice HACCP for Regulators (FDA video)			
Principles of Seafood HACCP			
Basic Seafood HACCP Class (classroom)			
<i>(Or</i> internet and one day)			

Seafood HACCP Regulators Course (FDA video)			
Seafood HACCP Encore (video)			
Seafood HACCP The Sequel (video)			
Seafood HACCP Hazard Guide Update, 3rd Edition (video)			

Advanced Food Inspection Curriculum Fieldwork				
Specialized food inspection:				
Joint Inspections		Completion Date	Inspector's Initials	Supervisor's Initials
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
Evaluations				
1.				
2.				
Specialized food inspection:				
Joint Inspections		Completion Date	Inspector's Initials	Supervisor's Initials
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
Evaluations				
1.				
2.				

Continuing Education Coursework				
Please provide the name and location of the course.	Completion Date	Contact Hours¹¹	Inspector's Initials	Supervisor's Initials

Continuing Education Fieldwork			
Joint Inspections	Completion Date	Inspector's Initials	Supervisor's Initials

¹¹ The inspector will earn contact hours at a rate of one contact hour for every course hour.

Please provide the name of the food plant and identification number.				
1.				
2.				

Appendix 3.1 Self-Assessment Worksheet

State agency: _____ State
program: _____

Does the State program meet the criteria contained in section
3.3 of the standard number 3?

Program Elements	Yes/No	If no, please specify why criteria are not met.
a. Risk-based inspection system		
1. Is the establishment inventory complete and accurate?		
2. Are establishments grouped based on identified risk factors?		
3. Are risk categories used to prioritize inspections, assign routine inspection frequencies, and allocate resources?		
b. Inspection protocol		
Does the program's inspection protocol require inspectors to:		
1. Review the establishment file, consumer complaints, and other relevant documents prior to inspection?		
2. Use appropriate equipment and forms?		
3. Establish jurisdiction?		
4. Select appropriate product/process (high risk products and processes)?		
5. Assess employee practices critical to the safe production and storage of food?		
6. Properly evaluate the likelihood that conditions, practices, components, and labeling could cause the product to be adulterated or misbranded?		
7. Recognize significant violative conditions or practices, and record findings consistent with program procedures?		
8. Distinguish between significant and insignificant observations, and isolated incidents and trends?		
9. Review and evaluate the appropriate operational records and procedures and apply the information obtained from this review?		

10. Collect adequate evidence and documentation in accordance with program procedures given the nature of the inspectional findings?		
11. Verify correction of deficiencies from a previous inspection?		
12. Behave professionally and demonstrate proper sanitary practices during the inspection?		

13. Use the “Fish and Fishery Products Hazards and Controls Guide” or the “Juice HACCP Hazards and Controls Guide,” to identify and evaluate the hazards associated with the product and process?		
14. Assess the firm’s implementation of sanitation monitoring for the applicable eight key areas of sanitation?		
15. Review the firm’s HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring verification and corrective action records, including those related to sanitation?		
16. Recognize deficiencies in the firm’s monitoring and sanitation procedures through in-plant observations?		
17. Identify himself/herself, present credentials, and make appropriate introductions, including explaining the purpose and scope of the inspection?		
18. Use suitable interviewing techniques?		
19. Explain findings clearly and adequately throughout the inspection?		
20. Alert the firm’s appropriate management when an immediate corrective action is necessary?		
21. Write findings accurately, clearly, and concisely on the State document?		
22. Answer questions and provide information in an appropriate manner?		
23. And, does the program have an adequate recordkeeping system and does this system contain prescribed records associated with inspections?		
c. Food recalls		
Does the recall system include:		
1. Guidance for sharing information?		
2. Procedures for prompt removal of recalled products?		
3. Procedures for recall audit checks?		
4. And, does the program have an adequate recordkeeping system and does this system contain prescribed records associated with food recalls?		
d. Consumer complaints		
1. Does the program have procedures for		

receiving, tracking, evaluating, responding to, and closing consumer complaints?		
2. Does the program have a recordkeeping system and are records associated with consumer complaints retained?		

e. Food industry inspection complaints		
1. Does the program have procedures for receiving, evaluating, responding to, and recording food industry complaints about inspections?		
2. Does the program have a recordkeeping system and are records associated with food industry inspection complaints retained?		

Name/title of auditor:

Signature: _____

Date: _____

Appendix 3.2

Risk Classification Criteria for Food Plants

Risk management is prioritizing opportunities to reduce risk and allocate food safety efforts and resources. Policymakers must consider the entire production-to-consumption chain and all of the participants (regulators, industry, researchers, health care providers, and consumers) when deciding how to best utilize resources to maximize food safety and reduce costs.

Standard number 3 focuses on one segment of the total food safety system – inspection of food plants. A key requirement of this standard is that the State program uses a science-based and risk-based method for classifying food plants into at least three risk categories with a baseline inspection frequency specified for each category. Although this standard does not prescribe a classification scheme or inspection frequency, frequencies could be established through: (1) risk-based assessment of foodborne hazards, (2) ranking the public health impacts of specific hazards, (3) measurement and valuation of the benefits of reducing risk, (4) evaluation of the effectiveness and cost of risk reduction intervention options, and (5) integration of these analyses to allocate resources.

When categorizing establishments by risk, State programs may consider several factors including: (1) the type of food and ingredients, (2) processing requirements, (3) volume of product manufactured or distributed, (4) intended consumer, and (5) compliance history of the food plant. The factors may be assigned numerical values that are tabulated to rank the food plants and prioritize inspections.

Foods with microbial hazards, especially those that require stringent temperature controls, are usually deemed high risk. Other foods such as unpasteurized juices may be classified as high risk based on epidemiologic implication in foodborne disease outbreaks. In addition to microbial hazards, chemical hazards should also be evaluated.

Complex manufacturing processes with many critical control points such as commercial sterilization, acidification, dehydration, formulation control, or mandatory HACCP systems are generally considered high risk. These operations must be properly controlled to prevent, eliminate, or reduce food safety hazards to acceptable levels. Reconditioning operations including food salvage are often

ranked as high risk because improper reconditioning could result in distribution of adulterated or misbranded products to consumers.

High volume manufacturers and distributors have the potential to expose more consumers to food safety hazards if product or process controls fail. When combined with other factors, they may be classified as high risk.

Risk Classification Criteria for Food Plants

Many classification schemes prioritize products intended for use by highly-susceptible populations¹² because these populations are more likely to experience foodborne illnesses compared to the general population.

Inspection or compliance history is commonly considered when establishing inspection frequencies. It is reasonable to expect those firms with a history of compliance to be inspected less frequently than those firms with a history of non-compliance. Some State programs factor the compliance history directly into the risk ranking while others use performance criteria to adjust the inspection frequency from a baseline established by other criteria.

Standard number 3 requires a State program to categorize food plants based on risk and to allocate resources and establish inspection frequencies based on that categorization. Standard number 3 does not prescribe how this must be done. State programs should document their classification system and inspection frequencies. Differences between agencies will exist for many reasons including variable resources, legislative mandates, localized industries and practices, and competing priorities.

The risk classification criteria listed on the next page are intended solely to assist State programs with establishing their own classification system.

¹² Highly-susceptible populations include immuno-compromised persons, preschool age children, or older adults; and persons who obtain food at a facility that provides services such as custodial care, health care, assisted living, a child or adult day care center, kidney dialysis centers, hospital or nursing home, or nutritional or socialization services (senior citizen centers).

Risk Classification Criteria for Food Plants

Risk	Type of processing
High	Canning low acid foods, acidifying foods, vacuum packaging, salvaging, smoking for preservation, curing
Medium	Cooking, cooling, holding under controlled temperatures, pasteurization
Low	Temperature control not required

Type of foods

High	Potentially hazardous foods frequently implicated in foodborne illness (sprouts, unpasteurized juices, raw shellfish, cream-filled pastries, filled macaroni products)
Medium	Potentially hazardous foods not typically implicated in foodborne illness
Low	Non-potentially hazardous foods

Volume of product manufactured/distributed

Higher distribution	High volume operations with broad distribution
Lower	Low volume operations or operations with localized distribution

Target population

Higher	Foods consumed by susceptible populations
Lower	Foods consumed solely or primarily by the general population

Compliance history

Higher	Businesses with an inconsistent or poor history of compliance with food safety requirements
Lower	Businesses routinely in compliance with food safety requirements

**Appendix 4.1
Self-Assessment Worksheet**

State agency: _____ **State program:** _____

The results of the field inspection and desk audits are summarized below. Performance ratings that fall below 80 percent indicate a need for improvement and require corrective action. Worksheets 4.2 – 4.4 can be used to identify the specific aspects of the inspection program that need improvement.

Overall Audit Rating (based on three-year averages)	
<i>Circle one:</i>	<i>Performance rating criteria:</i>
Acceptable	All performance rating averages \geq 80 percent.
Needs improvement	One or more performance rating averages $<$ 80 percent.

	Audits		
	Field inspection	Inspection report	Sample report
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Three-year average	_____	_____	_____
	[]	[]	[]

Recommendations:

Name/title of auditor: _____

Signature: _____

Date: _____

Worksheet 4.2 Calculation of the performance rating for the field inspection audits.

State program: _____	Performance period: _____
----------------------	---------------------------

Performance factors (5)	Auditor's initials and date of audit (1)														A _t (3)	NI _t (3)		
	Performance ratings (2)																	
I.1																		
I.2																		
II.1																		
II.2																		
II.3																		
II.4																		
II.5																		
II.6																		
II.7																		
II.8																		
II.9																		
II.10																		
IIA.1																		
IIA.2																		
IIA.3																		
IIA.4																		
III.1																		
III.2																		
III.3																		
III.4																		
III.5																		
III.6																		
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																	
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																	

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.

Worksheet 4.2
Continuation sheet

State program: _____ Performance period: _____

Performance factors (5)	Auditor's initials and date of audit (1)												A _t (3)	NI _t (3)
Performance ratings (2)														
I.1														
I.2														
II.1														
II.2														
II.3														
II.4														
II.5														
II.6														
II.7														
II.8														
II.9														
II.10														
IIA.1														
IIA.2														
IIA.3														
IIA.4														
III.1														
III.2														
III.3														
III.4														
III.5														
III.6														
Total	<i>Enter the sums of (3).</i>													

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.2

Summary of Field Inspection Audit Findings

The summary of the performance factor ratings for all field inspection audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Worksheet 4.2 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in appendix 4.5. A rating below 80 percent indicates a need for improvement and requires corrective action.

- INSTRUCTIONS:**
- (1) For each field inspection audited, record the auditor’s initials and date of audit in the box.**

 - (2) For each field inspection audited, record the rating for each performance factor listed in appendix 4.5.**
A = acceptable; NI = needs improvement.

 - (3) Record the A_t and NI_t for each performance factor.**
 A_t = horizontal total of acceptable ratings.
 NI_t = horizontal total of needs improvement ratings.

 - (4) Calculate the overall rating for the field inspection audits.**
Record the rating in the space provided in the box located at the top of worksheet 4.2.

FORMULA:

Field inspection audit performance rating =

$$[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$$

NOTE: Σ is the statistical symbol for the sum of all numbers.

ΣA_t = vertical sum of acceptable ratings.

ΣNI_t = vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of worksheet 4.2 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

Worksheet 4.3 Calculation of the performance rating for the inspection report audits.

State program: _____ Performance period: _____

 Inspection report audit performance rating (4): _____
 Name/title of reviewer: _____ Office: _____ Date: _____

Performance factors (5)	Firm identification number and date of inspection (1)																A _i (3)	NI _i (3)	
	Performance ratings (2)																		
I.1																			
I.2																			
II.1																			
II.2																			
II.3																			
II.4																			
II.5																			
II.6																			
II.7																			
II.8																			
II.9																			
II.10																			
II.11																			
II.12																			
III.1																			
III.2																			
III.3																			
III.4																			
IV.1																			
IV.2																			
IV.3																			
IV.4																			
IV.5																			
IV.6																			
V.1																			
V.2																			
V.3																			
V.4																			
V.5																			
V.6																			
V.7																			
V.8																			
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																		
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																		

Worksheet 4.3
Continuation sheet

State program: _____	Performance period: _____
----------------------	---------------------------

Performance factors (5)	Firm identification number and date of inspection (1)																A _t (3)	NI _t (3)
Performance ratings (2)																		
I.1																		
I.2																		
II.1																		
II.2																		
II.3																		
II.4																		
II.5																		
II.6																		
II.7																		
II.8																		
II.9																		
II.10																		
II.11																		
II.12																		
III.1																		
III.2																		
III.3																		
III.4																		
IV.1																		
IV.2																		
IV.3																		
IV.4																		
IV.5																		
IV.6																		
V.1																		
V.2																		
V.3																		
V.4																		
V.5																		
V.6																		
V.7																		
V.8																		
Total	<i>Enter the sums of (3).</i>																	

Worksheet 4.3

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.

Appendix 4.3

Summary of Inspection Report Audit Findings

The summary of the performance factor ratings for all inspection report audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Worksheet 4.3 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in appendix 4.6. A rating below 80 percent indicates a need for improvement and requires corrective action.

INSTRUCTIONS: (1) For each inspection report audited, record the firm identification number and date of the inspection in the box.

(2) For each inspection report audited, record the rating for each performance factor listed in appendix 4.6.

A = acceptable; NI = needs improvement.

(3) Record the A_t and NI_t for each performance factor.

A_t = horizontal total of acceptable ratings.

NI_t = horizontal total of needs improvement ratings.

(4) Calculate the overall rating for the inspection report audits.

Record the rating in the space provided in the box located at the top of worksheet 4.3.

FORMULA:

Inspection report audit performance rating =

$$[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$$

NOTE: \sum is the statistical symbol for the sum of all numbers.

$\sum A_t$ = vertical sum of acceptable ratings.

$\sum NI_t$ = vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the blank page of worksheet 4.3 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

Worksheet 4.4 Calculation of the performance rating for the sample report audits.

State program _____	Performance period: _____
Sample report audit performance rating (4): _____	
Name/title of reviewer: _____	Office: _____ Date: _____

Performance factors (5)	Sample report identification number and date of sample collection (1)														
	Performance ratings (2)														
I.1															
I.2															
I.3															
I.4															
I.5															
II.1															
II.2															
II.3															
II.4															
II.5															
II.6															
II.7															
III.1															
III.2															
III.3															

Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.

Worksheet 4.4
Continuation sheet

State program: _____	Performance period: _____
----------------------	---------------------------

Performance factors (5)	Sample report identification number and date of sample collection (1)																A _t (3)	NI _t (3)	
	Performance ratings (2)																		
I.1																			
I.2																			
I.3																			
I.4																			
I.5																			
II.1																			
II.2																			
II.3																			
II.4																			
II.5																			
II.6																			
II.7																			
III.1																			
III.2																			
III.3																			
Total	<i>Enter the sums of (3).</i>																		

5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.

Appendix 4.4

Summary of Sample Report Audit Findings

The summary of the performance factor ratings for all sample report audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Worksheet 4.4 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in appendix 4.7. A rating below 80 percent indicates a need for improvement and requires corrective action.

- INSTRUCTIONS:**
- (1) For each sample report audited, record the sample report identification number and date of sample collection in the box.
 - (2) For each sample report audited, record the rating for each performance factor listed in appendix 4.7.
A = acceptable; NI = needs improvement.
 - (3) Record the A_t and NI_t for each performance factor.
 A_t = horizontal total of acceptable ratings.
 NI_t = horizontal total of needs improvement ratings.
 - (4) Calculate the overall rating for the sample report audits.
Record the rating in the space provided in the box located at the top of worksheet 4.4.

FORMULA:

Sample report audit performance rating =

$$\left[\frac{\sum A_t}{(\sum A_t + \sum NI_t)} \right] \times 100$$

NOTE: \sum is the statistical symbol for the sum of all numbers.

$\sum A_t =$ vertical sum of acceptable ratings.

$\sum NI_t =$ vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of worksheet 4.4 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

Appendix 4.5a Guidance for Completing the Contract Audit Form (FDA Form 3610)

This document provides guidance on assigning ratings during an audit for each of the performance factors listed on the Contract Audit Form. For each performance factor examples of actions and observations that would likely result in a “needs improvement” rating are provided.

I. Pre Inspection Assessment

1. **Did the inspector review the State’s establishment file for the previous inspection report and possible complaints or access other available resources in preparation for the inspection?**

I. References:

- State program’s establishment files
- FDA compliance programs referenced in the contract

II. Examples of a “needs improvement” rating

- a. The inspector does not review the State’s previous inspection report and follow-up on previously cited deficiencies.
- b. The inspector does not review a firm’s response letter to the State’s previous establishment inspection where corrective actions were promised.
- c. The inspector does not verify the firm’s normal days of operation or seasonal hours.
- d. The inspector does not follow-up on a consumer complaint contained in the State's establishment file.

2. **Did the inspector have the appropriate equipment and forms to properly conduct the inspection?**

References:

- FDA compliance programs referenced in the contract
- FDA inspection guides

EXAMPLES OF A “NEEDS IMPROVEMENT” RATING:

- a. During an inspection of a cream-filled pie manufacturer, the inspector does not have a calibrated thermometer to check the temperature of the pie.
- b. During an inspection of a cooked, ready-to-eat food processor, the inspector does not have a method to test the concentration of iodine sanitizer in the hand dip station.
- c. The inspector does not have a flashlight to examine poorly lit raw material storage areas in the plant.

II. Inspection Observations and Performance

1. Was FDA jurisdiction established?

References:

- FDA Investigations Operations Manual (IOM), subchapter 432 - Documenting Interstate Shipments
- IOM, subchapter 701 – Statutory Authority

Examples of a “needs improvement” rating

- a. The inspector fails to confirm interstate movement of a product or ingredients.
- b. The inspector fails to verify interstate shipment of food by a manufacturer that has not shipped product in interstate commerce during the past 24 months nor has the manufacturer received interstate shipments of ingredients or packaging components.

2. Did the inspector select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the firm was producing?

References:

- FDA compliance programs referenced in the contract

Examples of a “needs improvement” rating

- a. *The inspector covers only a low-risk product while the firm is producing a high-risk product on the day of the inspection.*

- b. The inspector does not cover a small ready-to-eat sandwich operation in a large frozen dinner processing plant.
- c. While inspecting a beverage bottling plant whose primary product is institutional-sized root beer syrup, the inspector ignores a bottled water processing operation on the premises.

3. Did the inspector assess the employee practices critical to the safe production and storage of food?

Examples of a “needs improvement” rating:

- a. The inspector fails to evaluate the hygienic practices of employees working in a food processing area.
- b. The inspector is unaware of the need for employees who are processing cooked, ready-to-eat foods to wash and sanitize their hands every time they touch an unclean surface.
- c. The inspector notices that the firm has a trash bin and a reclaim bin in the same area. He/she does not, however, recognize the potential hazard. Consequently, the inspector misses an employee placing trash in the reclaim bin that contains product reintroduced into the manufacturing process.

4. Did the inspector properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?

References:

- FDA compliance programs referenced in the contract
- NLEA inspection guide

Examples of a “needs improvement” rating:

- a. The inspector fails to recognize when a firm’s finished product labeling does not contain a sulfite declaration, even though the raw material does contain a sulfite declaration.
- b. The inspector fails to note the significance of “back hauling” raw eggs in a tanker used to carry pasteurized ice cream mix.
- c. During an inspection of a baby food manufacturer, the inspector observes a belt moving rapidly, glass jars rattling, and shards of glass on the belt. The inspector fails to determine if such observations are related to a recent increase in complaints of glass in baby food.

- d. The inspector fails to recognize the addition of an allergen during the production of a breaded product, and he/she doesn't review the product label.

5. **Did the inspector recognize significant violative conditions or practices, if present, and record findings consistent with State procedures?**

III. Examples of a “needs improvement” rating:

- a. The inspector fails to recognize that the food residues and mold growth on food contact surfaces are violations.
- b. The inspector does not recognize that employees handling cooked, ready-to-eat product with soiled hands is a deficiency.
- c. The inspector fails to notice that WD-40™, observed in the processing area, is being used to lubricate machine parts above food contact surfaces.
- d. The inspector fails to recognize that condensate dripping from a freezer onto finished product may cause cross contamination.

6. **Did the inspector demonstrate the ability to distinguish between significant versus insignificant observations and isolated incidents versus trends?**

References:

- FDA compliance programs referenced in the contract

Examples of a “needs improvement” rating:

- a. The inspector notes minor deficiencies such as chewing gum and nail polish while failing to note places where cross contamination of cooked and raw product might occur.
- b. The inspector identifies record keeping deficiencies in records that are two months old. The inspector objects to these deficiencies without appropriately considering that the firm’s weekly management review of the records has identified the deficiencies, which have not been repeated within the last seven weeks.
- c. During an inspection of a ready-to-eat salad processor, the inspector focuses primarily on filthy, non-food contact surfaces.
- d. During the inspection of a warehouse, the inspector focuses primarily on products being stored against the walls but fails to notice several pallets of rice infested with moths.

- 7. Did the inspector review and evaluate the appropriate records and procedures for this establishment's operation and effectively apply the information obtained from this review?**

IV.

EXAMPLES OF A "NEEDS IMPROVEMENT" RATING:

- a. During a review of the processing records, the inspector fails to detect that cooking times are outside the scheduled process.
 - b. The inspector fails to detect possible evidence of record falsification such as inconsistencies among different types of records, unrealistic and repetitive data, and inconsistencies in signatures.
 - c. Can teardown records are reviewed, but the inspector doesn't recognize that teardown measurements were not done at appropriate intervals.
- 8. Did the inspector collect adequate evidence and documentation in accordance with State procedures given the nature of the inspectional findings?**

Examples of a "needs improvement" rating

- a. The inspector fails to adequately document findings according to State requirements when violations are found in the firm.
 - b. The inspector fails to follow State requirements when collecting samples of processed food necessary to document violative conditions.
 - c. In an acidified food processing plant, the pH of the final product is questionable. The inspector does not, however, collect a sample of the product for pH determination.
- 9. Did the inspector verify correction of deficiencies identified during the previous State inspection?**

Examples of a "needs improvement" rating:

- a.** Although significant time and temperature abuse of coconut cream pies was identified during the previous inspection, the inspector does not determine if these deficiencies were corrected.

b. In the previous inspection, the inspector reported that a private well was not equipped with a sanitary seal. During the current inspection, the manager tells the inspector that the well was repaired, and the lab results were acceptable. The inspector reviews the microbiological lab results, but does not go to the well to verify that the sanitary seal was installed.

c. The inspector fails to follow up on deficiencies from the previous inspection for cooked, ready-to-eat product because that product was not being made at the time of the inspection. Nor does the inspector review process records for the product to determine if the firm took appropriate corrective actions.

10. Did the inspector act in a professional manner and demonstrate proper sanitary practices during the inspection?

Examples of a “needs improvement” rating:

- a. The inspector does not use the boot bath when entering in the firm's processing areas.
- b. The inspector fails to sanitize his/her thermometer prior to probing product.
- c. The inspector fails to wear protective clothing when entering an aseptic processing area.
- d. The inspector wears jewelry, which is prohibited by the firm, in the manufacturing areas.

II. A. Inspection Observation and Performance for ‘HACCP-Required’ Facilities

[Note: These four questions may be left blank if the firm is not required by regulations to have a HACCP plan.]

References:

- FDA compliance programs referenced in the contract
- Title 21 Code of Federal Regulations (21 CFR) parts 110, 120, 123, and 1240
- Fish and Fishery Products Hazards & Controls Guide
- HACCP Regulation for Fish & Fishery Products: Questions and Answers
- Juice HACCP Hazards and Controls Guide

1. Did the inspector use the “Fish and Fishery Products Hazards and Controls Guide” and the “Juice HACCP Hazards and Controls Guide”, as

appropriate, to identify and evaluate the hazards associated with the product and process?

Examples of a “needs improvement” rating:

- a. In a tuna processing plant, the inspector fails to identify histamine as a hazard inherent to the incoming raw material and fails to question its absence in the firm’s HACCP plan. (Failure to identify a hazard reasonably likely to occur.)
 - b. A firm is producing fresh, raw, refrigerated fish in cryovac packaging. The inspector is not aware that *C. botulinum* is a significant hazard.
 - c. An inspector incorrectly identifies aquaculture drugs as a significant hazard for a secondary processor of a product that it receives from the primary processor. (Identification of a hazard not reasonably likely to occur.)
 - d. The inspector fails to recognize that a batter tank in a breaded shrimp processing operation is a possible CCP. (Failure to recognize an appropriate CCP.)
- 2. Did the inspector assess the firm’s implementation of sanitation monitoring for the applicable eight key areas of sanitation?**

Examples of a “needs improvement” rating:

- a. The inspector insists on the need for the firm to perform medical check-ups for crabmeat pickers.
 - b. The inspector is unaware of which of the eight areas of sanitation are relevant to the firms operations.
 - c. The inspector fails to inquire about the firms SSOPs and monitoring practices.
- 3. Did the inspector review firm’s HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring, verification, and corrective action records, including those related to sanitation?**

Examples of a “needs improvement” rating:

- a. After conducting a brief walk through a crabmeat processor, the inspector relies on a review of the firm’s records to assess the firm’s implementation of its HACCP plan. The inspector does not return to the crab picking room to determine if picking and packing critical limits are being met or if the firm has the equipment to properly monitor the critical limits as specified in the plan.
- b. The inspection reveals that the firm is processing a product that requires a HACCP plan. The inspector cites the firm’s failure to have a HACCP plan,

but the inspector does not determine if the necessary controls were put into place without a HACCP plan.

- c. Although the inspector is told that the firm uses well water, not potable water, as its source for ice, the inspector does not verify that the firm has the water tested for coliforms to ensure its safety.
- d. The inspector does not ask the plant manager for records of pest control after learning that the service is contracted to a private company.
- e. The inspector fails to accompany the firm's sanitarian on a pre-operation inspection when there were indications that sanitary practices may be inadequate.

4. Did the inspector recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations?

Examples of a "needs improvement" rating:

- a. The inspector fails to recognize that cumulative times and temperatures for cooling, holding, and picking of cooked crabs were substantially above such times and temperatures specified in the firm's HACCP plan.
- b. The inspector fails to recognize that a firm's finished product labeling does not contain a sulfite declaration even though an ingredient contains a sulfite declaration.
- c. The inspector fails to recognize that the presence of food residues and mold growth on processing equipment immediately prior to processing is evidence of unsanitary conditions.
- d. The inspector does not recognize that food-contact surfaces are being sanitized with a product that is not approved for use on food contact surfaces.

III. Oral and Written Communication

1. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope of the inspection?

Examples of a "needs improvement" rating:

- a. The inspector fails to explain why he/she is at the firm.

b. The inspector enters through the back door and begins examining a storage area without notifying anyone at the firm.

2. Did the inspector use suitable interviewing techniques?

Examples of a “needs improvement” rating:

- a.** The inspector requests for information are vague; consequently, the firm provides documents that are unrelated to the inspection.
- b.** Because the inspector’s requests for information contain jargon, the employees are confused and unable to respond to his/her requests.
- c.** When the plant manager’s responses are evasive, the inspector does not ask follow-up questions to obtain the necessary information. Consequently, the answers to the questions are incomplete.

3. Did the inspector explain findings clearly and adequately throughout the inspection?

Examples of a “needs improvement” rating:

- a. The inspector does not discuss the inspection observations with the firm managers at the end of the inspection.
- b. The inspector does not discuss with the general manager a significant deficiency observed in the processing area before going to the packing area of the cannery.
- c. The inspector is vague during his discussion with the managers at the end of the inspection. Therefore, the managers are unaware of the significance of the observations and that corrective actions are needed.

4. Did the inspector alert the firm’s appropriate management when an immediate corrective action was necessary?

Examples of a “needs improvement” rating

- a. The inspector fails to alert the appropriate manager that food containing undeclared FD&C Yellow #5 is being packaged, and, if shipped, could result in a health hazard.
- b. The inspector fails to tell the appropriate manager about blood dripping from boxes of boneless beef onto raw carrots.
- c. After witnessing product being contaminated with a toxic chemical, the inspector immediately notifies the cleaning lady to clean up the toxic chemical to prevent further product contamination.

5. Did the inspector answer questions and provide information in an appropriate manner?

Examples of a “needs improvement” rating:

- a. The inspector tells the plant manager about FDA’s legal action against a competitor.
- b. The inspector gives a competitor’s product formula to a friendly plant manager.
- c. The inspector fabricates an answer to a policy question, which may lead the firm to take an inappropriate corrective action.
- d. The inspector dictates an inappropriate corrective action for a deficiency.

6. Did the inspector write their findings accurately, clearly, and concisely on the State form/document left with the firm?

References:

- FDA compliance programs referenced in the contract

Examples of a “needs improvement” rating:

- a. The inspector fails to write that the firm has a significant process deviation on the list of findings.
- b. The inspector fails to write on the list of findings that he/she observed excreta pellets in bags of rice.
- c. The list of findings shows that the “Firm did not control hazards” with

no further explanation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
CONTRACT AUDIT		
FDA AUDITOR	STATE INSPECTOR	
FIRM	CFN / FEI NUMBER	
FIRM ADDRESS		
PRODUCT(S) COVERED		
TIME IN	TIME OUT	OVERALL RATING <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement
I. PREINSPECTION ASSESSMENT		
<p>1. DID THE INSPECTOR REVIEW THE STATE'S ESTABLISHMENT FILE FOR THE PREVIOUS INSPECTION REPORT AND POSSIBLE COMPLAINTS OR ACCESS OTHER AVAILABLE RESOURCES IN PREPARATION FOR THE INSPECTION?</p> <p> <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement </p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>		
<p>2. DID THE INSPECTOR HAVE THE APPROPRIATE EQUIPMENT AND FORMS TO PROPERLY CONDUCT THE INSPECTION?</p> <p> <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement </p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>		

II. INSPECTION OBSERVATIONS AND PERFORMANCE	
<p>1. WAS FDA JURISDICTION ESTABLISHED?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>	
<p>2. DID THE INSPECTOR SELECT AN APPROPRIATE PRODUCT FOR THE INSPECTION AND, IF NECESSARY, MAKE APPROPRIATE ADJUSTMENTS BASED ON WHAT THE FIRM WAS PRODUCING?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>	
<p>3. DID THE INSPECTOR ASSESS THE EMPLOYEE PRACTICES CRITICAL TO THE SAFE PRODUCTION AND STORAGE OF FOOD?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>	

4. DID THE INSPECTOR PROPERLY EVALUATE THE LIKELIHOOD THAT CONDITIONS, PRACTICES, COMPONENTS, AND/OR LABELING COULD CAUSE THE PRODUCT TO BE ADULTERATED OR MISBRANDED?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

5. DID THE INSPECTOR RECOGNIZE SIGNIFICANT VIOLATIVE CONDITIONS OR PRACTICES IF PRESENT AND RECORD FINDINGS CONSISTENT WITH STATE PROCEDURES?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

6. DID THE INSPECTOR DEMONSTRATE THE ABILITY TO DISTINGUISH BETWEEN SIGNIFICANT VERSUS INSIGNIFICANT OBSERVATIONS AND ISOLATED INCIDENTS VERSUS TRENDS?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

<p>7. DID THE INSPECTOR REVIEW AND EVALUATE THE APPROPRIATE RECORDS AND PROCEDURES FOR THIS ESTABLISHMENT'S OPERATION ANDEFFECTIVELY APPLY THE INFORMATION OBTAINED FROM THIS REVIEW?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>
<p>8. DID THE INSPECTOR COLLECT ADEQUATE EVIDENCE AND DOCUMENTATION IN ACCORDANCE WITH STATE PROCEDURES GIVEN THE NATURE OF THE INSPECTIONAL FINDINGS?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>
<p>9. DID THE INSPECTOR VERIFY CORRECTION OF DEFICIENCIES IDENTIFIED DURING THE PREVIOUS STATE INSPECTION?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>

II. INSPECTION OBSERVATIONS AND PERFORMANCE (Continued)	
<p>10. DID THE INSPECTOR ACT IN A PROFESSIONAL MANNER AND DEMONSTRATE PROPER SANITARY PRACTICES DURING THE INSPECTION?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS (required for Needs Improvement)</p>	
II. A. INSPECTION OBSERVATIONS AND PERFORMANCE FOR 'HACCP-REGULATED' FACILITIES	
<p>Note to Auditor: These four questions apply to only firms subject to HACCP regulations. These four questions should be left blank for firms not subject to HACCP regulations.</p>	
<p>1. DID THE INSPECTOR USE THE "FISH AND FISHER PRODUCTS HAZARDS AND CONTROLS GUIDE" OR THE "JUICE HACCP HAZARDS AND CONTROLS GUIDE," AS APPROPRIATE, TO IDENTIFY AND EVALUATE THE HAZARDS ASSOCIATED WITH THE PRODUCT AND PROCESS?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS (required for Needs Improvement)</p>	
<p>2. DID THE INSPECTOR ASSESS THE FIRM'S IMPLEMENTATION OF SANITATION MONITORING FOR THE APPLICABLE EIGHT KEY AREAS OF SANITATION?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS (required for Needs Improvement)</p>	

3. DID THE INSPECTOR REVIEW THE FIRM'S HACCP PLAN (OR NECESSARY PROCESS CONTROLS IN THE ABSENCE OF A HACCP PLAN) AND APPLICABLE MONITORING, VERIFICATION AND CORRECTIVE ACTION RECORDS, INCLUDING THOSE RELATED TO SANITATION?

- Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

4. DID THE INSPECTOR RECOGNIZED EFICIENCIES IN THE FIRM'S MONITORING AND SANITATION PROCEDURES THROUGH IN-PLANT OBSERVATIONS?

- Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION

1. DID THE INSPECTOR IDENTIFY HIMSELF/HERSELF AND MAKE APPROPRIATE INTRODUCTIONS, WHICH INCLUDE EXPLAINING THE PURPOSE AND SCOPE OF THE INSPECTION?

- Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

<p>2. DID THE INSPECTOR USE SUITABLE INTERVIEWING TECHNIQUES?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>
<p>3. DID THE INSPECTOR EXPLAIN FINDINGS CLEARLY AND ADEQUATELY THROUGHOUT THE INSPECTION?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>
<p>4. DID THE INSPECTOR ALERT THE FIRM'S APPROPRIATE MANAGEMENT WHEN AN IMMEDIATE CORRECTIVE ACTION WAS NECESSARY?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS <i>(required for Needs Improvement)</i></p>

5. DID THE INSPECTOR ANSWER QUESTIONS AND PROVIDE INFORMATION IN AN APPROPRIATE MANNER?

Acceptable Needs Improvement

COMMENTS (*required for Needs Improvement*)

6. DID THE INSPECTOR WRITE THEIR FINDINGS ACCURATELY, CLEARLY AND CONCISELY ON THE STATE FORM/DOCUMENT LEFT WITH THE FIRM?

Acceptable Needs Improvement

COMMENTS (*required for Needs Improvement*)

NOTE: EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS JUDGED AS NEEDING IMPROVEMENT.

Overall Rating:

If three or less items are marked "needs improvement," the overall rating is "acceptable." If four or more items are marked "needs improvement," the overall rating is "needs improvement." The overall rating must be marked in the space provided in the header on the first page.

All questions must be answered "acceptable" or "needs improvement," except for section II.A. *Inspection Observations and Performance for 'HACCP-Regulated' firms*. **If the establishment is not subject to Seafood or Juice HACCP regulations, leave the scoring for these four questions blank.**

If four or more evaluated items are marked as "needs improvement," the state program manager must be notified by the appropriate FDA liaison that additional training or other performance improvement measures for then inspector being audited should be initiated. All contract inspectors who receive an overall audit score of "needs improvement" shall receive remedial training in deficient areas or as agreed upon by the FDA Project and Co-Project Officers prior to resuming contract inspection duties.

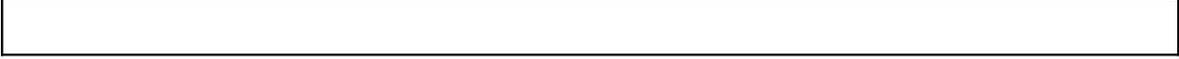
ADDITIONAL COMMENTS

SIGNATURE OF FDA AUDITOR	DATE

Appendix 4.6

Manufactured Food Regulatory Program Standards Inspection Report Audit Form	
Auditor	Date of audit
Firm identification number	Date of inspection
I. Introduction	
<p>1. FORMAT OF THE INSPECTION REPORT FOLLOWED THE STATE PROGRAM'S CURRENT PROCEDURES AND POLICIES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>	
<p>2. REQUIRED FIELDS ON INSPECTION REPORT OR RELATED REPORT FORMS ARE COMPLETED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>	
II. Evidence Development	
<p>1. IDENTIFIED FIRM MANAGERS AND KEY PERSONNEL AND DESCRIBED THEIR RESPONSIBILITIES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>	
<p>2. VERIFIED LEGAL STATUS OF FIRM AND CORPORATE OFFICERS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>	
<p>3. DOCUMENTED INDIVIDUAL RESPONSIBILITY. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>	
<p>4. REVIEWED QUALITY ASSURANCE PROGRAM AND FIRM'S PROCEDURES FOR IDENTIFYING RISK AND MAINTAINING CONTROLS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>	
<p>5. IDENTIFIED VIOLATIONS.</p>	

<input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
Page 2
6. DOCUMENTED SIGNIFICANT FINDINGS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
7. DOCUMENTED POSSIBLE CAUSES OF CONTAMINATION. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
8. COLLECTED SUFFICIENT SAMPLES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
9. COLLECTED EXHIBITS, PHOTOGRAPHS, OR PHOTOCOPIES TO DOCUMENT FINDINGS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
10. DESCRIBED FIRM'S SYSTEM FOR PRODUCT AND LOT CODING. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
11. REPORTED PRODUCT DISTRIBUTION. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
12. REVIEWED RECORDS OF COMPLAINTS RECEIVED BY FIRM. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
III. Discussions With Management
1. DISCUSSED FINDINGS AND VIOLATIONS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)



Page 3	
2.	REPORTED RESPONSES OR REPLIES FROM THE FIRM. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
3.	RECORDED ANY WARNINGS OF POSSIBLE FURTHER ACTIONS (REINSPECTION, EMBARGO, REVOCATION OF LICENSE, OR LEGAL CONSEQUENCES OF VIOLATIVE CONDITIONS) GIVEN TO THE FIRM. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
4.	RECORDED ANY REFUSALS ENCOUNTERED DURING THE INSPECTION. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
IV. Organization of the Report	
1.	REFERENCED EXHIBITS IN THE REPORT. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
2.	WRITTEN OBSERVATIONS WERE CLEAR AND CONCISE. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
3.	OBSERVATIONS WERE FACT BASED AND SUPPORTED BY LAWS AND REGULATIONS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
4.	EMPHASIZED SIGNIFICANT OBSERVATIONS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
5.	OBSERVATIONS WERE REPETITIOUS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)

Page 4	
6.	<p>SUBMITTED REPORT WITHIN TIMEFRAMES.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
V. Supervisory Review	
1.	<p>STATED THE REASON FOR THE INSPECTION, A BRIEF HISTORY OF THE FIRM, AND FOLLOW-UP TO THE PREVIOUS INSPECTION, IF NECESSARY.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
2.	<p>A SUMMARY OF FINDINGS AND DISPOSITION OF INSPECTION WERE RECORDED IN THE REPORT.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
3.	<p>REINSPECTION SCHEDULE AND RECOMMENDATION FOR COMPLIANCE FOLLOW UP WERE GENERATED AND RECORDED.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
4.	<p>CLASSIFICATION AND FOLLOW-UP WERE CONSISTENT WITH THE LAW, CURRENT POLICIES, AND INSPECTIONAL FINDINGS.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
5.	<p>SUPERVISORY REVIEW AND ACTION WERE DONE WITHIN ADMINISTRATIVE TIMEFRAMES.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
6.	<p>VERIFIED AND DESCRIBED CORRECTIVE ACTIONS FROM PREVIOUS INSPECTION FINDINGS.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>

Page 5	
7.	DATES IN REPORT, COVERSHEET, AND CODING OR OTHER ADMINISTRATIVE DATA WERE RECORDED ACCURATELY. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
8.	DISTRIBUTION OF REPORT WAS RECORDED ACCURATELY ON THE COVERSHEET. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)

Appendix 4.7

Manufactured Food Regulatory Program Standards Sample Report Audit Form	
Auditor	Date of audit
Sample identification number	Date of collection
I. Introduction	
3. REASON FOR SAMPLE COLLECTION WAS RECORDED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS <i>(required for needs improvement)</i>	
4. SAMPLE SIZE WAS DESCRIBED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS <i>(required for needs improvement)</i>	
5. LOT AND PRODUCT CODING WERE RECORDED ON SAMPLE REPORT. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS <i>(required for needs improvement)</i>	
6. MANUFACTURER, SHIPPER, DEALER, AND THE RESPONSIBLE FIRM WERE RECORDED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS <i>(required for needs improvement)</i>	
7. REQUIRED FIELDS ON THE SAMPLE REPORT (SR) OR RELATED REPORT FORMS ARE COMPLETED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS <i>(required for needs improvement)</i>	
II. Evidence Development	
1. METHOD OF COLLECTION WAS APPROPRIATE FOR TYPE OF PRODUCT. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS <i>(required for needs improvement)</i>	
2. METHOD OF COLLECTION, INCLUDING SAMPLE SIZE, WAS APPROPRIATE FOR THE LABORATORY ANALYSES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS <i>(required for needs improvement)</i>	
3. SAMPLE LABELS AND LABELING BEARING IDENTIFICATION NUMBERS AND OTHER LOGICALLY REPORTED ON <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS <i>(required for needs improvement)</i>	

Page 2	
4. PRODUCT LABEL AND LABELING WERE SUBMITTED WITH SR. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)	
5. RECEIPT FOR SAMPLE WAS OBTAINED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)	
6. AFFIDAVITS WERE CLEAR, LEGIBLE, AND COMPLETE. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)	
7. SR WAS SUBMITTED WITHIN TIMEFRAMES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)	
III. Sample Integrity	
1. SAMPLE WAS HANDLED, PACKAGED, AND SHIPPED TO PREVENT COMPROMISING THE CONDITION OR INTEGRITY OF THE SAMPLE. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)	
2. SAMPLE WAS DELIVERED OR SHIPPED TO THE APPROPRIATE LABORATORY WITHIN ACCEPTABLE TIMEFRAMES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)	
3. SAMPLE DELIVERY (DATE AND CUSTODIAN) WAS RECORDED ON SR. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)	

Appendix 4.8
Corrective Action Plan

The corrective action for each deficiency reported during an audit should be described in the table below. Supporting documents should be referenced and maintained by the State program.

State agency: _____ State program:

Type of audit: **FIELD INSPECTION** **INSPECTION REPORT**
SAMPLE REPORT
(circle one)

Performance factor (record number from audit form)	Description of deficiency	Corrective action(s)	Date of next audit

**Appendix 5.1
Self-Assessment Worksheet**

State agency: _____ **State program:**

Does the State program meet the criteria contained in standard number 5, section 5.3?

Program Elements	Yes/ No	If no, specify why criteria are not met.
The State program uses epidemiological information from other agencies.		
1. Is the State program responsible for epidemiological investigations identified?		
2. Is there a system to coordinate agreements between the food and epidemiology programs and that clearly identifies the roles, duties, and responsibilities of each program?		
The State program has an established system to investigate reports of illness, injury, and suspected outbreaks.		
1. Are complaints alleging food-related illness, injury, or terrorism maintained in a log or database?		
2. Does the State program initiate a response to reports of illness or injury within established timeframes?		
3. Does the State program use established epidemiology procedures to conduct illness or injury investigations and collect information?		
4. Are the factors that caused the illness, injury, or incidents reported?		
The State program disseminates information to the public.		
1. Is a procedure in place that outlines criteria for releasing information to the public?		
2. Does the State program provide food safety education to the public and regulated industry?		
3. Are enforcement tools utilized to reduce and contain illness and injury?		

Program Elements	Yes/ No	If no, specify why criteria are not met.
Outbreak reports and surveillance summaries are distributed to the appropriate agencies.		
1. Does the State program maintain a current list of communication links with the appropriate agencies?		
2. Is a coordinator designated to guide investigative efforts of all agencies involved?		
3. Are investigations coordinated with the appropriate agencies?		
4. Is a procedure in place to conduct tracebacks of food implicated in an illness, injury, or outbreak, including coordination with the appropriate agencies?		
5. Are final reports of the State program's findings of foodborne illness and injury investigations maintained and shared with the appropriate agencies?		
The State program provides guidance for immediate notification of appropriate law enforcement agencies when intentional food contamination or terrorism is suspected or threatened.		
1. Is a written policy in place for handling reports or threats of intentional food contamination or terrorism?		
2. Has the State program identified a coordinator to lead investigations of suspected or threatened intentional food contamination and terrorism?		
3. Has the State program identified the appropriate agencies to be contacted and the name and phone number of designated contact persons in such agencies?		
4. Does the State program collaborate as necessary with FDA and other Federal authorities under conditions of increased threat of intentional contamination?		

Name/title of auditor: _____

Signature: _____

Date: _____

Appendix 5.2

Memorandum of understanding between the department of health and the department of agriculture concerning the investigation of foodborne illnesses associated with food service establishments and food plants

I. GENERAL

This Memorandum of Understanding (MOU) replaces the MOU dated _____, and effective on _____, between the Department of Health (Health) and the Department of Agriculture (Agriculture).

The purpose of this MOU is to clarify the respective responsibilities of Agriculture and Health in the surveillance for, and investigation of, foodborne illnesses, and in furtherance of such purpose, to broaden cooperative efforts between the two agencies.

Responsible Agencies

Agriculture and Health are the responsible agencies for the implementation of this MOU. Under the authority of Sections _____ of the Public Health Law and pursuant to the power granted to the State Commissioner of Health by Agriculture Law to certify and approve service food establishment permit and inspection programs of local health agencies, the State Commissioner of Health, by execution of this instrument, binds all city and county health departments and State district health offices (local health units) to its terms and conditions.

For purposes of this agreement, Health and Agriculture will be responsible for its implementation.

Jurisdiction

This MOU applies to the entire State and includes all city and county health departments.

Effective Date

This agreement will be effective _____.

Legal Authority

The _____ provides requisite authority for Agriculture and Health to enter into this MOU. Section _____ of the Public Health Law and Section _____ of the Agriculture Law also authorize this MOU.

II. RESPONSIBILITIES AND IMPLEMENTATION

Determination of Responsibility

When a food-related illness from a manufactured food product regulated by Agriculture, Health, and local health departments is reported, Health will be responsible for conducting the epidemiologic investigation. Agriculture will be responsible for investigating the food preparation areas and conducting an investigation at the food plant. Agriculture will send a copy of these reports to Health. Agriculture will also coordinate any resulting actions to remove the contaminated food from distribution. Laboratory support for investigations will be coordinated by each agency under separate existing agreements.

Implementation

Agriculture will inform its field representatives of their areas of responsibility. Health will define areas of responsibility among its local health units. Responsibilities of other State and Federal agencies also will be specified.

Health, Agriculture, and local health units will provide or sponsor joint training sessions in the interpretation and application of principles, regulations, standards, and techniques of common concern or interest.

III. MECHANISMS FOR INFORMATION EXCHANGE

Health, Agriculture, and each local health unit shall maintain rosters of regional and local Health officials and Agriculture food program supervisors and make such rosters available to each other.

If Agriculture becomes aware of actual or suspected cases of foodborne illness, it shall report such cases by telephone--without delay--to the local health unit having jurisdiction for that locality. Health and Agriculture will jointly investigate and complete final reports involving illnesses that occur at, or due to, establishments regulated by Agriculture. These reports will be forwarded to Agriculture and to Health.

Whenever one agency learns of an FDA Class I or similar recall of food or food products, it shall immediately notify the other agency of such recall. Throughout the recall process, both agencies at all levels will make a maximum effort to keep the other agency informed and cooperate in every way possible to expedite the removal of hazardous food from the marketplace.

IV. MECHANISMS FOR EMBARGO/SEIZURE OF FOOD SOURCES IMPLICATED IN EPIDEMIOLOGIC INVESTIGATIONS

Epidemiologic Investigation

Health will investigate foodborne disease outbreaks. These investigations are conducted by county, city health departments, and/or State health departments following procedures outlined in the "Environmental Health Manual." Health will notify Agriculture of all on-going investigations where a contaminated food source is the suspected cause of a disease outbreak. Agriculture will provide assistance in the investigation and may play the lead role in tracing contaminated foods back to their source by visiting retailers, wholesalers, and producers to review and obtain records that document the chain of distribution for the products. Health will analyze the findings of the epidemiologic and source investigations and make a determination as to the likelihood of an association between the illness outbreak and its cause being one or more sources. When warranted, based on the evaluation of the investigation data and analysis, the Commissioner of Health will certify to the Commissioner of Agriculture that food from the source(s) constitute(s) a danger to the health of the people of the State and that such source(s) is/are unapproved source(s) for food service establishments in the State.

Embargo, Seizure, Recall, and Public Notification

After receiving certification from the Commissioner of Health, the Commissioner of Agriculture shall direct the seizure quarantine and/or destruction of the food in question pursuant to the provisions of Section ____ of the Agriculture Law, following his or her determination that said food is adulterated within the meaning of Section ____ of the Agriculture Law and, as such, that the manufacture, processing, possession, sale, offering, or exposure for sale of such food would violate Section _____ of the Agriculture Law. Where they deem it appropriate, the Commissioners of Health and Agriculture shall direct that a recall of such adulterated food be implemented and that the public be notified of such recall. Health shall assist in cases involving such seizures, quarantines, destructions, and recalls by assuring the removal of any remaining contaminated food from food service establishments and food plants and by making available witnesses for any administrative proceedings and/or litigation associated with such actions.

Nothing herein contained shall be construed to restrict the power of the Commissioner of Health to take Summary Action under Public Health Law Section ____ to require the discontinuance of conditions or activities constituting a danger to public health when such action is deemed appropriate under the circumstances.

V. REVIEW OF AGREEMENT

This agreement between the two departments shall be submitted annually to the Governor's Office and the Division of the Budget for their review of effectiveness and to solicit their recommendations to both Agriculture and Health as to changes of policies and procedures with respect to this agreement.

For the Department of Agriculture

Signature _____

Title _____

Date _____

For the Department of Health

Signature _____

Title _____

Date _____

Appendix 6.1
Self-Assessment Worksheet

State agency: _____ **State program:** _____

The State program will provide an overview of its compliance and enforcement program. References to sources such as laws, regulations, and manuals are acceptable.

1. Describe the compliance and enforcement program and include references to sources.

2. Describe how the State program uniformly applies enforcement strategy(ies).

3. Describe the methods (including electronic systems) used by the State program to track critical and chronic violations and violators.

4. Describe the risk-based process used to determine when a directed investigation, follow-up, or a re-inspection is needed.

5. Provide the established timeline for progressive compliance actions including but not limited to license revocation, embargoes, warning letters, and injunctions.

6. Describe how the State program delivers verbal and written policy and guidance impacting compliance decisions to non-operational and operational staff.

Name/title of auditor: _____

Signature: _____

Date: _____

Appendix 6.2

Summary of Compliance and Enforcement Activities

Worksheet 6.2 is used to record the enforcement actions recommended in the previous 12 months and to calculate the State program's rating for conformance to compliance procedures. Supporting documents should be referenced and maintained by the State program. Please indicate if an action was taken because voluntary compliance was not achieved.

It is recommended that all cases be reviewed and compiled. State programs with a volume of cases, however, may use a statistical approach and review representative cases. Use continuation sheets as necessary.

- INSTRUCTIONS:**
- (1) Record the food firm identification number and the recommended enforcement action.
 - (2) For each type of enforcement action, record the level of conformance to compliance procedures.
A = acceptable; NI = needs improvement
 - (3) Record the A_t and NI_t .
 A_t = vertical sum of acceptable ratings.
 NI_t = vertical sum of needs improvement ratings.
 - (4) Calculate the overall rating for the State program's conformance to compliance procedures. Record the rating in the space provided in the box located at the top of Worksheet 6.2.

FORMULA:

$$\text{Performance factor rating} = [A_t / (A_t + NI_t)] \times 100$$

Worksheet 6.2
Calculation of the level of conformance to compliance procedures

State agency: _____ State program: _____

Rating for conformance to compliance procedures (4):

Total Food firm identification number (1)	<i>Enter the final sums subtotal + sums of Enforcement action (2) -- on this form recommended (1)</i>	A _t =	NI _t =	USE THIS SPACE TO EXPLAIN IMPROVEMENTS NEEDED TO FOLLOW COMPLIANCE PROCEDURES
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>	A _t =	NI _t =	

Name/title of auditor: _____

Signature: _____

Date: _____

Worksheet 6.2
Continuation sheet

Food firm identification number (1)	Enforcement action recommended (1)	Compliance procedures followed? (2)		USE THIS SPACE TO EXPLAIN IMPROVEMENTS NEEDED TO FOLLOW COMPLIANCE PROCEDURES	
Total	<i>Enter the sums of (2).</i>	A _t =	NI _t =		

Appendix 7
Self-Assessment Worksheet

State agency: _____ **State program:**
_____ **Year** _____

List all industry and community outreach activities in the following table.

Date	Topic	Description	Audience Type	Number of Attendees	Location

Name/title of auditor: _____
Signature: _____ **Date:** _____

**Appendix 8.1
Self-Assessment Worksheet**

State agency: _____ **State program:**

Does the State program have sufficient funds, staff, equipment, and resources necessary to meet the program standards? Answer yes or no in each block. If no, please explain. Use additional pages as needed.

	Standard	Funding	Staffing	Equipment	Other resources needed
1	Regulatory Foundation				
2	Training Program				
3	Inspection Program				
4	Inspection Audit Program				
5	Food-related Illness ...Outbreaks...Food Defense...				
6	Compliance and Enforcement				
7	Industry and Community Relations				
8	Program Resources				
9	Program Assessment				
10	Laboratory Support				

Name/title of auditor: _____

Signature: _____ **Date:** _____

Appendix 8.2

I. Calculation for determining a required number of inspectors

This appendix provides a sample calculation for the number of field staff required to conduct inspections¹³ of food plants. The data in the following table will vary significantly based on local or regional conditions.

Risk category	Number in inventory	Inspection frequency	Average inspection time (include travel) ¹⁴	Reinspection frequency
High	1,000	12 months	7.2 hours	10%
Medium	2,000	18 months	5.7 hours	10%
Low	1,000	24 months	4.2 hours	10%

1. Calculate available annual inspection time per full time equivalent (FTE).

For example, the State agency determines that after allowances for annual leave, sick leave, holidays, training, administrative time, and other activities each State program FTE has 1200 hours available for conducting inspections.

2. Calculate the number of hours required to inspect establishments in each risk category.

Formula for high risk establishment inspection time:

1000 firms x 100% coverage = 1000 inspections + 10% reinspection = 1100 total inspections per year x 7.2 hours = 7920 hours

Formula for medium risk establishment inspection time:

2000 firms x 66.6% coverage = 1333 inspections + 10% reinspection = 1466 total inspections per year x 5.7 hours = 8356 hours

Formula for low risk establishment inspection time:

1000 firms x 50% coverage = 500 inspections + 10% reinspection = 550 inspection total inspections x 4.2 hours = 2320 hours

3. Calculate the number of FTE's required. Formula:

7920 hours for high risk + 8356 hours for medium risk + 2320 hours for low risk = 18596 inspection hours required / 1200 inspection hours available per FTE = **15.5 FTEs**

¹³ Includes routine surveillance, reinspections, complaint or outbreak investigations, compliance follow-up investigations, risk assessment reviews, process reviews, and other direct establishment contact time such as on-site training.-

¹⁴ Inspection times based on calculations presented in "DHHS Office of Inspector General's FDA Oversight of State Food Firm Inspections" dated June 2000.

Appendix 8.3

Inspection Equipment

Equipment	Assigned	Available	<i>Wish list</i>
Computer and printer			X
Camera	X		
Digital camera			X
Credentials	X		
Important phone numbers (supervisor and servicing laboratory)	X		
Regulation and policies	X		
Paper, pen, masking tape, and permanent marker	X		
Clipboard	X		
Required forms ¹⁵	X		
Alcohol swabs and wipes	X		
Flashlight and holder	X		
Blacklight		X	
Light meter		X	
Thermometer	X		
Infrared thermometer	X		
Exacto knife and scissors	X		
Putty knife and scraper	X		
Sampling devices (sieves, triers, and swabs)		X	
Sampling equipment (sterile containers and scoops)		X	
Coolant (ice and freezer paks)		X	
Shipping containers		X	
Appropriate sanitizer test strips	X		
Official seals	X		
Protective clothing (lab coat, gloves, and boots)	X		
Eye protection	X		
Hair restraint	X		
Hearing protection	X		
Hard hat	X		

¹⁵ States will attach to appendix 8.3 a list of its required inspection forms.

Safety shoes			X
Respirator		X	

Worksheet 9
Self-Assessment and Improvement Tracking

State agency: _____ State program: _____

Year: _____

	STANDARD	INITIAL SELF-ASSESSMENT	VERIFICATION ON AUDIT	PROGRAM IMPROVEMENT PLAN	SUBSEQUENT SELF-ASSESSMENT
1	Regulatory Foundation	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
2	Training Program	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
3	Inspection Program	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
4	Inspection Audit Program	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
5	Food-related Illness... Outbreaks...Food Defense...	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
6	Compliance and Enforcement	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
7	Industry and Community Relations	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
8	Program Resources	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
9	Program Assessment	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
10	Laboratory Support	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:

Name/title of auditor: _____

Signature: _____ Date: _____

Appendix 10
Self-Assessment Worksheet

State agency: _____ **State program:** _____

Does the State program meet the assessment criteria?

Program Elements	Yes/No	If no, please specify why criteria are not met.
Does the program have:		
a. A current list of servicing laboratories		
b. A list of analytical capabilities for each servicing laboratory		
c. A servicing laboratory to analyze samples that may contain biological hazards.		
d. Contracts or written agreements with servicing laboratories.		
e. Verification of the servicing laboratory's accreditation or certification		
The servicing laboratory's QAP contains the requirements listed here:		
a. Calibration, verification, and maintenance of equipment		
b. Documentation of analytical results		
c. Recordkeeping (worksheets, sample records)		
d. Sample accountability		
e. Sample integrity and chain of custody		
f. Qualifications of analysts (training included)		
g. Audit procedures		

Name/title of auditor: _____

Signature: _____

Date: _____

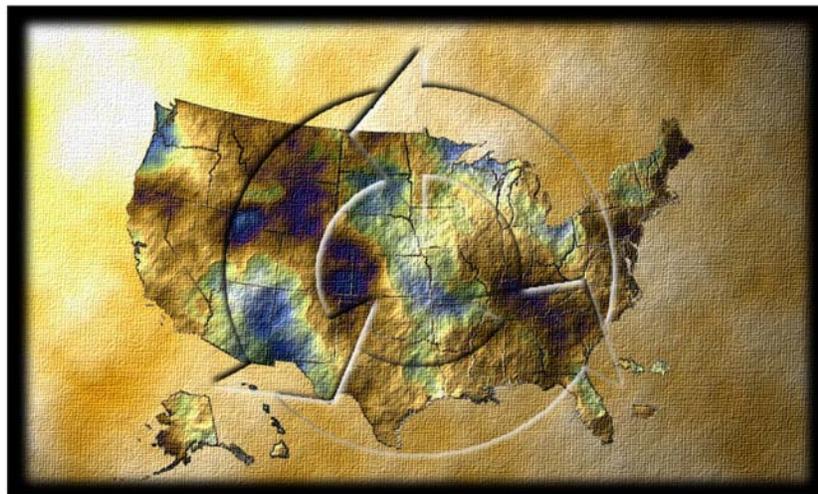


U.S. Food and Drug Administration



Voluntary National Retail Food Regulatory Program Standards

April 2009



“Standards of Excellence for Continual Improvement”

Developed and recommended by the U.S. Food and Drug Administration with input from federal, state, and local regulatory officials, industry, trade associations, academia, and consumers.

OMB Control No. 0910-0621

Expiration Date: 03-31-2011

Additional PRA statement on the following page.

PAPERWORK REDUCTION ACT OF 1995

This document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 157.1 annual hours per recordkeeper for each enrolled jurisdiction to complete the management tasks for recordkeeping for self-assessment, baseline data collection, and verification audit. FDA estimates a total of 24 minutes annually for each enrolled jurisdiction to complete the following: FDA Form 3519, "FDA National Registry Report," Form 3520, "Permission to Publish in National Registry," "ATN Field Training Worksheet" and "Documentation of Successful Completion – Field Training Process" forms. FDA's recordkeeping and reporting burden estimate includes time required for a state, local, or tribal agency to review the instructions in the Program Standards, compile information from existing sources, and create any records recommended in the Program Standards that are not already kept in the normal course of the agency's usual and customary activities. Worksheets (Appendices) are provided to assist in this compilation. Send comments regarding this burden estimate or suggestions for reducing this burden to: Office of Food Safety, Retail Food – Cooperative Programs Coordination Staff, (HFS-320), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0621 (expires 03-31-2011).

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INTRODUCTION

Achieving national uniformity among regulatory programs responsible for retail food protection in the United States has long been a subject of debate among the industry, regulators and consumers. Adoption of the FDA Food Code at the state, local and tribal level has been a keystone in the effort to promote greater uniformity. However, a missing piece has been a set of widely recognized standards for regulatory programs that administer the Food Code. To meet this need FDA has developed the Voluntary National Retail Food Regulatory Program Standards (Program Standards) through ideas and input from federal, state, and local regulatory officials, industry, trade and professional associations, academia and consumers on what constitutes a highly effective and responsive retail food regulatory program.

In March of 1996, the FDA hosted a meeting to explore ways in which its retail food protection program could be improved. Participants in the meeting included FDA Retail Food Specialists, FDA headquarters personnel, state and local regulatory officials from the six FDA regions, the president of the Association of Food & Drug Officials, and industry representatives. Following that meeting, FDA established a National Retail Food Team comprised of the Regional Retail Food Specialists, CFSAN personnel and other FDA personnel directly involved in retail food protection. A Retail Food Program Steering Committee was established and tasked with leading the team to respond to the direction given by the participants in the meeting, i.e. providing national leadership, being equal partners, being responsive, and providing communication and promoting uniformity.

The Steering Committee was charged with developing a five-year operational plan for FDA's retail food program. The Steering Committee was also charged with ensuring the operational plan was in keeping with the goals and mission of the President's Food Safety Initiative. FDA solicited input from the regulatory community, industry and consumers in developing the plan. The resulting Operational Plan charted the future of the National Retail Food Program and prompted a reassessment of the respective roles of all stakeholders and how best to achieve program uniformity.

From the goals established in the Operational Plan, two basic principles emerged on which to build a new foundation for the retail program:

- Promote active managerial control of the risk factors most commonly associated with foodborne illness in food establishments, and
- Establish a recommended framework for retail food regulatory programs within which the active managerial control of the risk factors can best be realized.

These principles led to the drafting of standards that encourage voluntary participation by the regulatory agencies at the state, local, and tribal level. The Program Standards were developed with input obtained through a series of meetings over a two-year period including: the 1996 stakeholders meeting, FDA Regional Seminars, meetings with state officials hosted by the Retail Food Specialists, and six Grassroots Meetings held around the country in 1997. Valuable input from industry associations, associations of regulatory officials, and others was

also obtained. The Program Standards were provided to the Conference for Food Protection for further input and to achieve broad consensus among all stakeholders.

In developing the Program Standards, FDA recognized that the ultimate goal of all retail food regulatory programs is to reduce or eliminate the occurrence of illnesses and deaths from food produced at the retail level and that there are different approaches toward achieving that goal. Federal, state, local, and tribal agencies continue to employ a variety of mechanisms with differing levels of sophistication in their attempt to ensure food safety at retail.

While the Program Standards represent the food safety program to which we ultimately aspire, they begin by providing a foundation upon which all regulatory programs can build through a continuous improvement process. The Standards encourage regulatory agencies to improve and build upon existing programs. Further, the Standards provide a framework designed to accommodate both traditional and emerging approaches to food safety. The Program Standards are intended to reinforce proper sanitation (good retail practices) and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to foodborne illness.

PURPOSE

The Program Standards serve as a guide to regulatory retail food program managers in the design and management of a retail food regulatory program and provide a means of recognition for those programs that meet these standards. Program manager and administrators may establish additional requirements to meet individual program needs.

The Program Standards are designed to help food regulatory programs enhance the services they provide to the public. When applied in the intended manner, the Program Standards should:

- Identify program areas where an agency can have the greatest impact on retail food safety
- Promote wider application of effective risk-factor intervention strategies
- Assist in identifying program areas most in need of additional attention
- Provide information needed to justify maintenance or increase in program budgets
- Lead to innovations in program implementation and administration
- Improve industry and consumer confidence in food protection programs by enhancing uniformity within and between regulatory agencies

Each standard has one or more corresponding appendices that contain forms and worksheets that facilitate the collection of information needed to fully assess a retail program.

Regulatory agencies may use existing, available records or may choose to develop and use alternate forms and worksheets that capture the same information.

SCOPE

The Program Standards apply to the operation and management of a retail food regulatory program that is focused on the reduction of risk factors known to cause or contribute to foodborne illness and to the promotion of active managerial control of these risk factors. The results of a self-assessment against the Standards may be used to evaluate the effectiveness of food safety interventions implemented within a jurisdiction. The Standards also provide a procedure for establishing a database on the occurrence of risk factors that may be used to track the results of regulatory and industry efforts over time.

These Standards do not establish recommendations or criteria for hiring qualifications and practices used by retail food regulatory programs nor do they establish criteria for the credentialing or certification of food safety inspection officers. Retail food regulatory programs should promote policies and practices that will attract a highly qualified and educated workforce with the ability to identify and communicate control of food safety hazards.

The Conference for Food Protection supports a minimum education for all Food Safety Inspection Officers of at least a bachelor's degree with 30 semester hours or 45 quarter hours in the basic sciences, including courses in biology, microbiology, chemistry, physics, agricultural science, other physical sciences, environmental health science, sanitary engineering, or environmental engineering.

NEW DEVELOPMENTS

The Program Standards were pilot tested in each of the five FDA regions in 1999. Each regulatory participant reported the results at the 2000 Conference for Food Protection. Improvements to the Standards were incorporated into the January 2001 version based on input from the pilot participants. Further refinements to the Standards were made in subsequent drafts leading up to the endorsement of the March 2002 version of the Program Standards by the 2002 Conference for Food Protection. Subsequent to this endorsement, the following general changes were made to the Program Standards document:

- The **April 2003** version contains enhancements to the forms and worksheets in the Appendices to improve their usefulness.
- The **January 2005** version contains revisions to Standard 1, 5, and 9 based on recommendations approved at the 2004 Conference for Food Protection.
- The **December 2007** version contains revisions to Standards 2, 3, 4, 6, and 9, Appendices B-1 through B-4 (Standard 2), Appendix D (Standard 4), and Appendix F (Standard 6), based on recommendations from the 2006 Conference for Food Protection. Further, the Office of Management and Budget assigned an OMB number to the project allowing the removal of the term “DRAFT” from the Standards.
- The **April 2009** version contains revisions to the Definitions, Standards 1, 2, 5, and 9, Appendix A (Standard 1), Appendices B-1 and B-2 (Standard 2), Appendix E (Standard 5), and Appendix F (Standard 6).

In maintaining these standards, FDA intends to allow for and encourage new and innovative approaches to the reduction of factors that are known to cause foodborne illness. Program managers and other health professionals participating in this voluntary program who have demonstrated means or methods other than those described here may submit those to FDA for consideration and inclusion in the Program Standards. Improvements to future versions of the Standards will be made through a process that includes the Conference for Food Protection to allow for constant program enhancement and promotion of national uniformity.

WEB-LINKS CONTAINED IN THIS DOCUMENT

Effective May 29, 2009, Phase One of the updated FDA web page will be completed. To access the enclosed links please go to: www.fda.gov then click on Food>Food Safety>Retail Food Protection. For web links for training and certification, please go to www.fda.gov, and search "ORAU State Training."

IMPACT ON PROGRAM RESOURCES

During pilot testing of the Program Standards in 1998, some jurisdictions reported that the self-assessment process was time consuming and could significantly impact an agency's resources. Collection, analysis, and management of information for the database were of special concern. However, participating jurisdictions also indicated that the resource commitment was worthwhile and that the results of the self-assessment were expected to benefit their retail food protection program. Advance planning is recommended before beginning the data collection process in order to use resources efficiently. It is further recommended that jurisdictions not attempt to make program enhancements during the self-assessment process. A better approach is to use the self-assessment to identify program needs and then establish program priorities and plans to address those needs as resources become available.

COMMENTS AND INQUIRIES

To promote uniform and reasonable application of these standards, interested persons are invited to submit comments and inquiries to their FDA Regional Retail Food Specialist or to the Retail Food Protection Team in the FDA Center for Food Safety and Applied Nutrition.

DEFINITIONS

The following definitions apply in the interpretation and application of these Standards.

- 1) **Active Managerial Control** – The purposeful incorporation of specific actions or procedures by industry management into the operation of a business to attain control over foodborne illness risk factors.
- 2) **Auditor** – 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.
- 3) **Baseline Survey** – See Risk Factor Study
- 4) **Candidate** – A regulatory officer whose duties include the inspection of retail food establishments.
- 5) **Compliance and Enforcement** – Compliance includes all voluntary or involuntary conformity with provisions set forth by the regulatory authority to safeguard public health and ensure that food is safe. Enforcement includes any legal and/or administrative procedures taken by the regulatory authority to gain compliance.
- 6) **Confirmed Foodborne Disease Outbreak** – A foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiologic analysis implicates the food as the source of the illness or epidemiological analysis alone implicates the food as the source of the illness
- 7) **Direct Regulatory Authority (DRA)** – The organizational level of government that is immediately responsible for the management of the retail program. This may be at the city, county, district, state, federal or tribal level.
- 8) **Enforcement Actions** – Actions taken by the regulatory authority such as, but not limited to, warning letters, revocation or suspension of permit, court actions, monetary fines, hold orders, destruction of food, etc., to correct a violation found during an inspection.
- 9) **Follow-up Inspection** – An inspection conducted after the initial routine inspection to confirm the correction of a violation(s).
- 10) **Food Code Interventions** – The preventive measures to protect consumer health stated below:
 1. Management's demonstration of knowledge;
 2. Employee health controls;
 3. Controlling hands as a vehicle of contamination;
 4. Time/temperature parameters for controlling pathogens; and
 5. Consumer advisory.
- 11) **Food-Related Injury** – An injury from ingesting food containing a physical hazard such as bone, glass, or wood.
- 12) **Foodborne Disease Outbreak** – The occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.
- 13) **Good Retail Practices (GRP's)** – Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the *Food Code* interventions or risk factors.

- 14) **Hazard** – A biological, chemical or physical property that may cause food to be unsafe for human consumption.
- 15) **National Registry of Retail Food Protection Programs (National Registry)** – A listing of retail food safety programs that have voluntarily enrolled as participants in the *Voluntary National Retail Food Regulatory Program Standards*.
- 16) **Person in charge (PIC)** – The individual present at a food establishment who is responsible for the operation at the time of inspection.
- 17) **Program Element** – One of the program areas for which a National Standard has been established such as regulations, training, inspection system, quality assurance, foodborne illness investigation, compliance and enforcement, industry and consumer relations, and program resources.
- 18) **Program Manager** – The individual responsible for the oversight and management of a regulatory retail food program.
- 19) **Quality Records** – Documentation of specific elements of program compliance with the National Standards as specified in each Standard.
- 20) **Risk Control Plan (RCP)** – A concisely written management plan developed by the retail or food service operator with input from the health inspector that describes a management system for controlling specific out-of-control risk factors.
- 21) **Risk Factors** – The improper employee behaviors or improper practices or procedures in retail food and food service establishments stated below which are most frequently identified by epidemiological investigation as contributing to foodborne illness or injury:
 1. Improper holding temperatures;
 2. Inadequate cooking;
 3. Contaminated equipment;
 4. Food from unsafe sources; and
 5. Poor personal hygiene.
- 22) **Risk Factor Study (Survey) (formerly Baseline Survey)** – A study on the occurrence of foodborne illness risk factors within institutional, foodservice, restaurants, and retail food facility types under a jurisdiction’s regulatory authority. Criteria for a Risk Factor Study (Survey) are detailed in Standard 9, including at a minimum:
 1. Data collection, analysis, and a written report;
 2. A collection instrument with data items pertaining to the five foodborne illness risk factors;
 3. A collection instrument that uses the convention of IN, OUT, NA, and NO to document observations;
 4. All facility types identified by FDA’s national study that are under the jurisdictions regulatory authority; and
 5. Studies subsequent to the initial study repeated at 5-year intervals.
- 23) **Routine Inspection** – A full review and evaluation of a food establishment's operations and facilities to assess its compliance with Food Safety Law, at a planned frequency determined by the regulatory authority. This does not include re-inspections and other follow-up or special investigations.
- 24) **Self-Assessment** – An internal review by program management to determine whether the existing retail food safety program meets the National Standards.
- 25) **Standardization Inspection** – An inspection used to demonstrate a candidate's

- knowledge, communication skills, and ability to identify violations of all regulatory requirements and to develop a risk control plan for identified, uncontrolled risk factors.
- 26) **Suspect Foodborne Outbreak** – An incident in which two or more persons experience a similar illness after ingestion of a common food or eating at a common food establishment/gathering.
- 27) **Trainer** - An individual who has successfully completed the following training elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.
1. Satisfactory completion of the prerequisite courses,
 2. Completion of a field training process similar to that contained in Appendix B-2, and
 3. Completion of 25 independent inspections and satisfactory completion of the remaining course curriculum.
- 28) **Training Standard** - A person who has successfully completed the following training elements as explained in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees. The training elements necessary are:
1. Satisfactory completion of the prerequisite courses,
 2. Completion of a field training process similar to that contained in Appendix B-2,
 3. Completion of 25 independent inspections and satisfactory completion of the remaining course curriculum, and
 4. Completion of a standardization process similar to the FDA standardization procedures.
- 29) **Verification Audit** - A systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment.

STANDARD NO. 1 REGULATORY FOUNDATION

This standard applies to the regulatory foundation used by a retail food program. Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment.

REQUIREMENT SUMMARY

The regulatory foundation includes provisions for:

1. The public health interventions contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*;
2. Control measures for the risk factors known to contribute to foodborne illness;
3. Good Retail Practices (GRPs) at least as stringent as the *Food Code* edition as specified in 1 above; and
4. Compliance and enforcement at least as stringent as the selected provisions from the *Food Code* and Annex 1 of the *Food Code* edition as specified in 1 above.

DESCRIPTION OF REQUIREMENT

A. Food Code Interventions and Risk Factor Control Measures

The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*. Jurisdictions meeting Standard 1 that may become noncompliant due to the release of a new edition of the *Code* are considered to continue meeting the Standard for a period of two years from the release date of the new *Code* edition in order to complete the process of updating its regulations.

To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed in Appendix A, Table A-1 and summarized in Table A-2, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations." For initial listing, the regulatory foundation must contain at least 9 of the 11 interventions and risk factor controls. In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.

B. Good Retail Practices

The regulations contain provisions that address Good Retail Practices that are at least as stringent as those described in the edition of the *Food Code* as specified in A.. To meet this element of the Standard, regulations must have a corresponding requirement for 95 percent of the *Food Code* sections as listed in Appendix A, Table A-3 and summarized in Table A-4, from #12 "Personnel" through #37 "Variance for Smoking."

C. Compliance and Enforcement

The regulations contain provisions that address Compliance and Enforcement requirements that are at least as stringent as those contained in the edition of the *Food Code* as specified in A.. To meet this element of the Standard, regulations must have a corresponding

requirement for each of the *Food Code* sections as listed in Appendix A, Table A-5, items 1 through 13; except item 12, Legal Remedies, where only one of the sections pertaining to criminal, injunctive, or civil penalties is required.

OUTCOME

The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

DOCUMENTATION

The quality records needed for this standard include:

1. The statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that govern the operation of a retail food establishment; and
2. The completed Appendix A and its accompanying tables.

STANDARD NO. 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

REQUIREMENT SUMMARY

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIOs) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1 – Completion of curriculum courses designated as “Pre” in Appendix B-1 prior to conducting any independent routine inspections.



STEP 2 – Completion of a minimum of 25 joint field training inspection,
AND
successful completion of the jurisdiction’s FSIO Field Training similar to the process outlined in Appendix B-2.



STEP 3 – Completion of a minimum of 25 independent inspections
AND
remaining course curriculum (designated as “post” courses) outlined in Appendix B-1.



STEP 4 – Completion of a standardization process similar to the FDA standardization procedures. (See FDA Procedures for Standardization of Retail Food Inspection/Training Officers at <http://www.cfsan.fda.gov/~ear/rfi-toc.html>).



STEP 5 – Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

DESCRIPTION OF REQUIREMENT

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIOs) shall have successfully completed the required elements of the 5-step training and standardization process as follows:

- Steps 1 through 4 within 18 months of hire or assignment to the retail food protection program.
- Step 5 every 36 months after the initial 18 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in prerequisite courses designated with a “Pre” in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of these prerequisite (“Pre”) courses.

OPTION 1:

Successful completion of the FDA ORA U prerequisite courses/exercises/examinations identified as “Pre” in Appendix B-1
AND
training on the jurisdiction’s prevailing statutes, regulations, and/or ordinances.

NOTE: *The estimated contact time for completion of the FDA ORA U prerequisite (“Pre”) courses is 42 hours.*

OPTION 2:

Successful completion of courses deemed by the regulatory jurisdiction’s food program supervisor or training officer to be equivalent to the FDA ORA U prerequisite (“Pre”) courses,
AND
training on the jurisdiction’s prevailing statutes, regulations, and/or ordinances,
AND
successful passing of one of the four written examination options (described later in this Standard) for determining whether a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the ORA U courses are listed on the following web site:

http://www.fda.gov/ora/training/orau/state/level_1_curriculum.htm

NOTE: *While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*

- *Training logs/records that are completed based on sign-in sheets; or*
- *Information validated from the certificate at the time-of-issuance; or*
- *A college transcript with a passing grade or other indication of successful completion of the course; or*
- *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
- *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORA U courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Professional - Food Safety (CP-FS) examination offered by the National Environmental Health Association;
2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable;
3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or
4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

NOTE: *Within the context of this Standard, the written examinations are part of a training process, NOT a standardization/certification process. The examinations listed are NOT to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any*

jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer or the jurisdiction's designated staff member, who has successfully completed all training elements (Steps 1 – 3) required by this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

Demonstration inspections are those in which the jurisdiction's trainer and/or designated staff person takes the lead and the FSIO observes the inspection process. Training inspections are those in which the person being trained takes the lead and demonstrates competencies identified in the jurisdiction's retail food program training plan. The jurisdiction's trainer is responsible for determining the appropriate combination of demonstration and trainee-led inspections based on the candidate's food safety knowledge and performance during the joint field training inspections.

The 25 joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food restaurant and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training process can be developed. To meet the intent of this Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

NOTE: *The CFP Field Training Manual is designed as a training process providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*

- *The CFP Field Training Manual is NOT intended to be used for certification or licensure purposes.*
- *The CFP Field Training Manual is NOT intended to be used for administrative purposes including but not limited to, job classifications, promotions, or disciplinary actions up to and including termination.*

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-

inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2005 FDA Food Code). The jurisdiction's trainer/food program manager can make a determination as to the FSIO's readiness to conduct independent inspections of risk category 1 establishments as defined in Appendix B-3 at any time during the training process.

NOTE: *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:*

- *Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and*
- *The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.*

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 18 months of hire or assignment to the regulatory retail food program, each new Food Safety Inspection Officer must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1 for the following six curricula areas, must be completed within this same 18 month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the prerequisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the prerequisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the prerequisite curriculum outlined in Step 1);
5. Epidemiology; and
6. HACCP.

All courses for each of the curriculum areas must be successfully completed within 18 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

NOTE: *The estimated contact time for completion of the FDA ORA U “post” courses is 13 hours. The term “post” refers to those courses in Appendix B-1 that were not included as part of the prerequisite coursework. This includes all the courses in Appendix B-1 that do not have the designation “Pre” associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the prerequisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses/exercises/exams listed under each curriculum area OR by completing courses deemed by the regulatory jurisdiction’s food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the ORA U courses are listed on the following web site:

http://www.fda.gov/ora/training/orau/state/level_1_curriculum.htm

Step 4: Food Safety Inspection Officer – Field Standardization

Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a “training standard” using a process similar to the “FDA Standardization Procedures.” The standardization procedures shall determine the inspector’s ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

NOTE: *The field standardization criteria described in Step 4 is intended to provide flexibility for a jurisdiction to use its own regulations or ordinances. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written*

standardization protocol must include the five performance areas outlined above in Step 4.

It is highly beneficial to use the FDA Food Code, standardization forms, and procedures for standardization even when a jurisdiction has adopted modifications to the Food Code. Usually regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections; however, to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel skilled in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors, and communicates vital information about the inspection in a way that can be received, understood and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to the regulatory agency, industry, and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard #2 criteria within the 18 month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (18 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, regulations, and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are specifically related to food safety or food inspection work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
 - WEB-based or online training courses (e.g., additional food safety courses offered through ORA U, industry associations, universities); and
 - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

6. Delivering presentations at professional conferences;
7. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
8. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period.

NOTE: *Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.*

A maximum of four (4) contact hours may be accrued for:

9. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education (CE) credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

NOTE: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of an employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.*

OUTCOME

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

DOCUMENTATION

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);
2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2;
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection staff attended and successfully completed the training and education steps outlined in this Standard;
7. Date of hire records or assignment to the retail food program; and,
8. Summary record of employees' compliance with the Standard.

The Standard 2 Program Self-Assessment and Verification Audit Form is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

STANDARD NO. 3 INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

REQUIREMENT SUMMARY

An inspection program that focuses on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

DESCRIPTION OF REQUIREMENT

Program management:

1. Implements the use of an inspection form that is designed for:
 - a) The identification of risk factors and interventions.
 - b) Documentation of the compliance status of each risk factor and intervention (i.e. a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
 - c) Documentation of all compliance and enforcement activities and
 - d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
4. Develops and implements a program policy that requires:
 - a) On-site corrective actions* as appropriate to the type of violation.
 - b) Discussion of long-term control** of risk factor options, and
 - c) Follow-up activities.
5. Establishes and implements written polices addressing code variance requests related to risk factors and interventions.
6. Establishes written polices regarding the verification and validation of HACCP plans when a plan is required by the code.

OUTCOME

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

DOCUMENTATION

The quality records needed for this standard include:

1. Inspection form that requires the selection of IN, OUT, NO, or NA,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,
3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

*Note: **On-site** corrective action as appropriate to the violation would include such things as:

- a. Destruction of foods that have experienced extreme temperature abuse,
- b. Embargo or destruction of foods from unapproved sources,
- c. Accelerated cooling of foods when cooling time limits can still be met,
- d. Reheating when small deviations from hot holding have occurred,
- e. Continued cooking when proper cooking temperatures have not been met.
- f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
- g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

STANDARD NO. 4 UNIFORM INSPECTION PROGRAM

This standard applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.

REQUIREMENT SUMMARY

Program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of laws, regulations, policies, and procedures.

DESCRIPTION OF REQUIREMENT

- 1) Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. The quality assurance program shall:
 - A. Be an on-going program.
 - B. Assure that each inspector:
 1. Determines and documents the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable is noted on the inspection form) through observation and investigation;
 2. Completes an inspection report that is clear, legible, concise, and accurately records findings, observations and discussions with establishment management;
 3. Interprets and applies laws, regulations, policies and procedures correctly;
 4. Cites the proper local code provisions for CDC-identified risk factors and Food Code interventions;
 5. Reviews past inspection findings and acts on repeated or unresolved violations;
 6. Follows through with compliance and enforcement;
 7. Obtains and documents on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation;
 8. Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of control risk factor occurred on consecutive inspections. Options may include but are not limited to risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans;
 9. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met; and
 10. Files reports and other documentation in a timely manner.
 - C. Describe the actions that will be implemented when the program analysis identifies deficiencies in quality or consistency in any program aspect listed in 1) B.

- 2) The quality assurance program must achieve an overall inspection program performance rating for each of the ten measured aspects [Items1-10] of at least 75% using the following self-assessment procedure and the appropriate Table in Supplement to Standard 4 (Appendix D).

An assessment review of each inspector's work shall be made 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 establishments, during every self-assessment period.

OUTCOME

A quality assurance program exists that ensures uniform, high quality inspections.

DOCUMENTATION

The quality records needed for this standard include:

1. A written procedure that describes the jurisdiction's quality assurance program that meets the criteria under the Description of Requirement section 1) B., including corrective actions for deficiencies, and
2. Documentation that the program achieves a 75 percent performance rating on each aspect using the self-assessment procedures described above and in Supplement to Standard 4 (Appendix D).

STANDARD NO. 5 FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in foodborne illness, food-related injury*, and outbreaks.

REQUIREMENT SUMMARY

The program has an established system to detect, collect, investigate and respond to complaints and emergencies that involve foodborne illness, food-related injury*, and intentional and unintentional food contamination.

DESCRIPTION OF REQUIREMENT

1. Investigative Procedures

- a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food-related injury*. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.
- b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.
- c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties and responsibilities of each party.
- d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.
- e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.
- f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or food-related injury* within 24 hours.
- g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.
- h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.

- i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

- a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.
- b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreak*s with CDC.

3. Laboratory Support Documentation

- a. The program has a letter of understanding, written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.
- b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

- a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

- a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.
- b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.
- c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

- a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

- a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.
- b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:
 - 1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment;
 - 2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type;
 - 3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food;
 - 4) Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food preparation processes;
 - 5) Number of confirmed foodborne disease outbreaks*;
 - 6) Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*;
 - 7) Contributing factors most often identified;
 - 8) Number of complaints involving real and alleged threats of intentional food contamination; and
 - 9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.
- c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection, and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak* investigations occur.

OUTCOME

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional, or deliberate food contamination.

DOCUMENTATION

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and food-related injury* complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, food-related injury*, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts or MOU's with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and defense.

*Note: See the Standards Definitions for the meaning of these defined terms.

STANDARD NO. 6 COMPLIANCE AND ENFORCEMENT

This standard applies to all compliance and enforcement activities used by a jurisdiction to achieve compliance with regulations.

REQUIREMENT SUMMARY

Compliance and enforcement activities result in follow-up actions for out-of-control risk factors and timely correction of code violations

DESCRIPTION OF REQUIREMENT

Compliance and enforcement encompasses all voluntary and regulatory actions taken to achieve compliance with regulations. Voluntary corrective action includes, but is not limited to, such activities as on-site corrections at time of inspection, voluntary destruction of product, risk control plans and remedial training. Enforcement action includes, but is not limited to, such activities as warning letters, re-inspection, citations, administrative fines, permit suspension and hearings. Compliance and enforcement options may vary depending on state and local law.

The program must demonstrate credible follow-up for each violation noted during an inspection, with particular emphasis being placed on risk factors that most often contribute to foodborne illness and *Food Code* interventions intended to prevent foodborne illness. The resolution of out-of-compliance risk factors and/or food code interventions must be documented in each establishment record. The essential program elements required to meet this standard are:

1. A written step-by-step procedure that describes how compliance and enforcement tools are to be used to achieve compliance.
2. Inspection report form(s) that record and quantify the compliance status of risk factors and interventions (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
3. Documentation on the establishment inspection report form or in the establishment file that compliance and/or enforcement action was taken to achieve compliance at least 80 percent of the time when out-of-control risk factors or interventions are recorded on a routine inspection measured using the procedures in Supplement to Standard 6, Appendix F.
4. Compliance and enforcement actions that follow the step-by-step procedure.

OUTCOME

The desired outcome of this standard is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

DOCUMENTATION

The quality records needed for this standard include:

1. A copy of the written step-by-step enforcement procedures.
2. Inspection form that meets the criteria.
3. Documentation that compliance and enforcement action was taken 80 percent of the time using the worksheet and procedures in Supplement to Standard 6, Appendix F, when out-of-control risk factors or code interventions are recorded on routine inspections.
4. A reference “Key” which identifies the major risk factors and Food Code interventions on the jurisdiction's inspection report form. [Note: A jurisdiction will not be penalized under Standard 6 for sections of the Food Code which have not yet been adopted].

STANDARD NO. 7 INDUSTRY AND COMMUNITY RELATIONS

This standard applies to industry and community outreach activities utilized by a regulatory program to solicit a broad spectrum input into a comprehensive regulatory food program, communicate sound public health food safety principles, and foster and recognize community initiatives focused on the reduction of foodborne disease risk factors.

REQUIREMENT SUMMARY

The jurisdiction documents participation in forums that foster communication and information exchange among the regulators, industry and consumer representatives.

The jurisdiction documents outreach activities that provide educational information on food safety.

DESCRIPTION OF REQUIREMENT

1. Industry and Consumer Interaction

The jurisdiction sponsors or actively participates in meetings such as food safety task forces, advisory boards or advisory committees. These forums shall present information on food safety, food safety strategies and interventions to control risk factors. Offers of participation must be extended to industry and consumer representatives.

2. Educational Outreach

Outreach encompasses industry and consumer groups as well as media and elected officials. Outreach efforts may include industry recognition programs, web sites, newsletters, FightBAC™ campaigns, food safety month activities, food worker training, school-based activities, customer surveys or other activities that increase awareness of the risk factors and control methods to prevent foodborne illness. Outreach activities may also include posting inspection information on a web site or in the press.

Agency participation in at least one activity in each of the above categories annually is sufficient to meet this standard.

OUTCOME

The desired outcome of this standard is enhanced communication with industry and consumers through forums designed to solicit input to improve the food safety program. A further outcome is the reduction of risk factors through educational outreach and cooperative efforts with stakeholders.

DOCUMENTATION

Quality records needed for this standard reflect activities over the most recent three-year period and include:

1. Minutes, agendas or other records that forums were conducted,
2. For formal, recurring meetings, such documents as by-laws, charters, membership criteria and lists, frequency of meetings, roles, etc.,
3. Documentation of performed actions or activities designed with input from industry and consumers to improve the control of risk factors, or
4. Documentation of food safety educational efforts.

Statements of policies and procedures may suffice if activities are continuous, and documenting multiple incidents would be cumbersome, i.e., recognition provided to establishments with exemplary records or an on-going web site.

STANDARD NO. 8 PROGRAM SUPPORT AND RESOURCES

This standard applies to the program resources (budget, staff, equipment, etc.) necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness.

REQUIREMENT SUMMARY

The program provides funding, staff and equipment necessary to accomplish compliance with the Voluntary National Retail Food Regulatory Program Standards.

DESCRIPTION OF REQUIREMENT

The program budget provides the necessary resources to develop and maintain a retail food safety program that meets the following criteria:

1. Staffing Level

A staffing level of one full-time equivalent (FTE) devoted to food for every 280 – 320 inspections performed*. Inspections for purposes of this calculation include routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training.

A process should exist for the regulated food establishments to be grouped into at least three categories based on food safety risk (See Standard 3). The number of inspections assigned per FTE should be adjusted within the 280 – 320 range depending upon the composition of low- to high-risk establishments in the assigned inventory. When an FTE is divided between program areas, the total number of food inspections planned for that FTE should be adjusted to compensate for the additional training time required to maintain competency in multiple program areas. An adjustment of planned inspections per FTE should also occur when food establishments are geographically dispersed due to increased travel time.

2. Inspection Equipment

Inspection equipment of each inspector to include head covers, thermocouples, flashlights, sanitization test kits, heat sensitive tapes or maximum registering thermometers, necessary forms and administrative materials. The following equipment must be available for use by inspectors when needed: computers, cameras, black lights, light meters, pH meters, foodborne illness investigation kits, sample collection kits, data loggers and cell phones.

3. Administrative Program Support

Equipment for administrative staff to include computers, software and/or items necessary to support the record keeping system utilized by the program. A system is in place to collect, analyze, retain and report pertinent information.

4. Trained Regulatory Staff

Training and training documentation for all regulatory staff to meet the level specified in Standard 2.

5. Inspection Program Based on HACCP Principles

Staff to meet all of the requirements in Standard 3, inspection based on HACCP principles.

6. Uniform Inspection Program

Administrative and supervisory staff to administer and monitor a uniform inspection program based on HACCP principles that meet Standards 3 and 4.

7. Foodborne Illness and Food Defense Preparedness & Response

Staff and resources to maintain a foodborne illness investigation and response system that meets Standard 5.

8. Compliance & Enforcement

A program that demonstrates follow-through on all compliance and enforcement actions initiated according to the written step-by-step procedures required in Standard 6.

9. Industry & Community Relations

An industry and consumer relations program as specified in Standard 7.

10. Program Assessment

Sufficient staff and resources to conduct regular program self-assessment and risk factor surveys as specified in Standard 9.

11. Accredited Laboratory

Funds to provide access to accredited laboratory resources in support of the program as specified under these nine Standards.

The essential program elements required to demonstrate compliance with this standard are:

- A. Full-time equivalent (FTE) personnel to inspections accomplished ratio as described in section 1.
- B. Inspection equipment assigned or available as described in section 2.
- C. Equipment and/or supplies required for administering the program as described in Section 3.
- D. A full and accurate completion of Appendix H for Standards 1-7 and Standard 9 whether or not those standards are met.

OUTCOME

The desired outcome of this standard is that resources are available to support a risk-based retail food safety program designed to reduce the risk factors known to contribute to foodborne illness.

DOCUMENTATION

The quality records needed for this standard include:

- 1. Documentation of FTE to inspections ratio,
- 2. Inventory of assigned and available inspection equipment,
- 3. Documentation and demonstration of records system and adequacy of support,
- 4. The completed Appendix H

*NOTE: An average workload figure of 150 establishments per FTE with two inspections per year was originally recommended in the 1976 Food Service Sanitation Manual, the standard originating from a book entitled, "Administration of Community Health Services." Annex 4 of the Code since 1993 has included a recommendation that 8 to 10 hours be allocated for each establishment per year to include all the activities reflected here in the definition of an inspection. The range of 280 – 320 broadly defined inspections per FTE is consistent with these previous recommendations. A measure of resources defined as inspections per FTE rather than establishments per FTE allows for the same unit of measure to be used for any jurisdiction regardless of the frequency of routine inspections conducted among the various priority categories.

STANDARD NO. 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

1. For listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure:
 - A. That the program manager conducts an initial *self-assessment* within 12 months of the date of enrollment in the National Registry and every 36 months thereafter; and,
 - B. That a *verification audit* is conducted within 36 months of the initial *self-assessment*. Subsequent verification audits are conducted every 36 months thereafter.
2. For achievement of Standard 9, a jurisdiction must assure:
 - A. That a Risk Factor Study (Survey) and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit; and
 - B. A Risk Factor Study (Survey) on the occurrence of foodborne illness risk factors and use of *Food Code* interventions is conducted at least once every five years thereafter to measure trends specific to the occurrence of the risk factors and use of *Food Code* interventions.
3. Reporting by means of the FDA National Registry Report form.

DESCRIPTION OF REQUIREMENT

For Listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that:

1. Self-Assessment

The program manager, or a designated representative, conducts an initial *self-assessment* of the retail food safety program within 12 months of the date of enrollment in the National Registry and every 36 months thereafter. The *self-assessment* will determine:

- A. The compliance status with each of the National Standards by completing the Appendix documents (hereafter referred to as the worksheets) or documents containing equivalent summary information for each Standard, and

- B. 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 are incomplete or provide inadequate information upon which to make a determination or to enable a verification audit, that standard is not met.

2. Verification Audit

The first *verification audit* is conducted within 36 months the initial *self-assessment*. An individual as defined in the definitions shall complete the verification audit. Subsequent verification audits are conducted every 36 months thereafter. Verification audits confirm and report on the accuracy of the *self-assessment* and the Risk Factor Study (Survey) reports. During the *verification audit*, the auditor will:

- A. Review the *quality records* and confirm that the *self-assessment* accurately reflects the current program compliance status in each of the program elements, and
- B. Confirm that the Risk Factor Study (Survey) collection procedures and tools similar to Appendix J have been used and that the conclusions are supported by the data.

3. Achievement of Standard 9

A jurisdiction must assure that a Risk Factor Study (Survey) and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit. A Risk Factor Study (Survey) 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.

The Risk Factor Study (Survey) information is updated at least once in every 5 years to measure trends specific to the occurrence of the risk factors and *Food Code* interventions. The subsequent Risk Factor Studies (Surveys) and reports will determine whether there has been a net change in the occurrence of the risk factors and use of *Food Code* interventions.

A data collection instrument similar to the FDA model form referenced in 2.B., 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 Risk Factor Study (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 study (survey) or with data from other jurisdictions.

4. Reporting

The FDA National Registry Report (Appendix I) will be completed and submitted to the appropriate FDA Regional office within 30 days following completion of the self-assessment, initial Risk Factor Study (Survey) report on the occurrence of foodborne illness risk factors and *Food Code* interventions, verification audits, and/or Risk Factor Study (Survey) updates. The FDA National Registry listing will be updated using data contained in this report. A current Release and Permission to Publish Form must accompany each FDA National Registry Report.

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. Risk Factor Study (Survey) reports on the occurrence of risk factors and *Food Code* interventions,
3. Verification audit reports,
4. FDA National Registry Report, and
5. Affidavit of Permission to Publish.

APPENDIX A - SUPPLEMENT TO STANDARD 1 – REGULATORY FOUNDATION

See instructions at end of each Table.

PART I

Table A- 1 Major Interventions and Risk Factors

Major Interventions/Risk Factor		
Section 1. Demonstration of Knowledge		
Code Section		
2-101.11	Assignment	
2-102.11	Demonstration	
2-103.11	Person in Charge	
Section 2. Employee Health		
Code Section		
2-201.11	Responsibility of PIC to Require Reporting by Food Employees/Applicants	
2-201.12	Exclusions and Restrictions	
2-201.14	Responsibility of a Food Employee or an Applicant to Report to the PIC	
2-201.15	Reporting by the Person in Charge	
Section 3. Consumer Advisory		
Code Section		
3-603.11	Consumer Advisory (Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens)	
Section 4. Approved Source		
Code Section	All Food from regulated food processing plants / no home prepared or canned foods	
3-201.11	Compliance with Food Law	
3-201.12	Food in a Hermetically Sealed Container	
3-201.13	Fluid Milk and Milk Products	
3-202.13	Shell Eggs	
3-202.14	Eggs and Milk Products, Pasteurized	
5-101.13	Bottled Drinking Water	
Code Section	All shellfish from NSSP listed sources / no recreationally caught shellfish received or sold	
3-201.14	Fish	
3-201.15	Molluscan Shellfish	
Code Section	Game and wild mushrooms approved by regulatory authority	
3-201.16	Wild Mushrooms	
3-201.17	Game Animals	
Code Section	Received at proper temperatures / protected from contamination during transport and receiving / safe and unadulterated food	
3-202.11	Temperature	
3-202.15	Package Integrity	
3-101.11	Safe, Unadulterated, and Honestly Presented	

Code Section	Shellstock tags retained for 90 days from the date the container is emptied	
3-202.18	Shellstock Identification	
3-203.12	Shellstock, Maintaining Identification	
Code Section	Written documentation of parasite destruction	
3-402.11	Parasite Destruction	
3-402.12	Records, Creation, and Retention	
Code Section	CCP monitoring records maintained in accordance with HACCP plan	
3-502.12	Variance Requirement	
Section 5. Time/Temperature		
Code Section		
3-401.11	Cooking; Raw animal Foods	
3-401.12	Microwave Cooking	
3-403.11	Reheating for Hot Holding	
3-501.14	Cooling*	
3-501.16	Potentially Hazardous Food, Hot and Cold Holding	
3-501.17	Ready-to-Eat, Potentially Hazardous Food, Date Marking	
3-501.18	Ready-to-Eat, Potentially Hazardous Food, Disposition	
3-501.19	Time as a Public Health Control*	
Section 6. Protection from Contamination		
Code Section		
3-302.11	Packaged/Unpackaged Food - Separation, Packaging, and Segregation	
3-304.11	Food contact with Equipment and Utensils	
3-306.14	Returned Food and Reservice of Food	
3-701.11	Discarding/ Reconditioning Unsafe, Adulterated, or Contaminated Food	
4-501.111	Manual Warewashing Equipment, Hot Water Sanitization Temperatures	
4-501.112	Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures	
4-501.113	Mechanical Warewashing Equipment, Sanitization Pressure	
4-501.114	Chemical Sanitization - Temperature, pH, Concentration, and Hardness	
4-501.115	Manual Warewashing Equipment, Chemical Sanitization Using Detergent Sanitizers	
4-601.11	Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils?	
4-602.11*	Equipment Food-Contact Surfaces and Utensils	
4-602.12	Cooking and Baking Equipment	
4-702.11*	Before Use After Cleaning	
4-703.11*	Hot Water and Chemical	
Section 7. Control of Hands as a Vehicle of Contamination		
Code Section		
2-301.11	Clean Condition	
2-301.12	Cleaning Procedure	
2-301.14	When to Wash	
2-301.15	Where to Wash	
2-301.16	Hand Sanitizers	
3-301.11	Preventing Contamination from Hands	
5-203.11	Handwashing Facilities (Numbers/Capacities)	

5-204.11	Handwashing Facilities (Location/Placement)	
5-205.11	Using a Handwashing Facility	
6-501.18	Maintaining and Using Handwashing Facilities	
6-301.11	Handwashing Cleanser, Availability	
6-301.12	Hand Drying Provision	
6-301.13	Handwashing Aids and Devices, Use Restrictions	
Section 8. Good Hygienic Practices		
Code Section		
2-401.11	Eating, Drinking, or Using Tobacco	
2-401.12	Discharges from the Eyes, Nose, and Mouth	
2-301.12	Cleaning Procedure	
Section 9. Chemical		
Code Section		
3-202.12	Additives	
3-302.14	Protection from Unapproved Additives	
7-207.11	Restriction and Storage	
7-207.12	Refrigerated Medicines, Storage	
7-208.11	Storage (First Aid Supplies)	
7-209.11	Storage	
7-101.11	Identifying Information, Prominence	
7-202.11	Restriction	
7-202.12	Conditions of Use	
7-203.11	Poisonous or Toxic Material Containers	
7-204.11	Sanitizers, Criteria	
7-204.12	Chemicals for Washing Fruits and Vegetables, Criteria	
7-204.13	Boiler Water Additives, Criteria	
7-204.14	Drying Agents, Criteria	
7-205.11	Incidental Food Contact, Criteria	
7-206.11	Restricted Use Pesticides, Criteria	
7-206.12	Rodent Bait Stations	
7-206.13	Tracking Powders, Pest Control and Monitoring	
7-301.11	Separation	
Section 10. Conformance with Approved Procedures		
Code Section		
8-103.12	Conformance with Approved Procedures (Variance, HACCP plans)	
Section 11. Highly Susceptible Populations		
Code Section		
3-801.11	Pasteurized Foods, Prohibited Reservice, and Prohibited Food	

***** End of Table A-1. *****

Instructions for Table A-1

Evaluate your jurisdiction's code, regulation or ordinance against each *Food Code* section grouped by interventions and risk factors listed in Table A-1 above. To obtain credit for the intervention/risk factor, each of the code sections must be checked in the block of the right hand column. A check mark indicates that your code/regulation contains language at least as stringent as the main requirements in the corresponding *FDA Food Code* section. For example, under the section "Good Hygienic Practices," each of the 3 items must have a check in the right-hand column indicating that your code/regulation meets the intent of all three *Food Code* sections.

Note: If your code requirement is as stringent or more stringent than the *Food Code* requirement, you receive credit for that section. For example, if your code/regulation requires the PERSON IN CHARGE to demonstrate knowledge of the Code by being a certified FOOD protection manager who has shown proficiency through passing a test that is part of an ACCREDITED PROGRAM but does not provide other options for demonstration of knowledge, consider this as meeting 2-102.11. You would then place a check mark in the right-hand column adjacent to 2-102.11

Table A- 2 Regulatory Foundation Summary –Interventions and Risk Factors

Major Food Code Interventions and CDC-identified Risk Factors		
	<i>Description</i>	<i>PASS/FAIL</i>
1	Demonstration of Knowledge	
2	Employee Health	
3	Consumer Advisory	
4	Approved Sources	
5	Time/Temperature	
6	Protection from Contamination	
7	Control of Hands as a Vehicle of Contamination	
8	Good Hygienic Practices	
9	Chemical	
10	Conformance with Approved Procedures	
11	Highly Susceptible Populations	
Assessment of _____ (regulatory agency) Conformance with Interventions / Risk Factors		Overall Rating PASS ↑ FAIL ↑

Instructions for Table A-2

1. Use the information from Table A-1 to complete this table. Determine a PASS or FAIL rating for each of the eleven (11) Interventions/Risk Factors by reviewing the check marks on Table A-1. If all of the *Code* sections listed under an Intervention/Risk Factor have a check mark in the right-hand column on Table A-1, give yourself a PASS rating for that item on Table A-2.

If any of the *Code* section provisions are missing, as indicated by a blank in the right-hand column of Table A-1, indicate FAIL for that Intervention/Risk Factor. For example: Under “Approved Source,” if your code/regulation does not address mushroom species picked in the wild, the right-hand column adjacent to 3-201.16 on Table A-1 would be blank. Therefore, the “Approved Source” Intervention/Risk Factor on Table A-2 would be marked as FAIL.

2. For initial participation and listing purposes, if you have achieved a PASS rating on at least 9 of the 11 items on Table A-2, you receive an overall PASS rating for the Interventions/Risk Factors. By the second scheduled audit, you must achieve a PASS rating on 11 of the 11 items in order to receive an overall PASS rating for the Interventions/Risk Factors portion of Standard 1.

PART II

Table A-3 Regulatory Foundation – Good Retail Practices

Section 12. Personnel				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
2-302.11				
2-303.11				
2-304.11				
2-402.11				

Section 13. Food & Food Protection				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-202.16				
3-202.17				
3-202.19				
3-203.11				
3-302.12				
3-302.13				
3-305.13				
3-501.11				
3-601.11				
3-601.12				
3-602.12				
6-404.11				

Section 14. Plant Food cooking for Hot Holding

FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-401.13				

Section 15. Protection from Contamination

FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-302.15				
3-303.11				
3-303.12				
3-304.11				
3-305.11				
3-305.12				
3-305.14				
3-306.11				
3-306.12				
3-306.13				
3-307.11				

Section 16. Facilities / Methods to Control Product Temperature				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-301.11				

Section 17. PHF Properly Thawed				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-501.12				
3-501.13				

Section 18. Dispensing of Food / Utensils Properly Stored				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-304.12				
4-204.13				
4-204.14				

Food Equipment

Section 19. Thermometers Provided and Conspicuous

FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-203.11				
4-203.12				
4-204.112				
4-302.12				

Section 20. Food and Nonfood Contact Surfaces: Designed, Constructed, Maintained, Installed, Located, Operated, Cleanable

FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-304.16				
3-304.17				
4-101.11				
4-101.12				
4-101.13				
4-101.14				
4-101.15				
4-101.17				
4-101.18				
4-101.19				
4-101.110				
4-101.111				
4-102.11				

Section 20. Food and Nonfood Contact Surfaces: Designed, Constructed, Maintained, Installed, Located, Operated, Cleanable				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-201.11				
4-202.12				
4-202.13				
4-202.14				
4-202.15				
4-202.16				
4-202.17				
4-204.12				
4-204.15				
4-204.16				
4-204.17				
4-204.18				
4-204.19				
4-204.110				
4-204.111				
4-204.121				
4-204.122				
4-204.123				
4-302.11				
4-401.11				
4-402.11				
4-402.12				
4-501.11				

Section 20. Food and Nonfood Contact Surfaces: Designed, Constructed, Maintained, Installed, Located, Operated, Cleanable				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-501.12				
4-501.13				
4-502.11				
4-601.11 (B)(C)				
4-602.13				
4-603.11				
4-603.17				
4-902.11				
4-902.12				

Section 21. Warewashing Facility: Designed, Constructed, Installed, Located, Operated, Cleanable, Used				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-203.13				
4-204.113				
4-204.114				
4-204.115				
4-204.116				
4-204.117				
4-204.118				
4-204.119				
4-204.120				

Section 21. Warewashing Facility: Designed, Constructed, Installed, Located, Operated, Cleanable, Used				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-301.12				
4-301.13				
4-302.13				
4-302.14				
4-501.14				
4-501.15				
4-501.16				
4-501.17				
4-501.18				
4-501.19				
4-501.110				
4-501.116				
4-603.12				
4-603.13				
4-603.14				
4-603.15				
4-603.16				

Section 22. Wiping Cloths, Linens, Napkins, Gloves, Sponges: Properly Used, Stored				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-304.13				
3-304.14				
3-304.15				
4-101.16				
4-801.11				
4-802.11				
4-803.11				
4-803.12				
4-901.12				
4-903.12				

Section 23. Storage, Handling of Clean Equipment, Utensils				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-901.11				
4-903.11				
4-903.12				
4-904.11				
4-904.12				
4-904.13				

Section 24. Single-Service / Single-Use Articles: Storage, Dispensing, Use, No Reuse				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-502.12				
4-502.13				
4-502.14				

Water

Section 25. Safe Water Source, Hot and Cold Under Pressure, Adequate Quantity				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-101.11				
5-102.11				
5-102.12				
5-102.13				
5-102.14				
5-103.11				
5-103.12				
5-104.11				
5-104.12				

Section 26. Plumbing: Installed, Maintained

FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-101.12				
5-201.11				
5-202.11				
5-202.12				
5-202.15				
5-203.13				
5-204.13				
5-205.13				
5-205.14				
5-205.15				
5-301.11				
5-302.11				
5-302.12				
5-302.13				
5-302.14				
5-302.15				
5-302.16				
5-303.11				
5-303.12				
5-303.13				
5-304.11				
5-304.12				
5-304.13				
5-304.14				

Section 27. Cross Connection, Back Siphonage, Backflow Prevention				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-202.13				
5-202.14				
5-203.14				
5-204.12				
5-205.12				

Toilet Facilities

Section 28. Number, Convenient, Accessible, Designed, Installed				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-203.12				
6-402.11				

Section 29. Toilet Rooms Enclosed, Self-closing Doors; Fixtures, Good Repair, Clean, Proper Waste Receptacles				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-501.17				
6-202.14				
6-302.11				
6-501.19				

Sewage

Section 30. Sewage and Waste Water Disposal				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-401.11				
5-402.11				
5-402.12				
5-402.13				
5-402.14				
5-402.15				
5-403.11				
5-403.12				

Garbage & Refuse Disposal

Section 31. Containers or Receptacles: Covered, Adequate Number, Insect / Rodent Proof, Frequency of Removal, Clean. Area Properly Constructed, Necessary Implements, Supplies				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
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				

Physical Facility

Section 32. Floors, Walls, Ceilings: Designed, Constructed, Maintained, Clean

FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
6-101.11				
6-102.11				
6-201.11				
6-201.12				
6-201.13				
6-201.14				
6-201.15				
6-201.16				
6-201.17				
6-201.18				
6-202.17				
6-202.18				
6-501.11				
6-501.12				
6-501.13				
6-501.17				

Section 33. Lighting, Ventilation, Dressing Rooms / Designated Areas Maintained				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-202.18				
4-204.11				
4-301.14				
6-202.11				
6-202.12				
6-303.11				
6-304.11				
6-305.11				
6-403.11				
6-501.14				
6-501.110				

Section 34. Premises Maintained Free of Litter, Unnecessary Articles, Cleaning and Maintenance Equipment Properly Stored				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
6-202.19				
6-501.15				
6-501.16				
6-501.113				
6-501.114				

Section 35. Complete Separation from Living / Sleeping Quarters; Laundry				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-301.15				
4-401.11 (C				
4-803.13				
6-202.111				
6-202.112				

Section 36. Presence of Insects / Rodents Minimized, Outer Openings Protected, Animals As Allowed				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
2-403.11				
6-202.13				
6-202.15				
6-202.16				
6-501.111				
6-501.112				
6-501.115				

Section 37. Variance for Smoking for Preservation, Curing, Brewing Alcoholic Beverages, Using Additives as Preservatives, or Using Reduced Oxygen to Package Food				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-502.11				

Instructions for Table A-3

To complete Table A-3, do the following: Evaluate your jurisdiction's code or ordinance against each *Food Code* section grouped by topics under the major section headings numbered 12 through 37 above. If your code/regulation has language meeting the full intent of the corresponding model *Food Code* section, place a check mark in column 3. Columns 4 and 5 are intended to serve as an analytical tool to help you identify gaps in your current code/regulation and to plan for future revisions.

Starting with Section Heading 12 entitled Personnel, count the total number of check marks in column 3 under this heading and transfer this number to column 2 of Table A-4. Do this for each of the numbered section headings until all the information is transferred to Table A-4.

Table A-4 Regulatory Foundation Summary – Good Retail Practices

Section Number	Good Retail Practices		
	Number Identified as "Yes" (column 3 - of Table A-3 worksheet)	<i>Maximum No. of "Yes" possible</i>	<i>Description</i>
12		4	Personnel
13		12	Food & Food Protection
14		1	Plant Food Cooking for Hot Holding
15		11	Protection from Contamination
16		1	Facilities/Methods to Control Product Temperature
17		2	PHF Properly Thawed
18		3	Dispensing Food/Utensils Properly Stored
19		4	Food Equipment
20		45	Food and Non-food Contact Surfaces
21		26	Warewashing Facilities: Designed, etc.
22		10	Wiping cloths, Linens, Napkins, Gloves/Used
23		6	Storage, Handling of Clean Equip / Utensils
24		3	Single-Service/Single-Use Articles
25		9	Safe Water Source, Hot / Cold Under Pressure
26		24	Plumbing: Installed, Maintained
27		5	Cross Connection, Back Siphonage, Backflow Pre
28		2	Toilet Facilities: Number, convenient, Accessible
29		4	Enclosed, Self-closing Doors; Fixtures, Good repair
30		8	Sewage and Waste Water Disposal
31		19	Garbage and Refuse Disposal: covered, number
32		16	Floors, Walls, Ceilings; Designed, Constructed
33		11	Lighting, Ventilation, Dressing Rooms
34		5	Premises Maintained, Free of Litter, etc.
35		5	Complete Separation from Living/Sleeping Quarters
36		7	Presence of Insects / Rodents Minimized
37		1	Variances
Total of col. 2 _____		244	
		(___ / 244) * 100% =	_____ %

Instructions for Table A-4

1. Starting with Section Heading 12 entitled Personnel, count the total number of check marks in column 3 under this heading and transfer this number to column 2 of Table A-4. Do this for each of the numbered section headings until all the information is transferred to Table A-4.
2. Total the numbers in column 2 of Table A-4 and record this number in the blank provided for the total in the bottom section of Table A-4.
3. Divide this number by 244 and multiply by 100 to determine the percentage of the Good Retail Practices provisions contained in your code/regulation. (_____ %)

A percentage equal to or greater than 95% is considered acceptable for meeting the Regulatory Foundation requirements for Sections 12 through 37.

PART III

Appendix A
Table A-5 Regulatory Foundation Summary – Compliance and Enforcement

Compliance and Enforcement Food Code Chapter 8			
Description of Compliance or Enforcement Action	Food Code Section	<i>Your Corresponding Statute, Code, Regulation or Ordinance section</i>	<i>Full intent of the main provisions of the Food Code sections are met ("Yes" / "No")</i>
1. Hold orders, embargo, and Destruction of food	8-801.10		
	8-803.10		
	8-803.30		
2. Permit / License required ; Right to deny	8-301.11		
	8-304.20		
3. Plan Review / Pre-operational inspection	8-201.11		
4. Inspection authority / right to access	8-402.20		
5. Restriction / Exclusion of Employees; Information Authority	8-501.10		
	8-501.20		
	8-501.30		
6. Authority to Require HACCP plans	8-201.13		
7. Granting of Variances -- or --	8-103.10		
	8-103.11		
	8-103.12		
Variances prohibited	-----		
8. Timely Correction of Critical Violations	8-405.11		
	8-405.20		
	8-406.11		
9. Imminent Health Hazard (Summary Suspension)	8-404.12		
	8-804.10		
10. License suspension / revocation	8-805.10		
	8-805.20		
11. Institution of Proceedings	8-810.10		
12. Legal Remedies			
a. Criminal Proceedings	8-811.10		
b. Petitions for Injunction	8-812.10		
c. Civil Penalties provided	8-813.10		

Instructions for Table A-5

1. For each *Food Code* section listed in column 2, review your code, regulation, rule, or statute for corresponding language.
2. List your corresponding code/regulation section in column 3.
3. Evaluate your code/regulation to determine whether it meets the full intent of the main requirements of the FDA *Food Code* section. If it does, mark “yes” in the last column. If it does not meet the full intent, mark “no” in the last column.
4. Meeting the Standard #1 criteria for the “Compliance and Enforcement” component requires a “Yes” for all *Food Code* Sections listed in Items 1 through 11. For example, to get credit for 2. Permit/License required, both code sections must be marked “yes.” For Item 12 pertaining to legal remedies, the jurisdiction needs to demonstrate a corresponding regulatory requirement for only one of the sections pertaining to criminal, injunctive, or civil penalties.

PART IV

Appendix A

Criteria	YES	NO
1. Your jurisdiction's code, ordinance, rule, or regulation meets the requirement of Standard 1, Regulatory Foundation, for the Major Interventions / Risk Factors.		
2. Your jurisdiction's code, ordinance, rule, or regulation meets the Good Retail Practices requirements of Standard 1, Regulatory Foundation.		
3. Your jurisdiction's code, ordinance, rule, regulation or statute meets the Compliance and Enforcement requirements of Standard 1, Regulatory Foundation.		

Use the information in Tables A-1 through A-5 to determine the correct answer each of the above questions. A “yes” affirmation to each statement is required to meet Standard 1.

APPENDIX B - Supplement to Standard 2 - Trained Regulatory Staff

STANDARD 2
TRAINED REGULATORY STAFF

Program Standard 2

APPENDIX B-1: CURRICULUM FOR RETAIL FOOD SAFETY INSPECTION OFFICERS

For state, local & tribal regulators to register on-line for free access to web courses, go to:
<http://www.fda.gov/ora/training/>

Prerequisite (“Pre”) curriculum courses

(to be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

PUBLIC HEALTH PRINCIPLES

Public Health Principles (90) FDA36

MICROBIOLOGY

Food Microbiological Control (series):

1. Overview of Microbiology (60) MIC01
- 2A. Gram-Negative Rods (60) MIC02
- 2B. Gram-Positive Rods & Cocci (90) MIC03
3. Foodborne Viruses (60) MIC04
4. Foodborne Parasites (90) MIC05
Mid-Series Exam (30) MIC16
5. Controlling Growth Factors (90) MIC06
6. Control by Refrigeration & Freezing (60)
MIC07
- 7A. Control by Thermal Processing (90) MIC08
- 7B. Control by Pasteurization (90) MIC09
10. Aseptic Sampling (90) MIC13
12. Cleaning & Sanitizing (90) MIC15

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Basic Food Law for State Regulators (60) FDA35

Basics of Inspection:

Beginning an Inspection (90) FDA38

Issues & Observations (90) FDA39

An Introduction to Food Security Awareness (60)
FD251 (ORA U internet site)

2005 Food Code

NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction

COMMUNICATION SKILLS

Communication Skills for Regulators

Curriculum (“Post”) courses

*(to be completed anytime prior to Food Code Standardization AND
within 18 months of hire or assignment to the regulatory retail food program)*

MICROBIOLOGY

Food Microbiological Control (series):

- 7C. Control by Retorting (90) MIC10
8. Technology-Based Food Processes (120) MIC11
9. Natural Toxins (90) MIC12

HACCP

Basics of HACCP (series):

1. Overview of HACCP (60) FDA16
2. Prerequisite Programs & Preliminary Steps (60)
FDA17
3. The Principles (60) FDA18

EPIDEMIOLOGY

Foodborne Illness Investigations (series):

1. Collecting Surveillance Data (90) FI01
 2. Beginning the Investigation (90) FI02
 3. Expanding the Investigation (90) FI03
 4. Conducting a Food Hazard Review (90) FI04
 5. Epidemiological Statistics (90) FI05
 6. Final Report (30) FI06
-

() Average time in minutes required to take the course, 60 minutes equals 0.1 CEU, 90-120 minutes equals 0.2 CEUs

Estimated total hours for “Pre” courses are 42 hours.

Estimated total hours for “Post” courses are 13 hours.

Estimated total hours for completion of all Program Standard 2 coursework are 55 hours.

Program Standard 2

Curriculum for Retail Food Safety Inspection Officers

“Application” Courses and “Hands-On” Training

To provide application and transfer of web instruction to the FSIO’s work environment, a jurisdiction’s training program (inclusive of both classroom instruction *and* field training inspections) for staff newly hired or newly assigned to the retail food protection program must include a minimum of eighty percent (80%) of the learning objectives contained in the ORA U *Application of Basics of Inspection/Investigation Course* (FD170). A jurisdiction may use any one of the following options to address learning objectives not covered in their existing training programs.

1. **Classroom Course: Application of the Basics of Inspection/Investigation FD170** (available at www.afdo.org/ or course contents are available on CD through FDA’s Division of Human Resource Development’s lending library).
2. **Courses and or field training exercises developed by State/local regulatory jurisdictions or other entities** containing learning objectives and exercises equivalent to Option 1 above.
3. **Discussions Questions & Exercises *** (Conducted in the office or during the 25 joint inspections)

* Under construction

The learning objectives for the ORA U Application of the Basics of Inspection/Investigation course (FD170) are included below:

APPLICATION OF THE BASICS OF INVESTIGATION/INSPECTION – FD170

Applying Knowledge and Principles to the Real World of Inspection and Investigation of Food Establishments

Learning Objectives: Upon completion of this course, participants will be able to:

1. Demonstrate their knowledge of relevant food laws and regulations and how to apply them properly during inspections.
2. Demonstrate hands-on competency in the use of equipment and instruments used during food establishment inspections.
3. Successfully perform a hands-on exercise of aseptic sampling with sterile sampling containers using deli-style food samples.
4. Identify biological, physical, and chemical hazards and risks associated with foods and the operation of food establishments and will apply this knowledge to determine if a food establishment is in compliance.
5. Identify good basic inspection and communication techniques used in food processing, storage, and retail facilities.
6. Demonstrate their ability to identify the causes and symptoms of foodborne illness, to identify implicated foods, to select proper foods for sampling, to determine individuals to interview, to identify the likely causative organism(s), and to recommend procedures that would prevent further outbreaks.
7. Demonstrate their ability to document quantitative observations, to distinguish fact from opinion, to gather, synthesize and document all facts, to avoid ambiguity, and to distinguish relevant from irrelevant facts

APPENDIX B-2: FIELD TRAINING MANUAL

CONFERENCE FOR FOOD PROTECTION

FIELD TRAINING MANUAL

**REGULATORY RETAIL FOOD SAFETY
INSPECTION OFFICERS**

DRAFT: January 7, 2008

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GLOSSARY OF TERMS

Competency: is the state or quality of being adequately or well qualified; having the ability to perform a specific duty, task or role as measured by comparison against a standard of performance.

As used in the context of this Field Training Manual, “competency” means:

- The demonstration of one or more skills (job tasks) based on knowledge derived from educational programs and experience;
- The ability to perform a task with expected outcomes under the varied circumstances of the real world; and
- The effective application of knowledge and skill in the work setting.

Moreover, “competencies” also refers to a specific list of job tasks appropriate for each described performance element.

Conference for Food Protection (CFP): is a biennial forum comprised of representatives from the food industry, government (local, state, federal), academia, and consumer organizations to identify and address emerging problems of food safety and to formulate consensus recommendations through a balanced and deliberative process. Although the Conference has no formal regulatory authority, it is an organization that influences the adoption of uniform model food safety laws and regulations among government agencies and the reduction of different interpretations and implementation of such laws and regulations.

Consistent pattern of behavior: is a recurring pattern of action or performance that is recognizable and distinctive. As used in the context of this *Field Training Manual*, a “consistent pattern of behavior” means:

- The trainee can explain the purpose/objective of a job task and the steps necessary to carry it out effectively;
- The demonstration of a clear understanding of a given competency; and
- A collective set of trainer observations which indicate that the trainee can successfully demonstrate the competency correctly and repeatedly.

Demonstration inspection: is a method used by an experienced trainer or designated staff member to visibly show and explain to a trainee the processes and procedures used to conduct a regulatory retail food safety inspection.

Establishment risk categories: is a defined grouping of types of food establishments for risk based inspections found in Standard 3 of the FDA Program Standards. Standard 3 requires that regulatory jurisdictions use a process that groups food establishments into categories based on potential and inherent food safety risks. Annex 5, Table 1 of the *FDA Food Code* provides an example of using risk categorization of food establishments with four categories. Jurisdictions can use their own system for grouping establishments into categories based on potential food safety risks.

FDA Voluntary National Retail Food Regulatory Program Standards: are a voluntary set of standards developed through the CFP process and offered by the US Food and Drug Administration to promote continuous improvement and uniformity among regulatory retail food protection programs. The Program Standards serve as a model program foundation and are designed to assist managers of regulatory retail food protection programs in their ability to enhance the services they provide to the public. When applied in the intended manner, the Program Standards should:

- Identify program areas where an agency can have the greatest impact on retail food safety;
- Promote wider application of effective risk-factor intervention strategies;
- Assist in identifying program areas most in need of additional attention;
- Provide information needed to justify maintenance or increase program budgets;
- Lead to innovations in program implementation and administration; and
- Improve industry and consumer confidence in retail food protection programs by enhancing uniformity within and between regulatory agencies.

This *Field Training Manual* was developed using the *FDA Voluntary National Retail Food Regulatory Program Standards, Standard 2 – Trained Regulatory Staff* as the basis for required elements. Standard 2 – Trained Regulatory Staff applies to the essential elements of a training program for regulatory staff and requires that staff have the knowledge, skills and abilities to adequately perform their required duties. Additional information can be found at <http://www.cfsan.fda.gov/~dms/ret3intr.html>.

Field Training Worksheet: is an optional form that can be used by a trainer to record their observations while a trainee is demonstrating the various competencies essential to conducting effective food safety inspections. The minimum performance element competencies (specific job related skills and tasks) that a Food Safety Inspection Officer is expected to perform in a work setting may be identified in the jurisdiction's Training Plan and can be included on the *Field Training Worksheet*.

Food Safety Inspection Officer (FSIO): is a regulatory employee responsible for conducting food safety inspections of one or more of the following types of establishments:

- Institutional foodservice;
- Restaurants and other facilities involved in retail foodservice; and
- Grocery stores or other retail food facilities.

Inspection Training Area: is a generalized grouping of like or similar performance elements combined together under a single category. As used in the context of this Field Training Manual, there are six (6) Inspection Training Areas:

- I. Pre-Inspection;
- II. Inspection Observations and Performance;
- III. Oral Communication;
- IV. Written Communication;
- V. Professionalism; and
- VI. Additional Inspection Areas (jurisdiction specific).

Performance Element: is a general description of a group of competencies (job tasks) to be performed by an employee in a particular area of work. Performance Element descriptions are highlighted in the gray shaded boxes of the *CFP Training Plan and Log*, and the Field Training Worksheets included with the Field Training Manual.

Prerequisite Curriculum: is a specified food safety training curriculum designed to provide Food Safety Inspection Officers (FSIO) with an understanding of the essential food safety and public health principles needed to effectively conduct food safety inspections. Areas of study include:

- Public health principles;
- Prevailing statutes, regulations, and ordinances;
- Communication skills; and
- Microbiology.

Newly hired FSIOs or those newly assigned to the regulatory retail food protection program should successfully complete the prerequisite curriculum prior to conducting independent food safety inspections. Specific web-based courses and learning objectives for the prerequisite curriculum are available on the FDA ORA-U website at:
<http://www.fda.gov/ora/training/>.

Trainee: is an individual who is newly hired or newly assigned to the regulatory retail food protection program. Regardless of their previous inspection experience, these individuals are in the process of learning and successfully demonstrating the competencies identified in the jurisdiction's training plan as essential for conducting effective food safety inspections.

Trainee-Led Inspections: is a joint field-training inspection that includes both the jurisdiction's designated trainer and the trainee, where the trainee takes the lead and is responsible for conducting the inspection per the jurisdiction's administrative procedures and policies. The trainee's inspection approach, communication techniques, and food safety priorities should reflect those which would be followed if he/she were conducting an independent inspection.

Trainee-led inspections provide an opportunity for the jurisdiction's trainer to observe the trainee as he/she demonstrates competencies, and identify those competencies that have yet to be learned or were not properly demonstrated.

Trainer: is an individual recognized by the regulatory jurisdiction’s food safety program manager as having the prerequisite knowledge, field experience and communication skills necessary to train other Food Safety Inspection Officers, and who has been assigned this training responsibility.

This individual is responsible for observing the trainee as he/she demonstrates competencies identified in the jurisdiction’s training plan, and providing feedback to the trainee throughout the course of the training process on their ability to demonstrate these competencies.

For jurisdictions enrolled in the *FDA Voluntary National Retail Food Regulatory Program Standards*, the trainer or designated staff member responsible for documenting the FSIO’s demonstration of a competency must have completed all the training elements in Steps 1-3 of Standard 2 – Trained Regulatory Staff. It is highly recommended that the trainer be standardized in a process similar to the “FDA Standardization Procedures” (See FDA Procedures for Standardization of Retail Food Inspection/Training Officers at <http://www.cfsan.fda.gov/~ear/rfi-toc.html>).

Training Plan and Log: is a structured approach for a regulatory retail food protection program to identify and document food protection training content, determine training methods, and track a Food Safety Inspection Officer’s progress in demonstrating competencies specific to their job responsibilities and essential for conducting independent food safety inspections.

Please see the Training Plan and Log included in this *Field Training Manual*.

I. Introduction

BACKGROUND

The Conference for Food Protection (CFP) has progressed through multiple stages in the development of a nationally recognized model for training and standardizing regulatory Food Safety Inspection Officers (FSIOs) responsible for conducting food safety inspections. Research conducted by CFP revealed that existing training and standardization programs were nearly as varied as the number of regulatory jurisdictions throughout the country. In response, a model multi-tiered approach for training and standardizing FSIOs was developed using the *FDA Voluntary National Retail Food Regulatory Program Standards, Standard 2 – Trained Regulatory Staff*.

This *Field Training Manual* focuses on two components of this multi-tiered approach contained in Standard 2 – the prerequisite coursework and the field training model for preparing newly hired FSIOs or individuals newly assigned to the regulatory retail food protection program to conduct independent food safety inspections. The instructions and worksheets provided in this manual constitute a training process, ***not*** a certification or audit process.

The model developed through the CFP process, consists of a training plan, trainer's worksheets, and procedures that may be used by ***any*** regulatory retail food protection program. Jurisdictions do ***not*** have to be enrolled in the *FDA Voluntary National Retail Food Regulatory Program Standards* to use, and benefit from, this training structure for preparing FSIOs to conduct independent food safety inspections. This manual was developed to assist jurisdictions that do not have the available staff resources and funding necessary to develop a comprehensive training process. The training model presented in this manual can be readily integrated into existing regulatory retail food protection programs.

The work within this document represents the culmination of years of research and review by subject matter experts comprised of psychometricians and representatives from state and local regulatory retail food protection programs, industry trade associations, retail food and foodservice operations, academia, and the FDA's Office of Regulatory Affairs University (ORA U). The coursework and training process are the basis for much of the criteria that is contained in Steps 1 and 2 of *Standard 2 – Trained Regulatory Staff, FDA Voluntary National Retail Food Regulatory Program Standards*. This manual is a working document and improvements will be made through the CFP Committee process.

With the availability of this document, state, local, and tribal regulatory retail food protection programs now have a nationally recognized model upon which to design basic training programs for FSIOs. Moreover, ongoing use of this model will both enhance the effectiveness of regulatory retail food safety inspections across the country and increase uniformity among regulatory professionals.

OVERVIEW – FIELD TRAINING MANUAL

All new employees or individuals new to the regulatory retail food protection program should complete prerequisite coursework and a field training process similar to that presented in this document. The national research conducted by CFP has been used to identify the minimum performance element competencies needed to conduct effective regulatory retail food safety inspections. The *CFP Training Plan and Log* along with the *Field Training Worksheets* provided in this manual are based on these minimum performance element competencies.

Flexibility has been built into the process to allow regulatory jurisdictions the opportunity to customize training content and methods to represent a jurisdiction's own administrative policies, procedures, and inspection protocol. As you read through this manual, it is important to keep in mind that jurisdictions are not obligated to use the forms; equivalent forms or training processes can be developed. The ultimate objective is to ensure FSIOs are trained on and provided an opportunity to successfully demonstrate the performance element competencies that are a vital part of their job responsibilities.

II. Prerequisite Curriculum

PREREQUISITE COURSES

The CFP has worked with the FDA to identify a prerequisite curriculum designed to provide a FSIO with a solid understanding of essential food safety and public health principles needed to conduct effective retail food safety inspections. The FSIO should complete the prerequisite coursework *prior* to conducting independent inspections. A trainer can, however, conduct joint field training inspections with the newly-hired FSIO while they are in the process of completing the prerequisite coursework.

The prerequisite curriculum, as available on the FDA ORA U web site, is reprinted below with the estimated amount of time (in minutes) to complete each module indicated in parenthesis followed by the course number.

PUBLIC HEALTH PRINCIPLES

Public Health Principles (90) FDA36

MICROBIOLOGY

Food Microbiological Control (series):

1. Overview of Microbiology (60) MIC01
- 2A. Gram-Negative Rods (60) MIC02
- 2B. Gram-Positive Rods & Cocci (90) MIC03
3. Foodborne Viruses (60) MIC04
4. Foodborne Parasites (90) MIC05
- Mid-Series Exam (30) MIC16
5. Controlling Growth Factors (90) MIC06
6. Control by Refrigeration & Freezing (60) MIC07
- 7A. Control by Thermal Processing (90) MIC08
- 7B. Control by Pasteurization (90) MIC09
10. Aseptic Sampling (90) MIC13
12. Cleaning & Sanitizing (90) MIC15

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Basic Food Law for State Regulators (60) FDA35

Basics of Inspection

Beginning an Inspection (90) FDA38

Issues & Observations (90) FDA39

An Introduction to Food Security Awareness (60) FD251

2005 Food Code

NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction

COMMUNICATION SKILLS

Communication Skills for Regulators

Two options are available for FSIOs to complete the prerequisite coursework:

OPTION 1 – FDA ORA U Web-based Training

All prerequisite courses can be completed via web-based training and are available from FDA's ORA University at: <http://www.fda.gov/ora/training/>. Employees of regulatory agencies can obtain free access to these course offerings; access passwords can be obtained on line. The time needed to complete the prerequisite courses will vary from one trainee to another. FDA ORA U has estimated the total time needed to complete the prerequisite coursework to be 42 hours.

OPTION 2 – Equivalent Coursework and Recognized Examination

A jurisdiction's trainer or food protection program manager can allow credit for coursework that a FSIO has completed from sources other than FDA ORA U. A course is deemed equivalent if it can be demonstrated to cover at least 80% of the learning objectives of the comparable ORA U course *and* documentation of successful completion is provided. The learning objectives for each of the ORA U courses are available from

the FDA web site: <http://www.fda.gov/ora/training/>.

FSIOs submitting documentation of equivalent coursework should also demonstrate a basic level of food safety knowledge by successfully passing a written examination from one of the following four (4) categories:

1. The Certified Professional - Food Safety (CP-FS) examination offered by the National Environmental Health Association (NEHA);
2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and developed using methods that are psychometrically valid and reliable;
3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or
4. A Registered Environmental Health Specialist (REHS) or Registered Sanitarian (RS) examination offered by NEHA or a State Registration Board.

NOTE: *Within the context of this manual, the written examinations are part of a training process, not a standardization or certification process. The examinations listed above are not to be considered equivalent to each other. They are to be considered only as training tools and have been incorporated as part of this Field Training Manual because each provides a method for determining whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

III. The CFP Training Plan and Log

CFP TRAINING PLAN AND LOG

The *CFP Training Plan and Log* (see Attachment A) provides a structured approach for identifying the training content, determining the training methods, and tracking the FSIO's progress in successfully demonstrating performance elements and competencies specific to their job responsibilities.

The *CFP Training Plan and Log* provides areas for documenting:

- Trainee and Trainer information;
- A jurisdiction's method of training for each of the competencies; and
- Completion of performance elements and/or competencies for each training area.

It also contains optional areas for:

- Maintaining a weekly training log for tracking accomplishments and identifying future training goals; and
- Tracking the number and type of retail food and/or foodservice establishments included as part of the field training inspections.

**Conference for Food Protection
TRAINING PLAN and LOG
Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer**

NOTE: The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers (FSIOs) should be reviewed prior to using the CFP Training Plan and Log. The manual provides jurisdictions with information that will be helpful in customizing the FSIO training plan and implementing a field training process that meets the specific needs of the jurisdiction.

Food Safety Inspection Officer's (FSIO) Name:	Start Date of the Training Process:
Food Safety Inspection Officer's (FSIO) Agency:	
Trainer's Name (if multiple trainers list all):	Trainer's Agency:
1.	
2.	
3.	
4.	
<i>(Signatures below indicate FSIO has completed all curriculum and field training elements and is ready to conduct independent retail food and/or foodservice inspections)</i>	
Completion Date of Pre-requisite Coursework:	
OPTION 1: <input type="checkbox"/> or OPTION 2: <input type="checkbox"/>	
Completion Date - (Performance Elements & Competencies):	
Food Safety Inspection Officer's (FSIO) Signature:	Trainer's or Food Program Manager's Signature:

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DESCRIPTION OF HEADER INFORMATION

Food Safety Inspection Officer's (FSIO's) Name – The name of the individual who will receive the training.

Food Safety Inspection Officer's (FSIO's) Agency – The name of the regulatory retail food protection program where the FSIO receiving training is employed.

Start Date of the Training Process – The date any part of the FSIO's training for conducting independent food safety inspections is initiated; this includes review of the jurisdiction's procedures, rules, and manuals; classroom or web-based coursework; joint field training inspections; or other training methods identified in the jurisdiction's training plan.

Trainer's Name (if multiple trainers, list all) – The name(s) of the individual(s) delivering or overseeing the training of the FSIO.

Trainer's Agency – The name of the regulatory retail food protection program or agency where the trainer is employed.

Completion Date of Prerequisite Coursework – The date the trainee completes all prerequisite coursework identified by the Conference for Food Protection as essential for conducting independent food safety inspections. Two options are available for completing the prerequisite course work:

OPTION 1 – Box is checked to indicate the FSIO has completed the FDA ORA U prerequisite ("Pre") courses/examinations/exercises, and has completed training on the jurisdiction's prevailing statutes, regulations, and or ordinances.

OR

OPTION 2 – Box is checked to indicate the FSIO has submitted documentation of completing coursework equivalent to the FDA ORA U prerequisite ("Pre") curriculum, and has completed training on the jurisdiction's prevailing statutes, regulations, and/or ordinances, and has certification or other documentation of successfully passing one of the written examination options in *Standard 2 – Trained Regulatory Staff, FDA Voluntary National Retail Food Regulatory Program Standards*.

Completion Date – (Performance Elements & Competencies) – The date the FSIO has successfully demonstrated all performance element competencies identified in the jurisdiction's training plan. At this point, the jurisdiction's trainer and/or retail food protection program manager has determined that the FSIO is now ready to conduct independent food safety inspections of retail food and/or foodservice establishments.

Food Safety Inspection Officer's (FSIO's) Signature – The signature of the FSIO that is applied when all performance element competencies have been successfully demonstrated.

Trainer's or Food Program Manager's Signature – The signature of the individual responsible for making the determination that the trainee has completed all the training areas and successfully demonstrated all the performance element competencies.

JURISDICTION'S TRAINING METHODS

The *CFP Training Plan and Log* is designed to incorporate a variety of training methods appropriate for each of the performance element competencies. Jurisdictions are free to select the training method most appropriate for their individual situation and needs. A table (see example below) is included in the *CFP Training Plan and Log* to document and summarize the various training methods that a jurisdiction may use. Examples of training methods include, but are not limited to, classroom presentations or exercises, laboratory workshops, office demonstrations, and joint field training inspections.

JURISDICTION'S TRAINING METHODS	
Code	Training Method
CE	Classroom Exercise
OD	Office Demonstration
LE	Laboratory Exercise
JFT	Joint Field Training
O	Other (described in Training Plan)

The column with the heading “*Code*” can be used to record an abbreviation that describes the training method. For example, the abbreviation “LE” in the above table is used to describe “Laboratory Exercise.” The abbreviation “JFT” is used to describe “Joint Field Training Inspections.”

INSPECTION TRAINING AREAS

The *CFP Training Plan and Log* is divided into six (6) inspection training areas:

- I. Pre-Inspection
- II. Inspection Observations and Performance
- III. Oral Communication
- IV. Written Communication
- V. Professionalism
- VI. Additional Inspection Areas (jurisdictions can add performance elements and competencies not contained in the *CFP Training Plan and Log*)

PERFORMANCE ELEMENTS

The *CFP Training Plan and Log* contains a total of 23 “performance elements” within the six (6) inspection training areas.

I. Pre-Inspection – (2 Performance Elements)

- Has the required equipment and forms to conduct the inspection.
- Reviews the establishment file for the previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance.

II. Inspection Observations and Performance – (7 Performance Elements)

- Provides identification as a regulatory official to the person in charge, confirming agency authority for the inspection and stating the purpose of the visit.
- Has knowledge of the jurisdiction's laws, rules, and regulations required for conducting retail food/foodservice inspections.
- Uses a risk-based inspection methodology to assess the regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.
- Obtains immediate corrective action for out of compliance employee practices and management procedures essential to the safe storage, preparation and service of food.
- Correctly assesses the compliance status of other regulations (Good Retail Practices) that are included in the jurisdiction's prevailing statutes, regulations, and/or ordinances.
- Verifies correction of out of compliance observations identified during the previous inspection.
- Correctly uses inspection equipment during the joint inspection.

III. Oral Communication – (6 Performance Elements)

- Asks questions and engages in a dialogue with the person in charge/employees to obtain information relevant to the inspection.
- Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.
- Uses available means (e.g., interpreter, drawings, demonstrations, diagrams, international food safety icons) to overcome language or communication barriers.
- Follows the jurisdiction's policy with regard to disclosure of confidential information.
- Uses effective communication and conflict resolution techniques to overcome inspection barriers.
- Conducts the exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.

IV. Written Communication – (3 Performance Elements)

- Completes inspection form per the jurisdiction's administrative procedures (e.g., observations, corrective actions, public health reasons, applicable code references, compliance dates).
- Includes with the inspection report any compliance or regulatory documents identified or cross-referenced in written statements (e.g., exhibits, attachments, sample forms, embargo forms, destruction forms, suspension notices).
- Presents the inspection report, and when necessary cross-referenced documents, to the person in charge.

V. Professionalism – (3 Performance Elements)

- Maintains a professional appearance consistent with the jurisdiction's policy (e.g., clean outer clothing, hair restraint).
- Demonstrates proper sanitary practices as expected from a food service employee.
- Only reports substantiated findings as violations.

VI. Additional Performance Elements – (Jurisdiction Specific)

- Uses an aseptic food sample collection method consistent with criteria established by the laboratory serving the jurisdiction.
- Uses an aseptic water sample collection method consistent with criteria established by the laboratory serving the jurisdiction.
- Other performance elements identified by the jurisdiction.

NOTE: *The CFP Training Plan lists 2 Performance Elements (aseptic food and water sample collection) under additional performance elements. The responsibility for aseptic sampling of food and water varies greatly from one jurisdiction to another. If FSIOs are expected to collect aseptic samples of food and/or water, even if it is to be done on a limited basis, these performance elements should be included in the jurisdiction's training plan.*

IV. Creating Your Training Plan

This section presents four (4) basic steps that jurisdictions should consider when developing a training plan for your regulatory retail food protection program:

- STEP 1** – Determine Performance Elements to be Included in Your Training Plan
- STEP 2** – Determine Competencies for Each Selected Performance Element
- STEP 3** – Determine Need for Additional Performance Elements and Competencies
- STEP 4** – Determine Appropriate Training Method for Each Competency

STEP 1 – DETERMINE PERFORMANCE ELEMENTS TO BE INCLUDED IN YOUR TRAINING PLAN

Performance elements appear in the **shaded areas** of the *CFP Training Plan and Log*. The jurisdiction’s trainer should review the performance elements contained in the *CFP Training Plan and Log* and determine those that are part of the job responsibility of a FISO in their jurisdiction. If a performance element is conducted by a FSIO, it is to be included in the training plan. An “X” is to be placed in the box adjacent to each performance element included in your jurisdiction’s training plan.

INSPECTION TRAINING AREAS

I. Pre-Inspection

<input checked="" type="checkbox"/> . Has required equipment and forms to conduct inspection.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>				
<input type="checkbox"/> Necessary inspection forms and administrative materials.				
<input type="checkbox"/> Lab coat or equivalent protection to cover street clothes.				
<input type="checkbox"/> Head cover: baseball cap, hair net, or equivalent.				
<input type="checkbox"/> Calibrated thermocouple temperature measuring device.				
<input type="checkbox"/> Maximum registering thermometer or temperature sensitive tapes for verifying hot water <u>warewashing</u> final rinse temperature.				
<input type="checkbox"/> Chemical test kits for chlorine, iodophor, and quaternary ammonia sanitizers.				
<input type="checkbox"/> Flashlight				
<input type="checkbox"/> Alcohol swabs.				
<input type="checkbox"/> <u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>				
<input type="checkbox"/>				
Comments:				
Trainee has demonstrated acceptable performance for all competencies listed				
Date:	Trainee's Initials:	Trainer's Signature:		
<input checked="" type="checkbox"/> . Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or supporting the issuance of a variance.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>				
<i>Review previous inspection report, complaints on file, and if applicable, required HACCP Plans or supporting the issuance of a variance.</i>				

Using the graphic above as an example, an “X” appears in the box for identified performance elements within the “Pre-Inspection” training area. In this example, the trainer has

determined that both of these performance elements are part of the FSIO’s job responsibility in their jurisdiction.

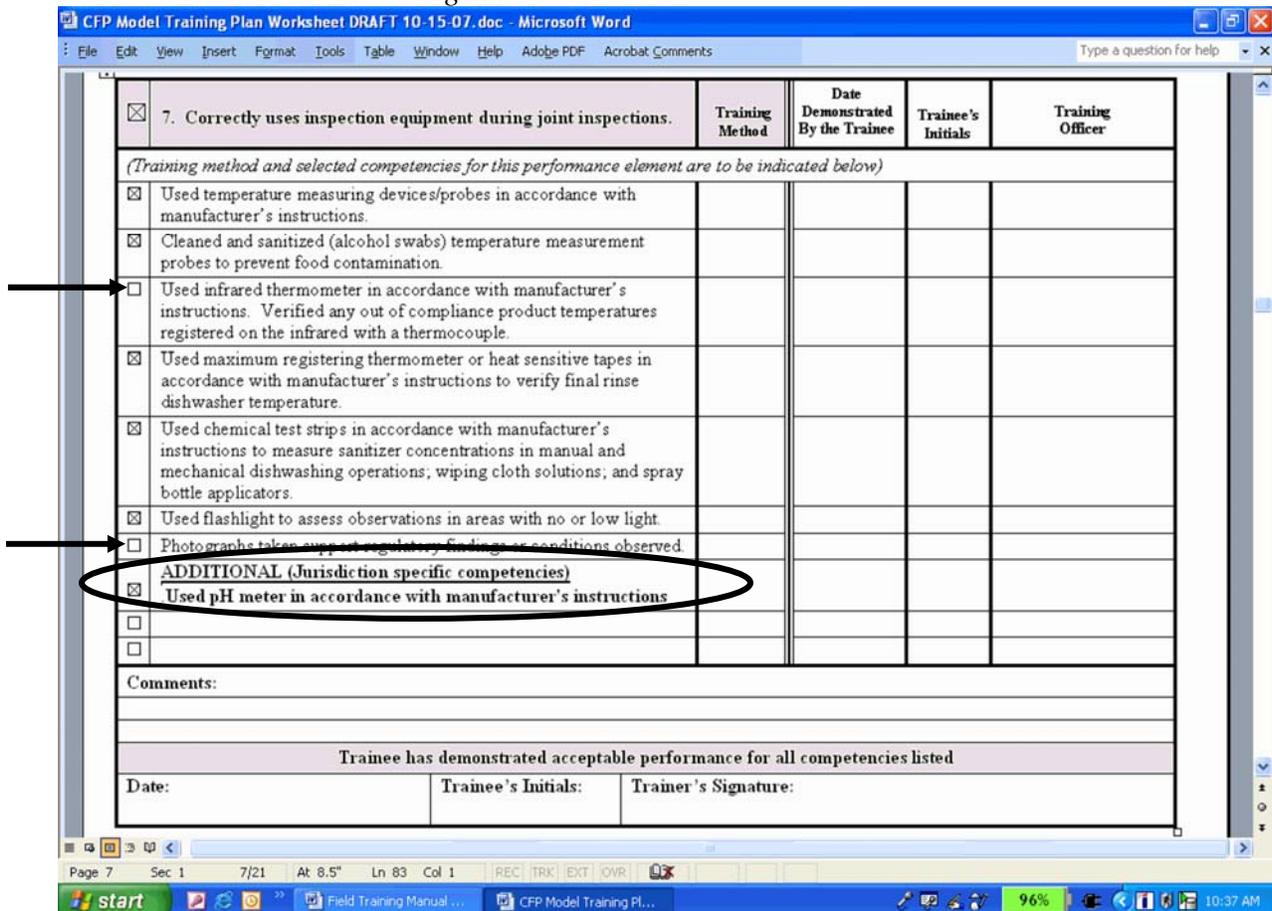
STEP 2 – DETERMINE COMPETENCIES FOR EACH SELECTED PERFORMANCE ELEMENT

The *CFP Training Plan and Log* provides a list of competencies (job tasks) under each performance element. These competencies are intended to serve as examples of job related tasks that a FSIO will be expected to successfully demonstrate during field training inspections.

The jurisdiction’s trainer should review competencies listed under the selected performance elements and place an “X” in the box for each of the competencies that are part of the FSIO’s job responsibility in their jurisdiction.

Some of the competencies listed for a performance element may not be applicable to a FSIO within a given jurisdiction. In the graphic below, infrared thermometers and cameras are not part of the standard issued equipment for inspection staff. The FSIO would not, therefore, be responsible for using this type of equipment. If this is the case, the boxes adjacent to these competencies are to be left blank as they would not be included in that jurisdiction’s training plan.

Competencies that are applicable to the FSIO’s job should not be arbitrarily removed or deleted from the *Field Training Worksheet*.

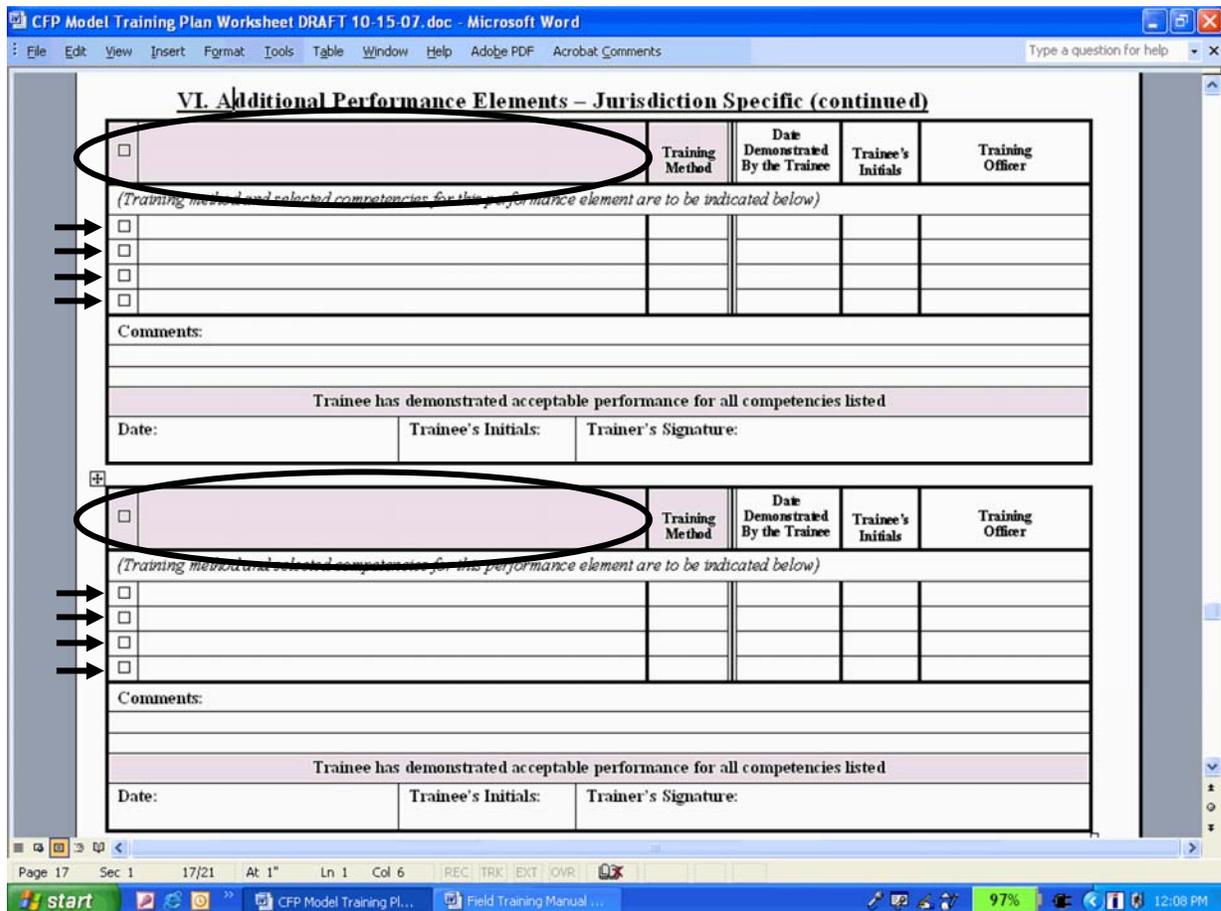


Conversely, there may be competencies not listed under a performance element that are important for a jurisdiction to include in a FSIO’s training. The *CFP Training Plan and Log* has been designed to accommodate “Additional” jurisdiction-specific competencies. In the example from the previous graphic, the jurisdiction issues pH test kits to all FSIOs for product assessments during inspections. If this is the case, the FSIO will need to successfully demonstrate the use of the pH test kit during training which will be included as part of the FSIO training plan.

STEP 3 – DETERMINE NEED FOR ADDITIONAL PERFORMANCE ELEMENTS AND COMPETENCIES

The performance element competencies that comprise the *CFP Training Plan and Log* represent a national model and the overwhelming majority of these apply to every jurisdiction. There will be instances, however, where a jurisdiction may need to add performance elements and competencies that are not listed on the *CFP Training Plan and Log*.

Section VI – Additional Performance Elements includes blank templates that a jurisdiction can use to further customize their training plan. Additional Performance Elements are placed in the shaded boxes circled in the graphic below. Any competencies that a FSIO will need to successfully demonstrate during the training process for this performance element need to be identified and listed in the spaces indicated with the arrows.



Feedback received from some jurisdictions that field tested the CFP training process suggested inclusion of the following additional performance element competencies in a FSIO training plan:

- Applies HACCP principles in the assessment of food processes and/or preparation procedures to determine if food safety hazards are controlled.
- Conducts menu-based reviews to determine inspection priorities based on potential food safety hazards.
- Demonstrates a thorough understanding of how the Food Code is organized and proper application of Food Code conventions.
- Develops risk control plans or other intervention strategies in accordance with the jurisdiction's administrative procedures to obtain long term control of contributing factors to foodborne illnesses.

STEP 4 – DETERMINE APPROPRIATE TRAINING METHOD FOR EACH COMPETENCY

Once the FSIO competencies have been identified in the training plan, consideration needs to be given as to how the training will be delivered. Training methods vary from jurisdiction to jurisdiction, and resources available to a jurisdiction (time, money, personnel, etc.) may have a significant impact on determining the type of training that can be provided. Whatever training methods are selected, it is important to ensure that the process will cover all the competencies (job tasks) that FSIOs are expected to successfully demonstrate during food safety inspections.

Training is most effective when it is delivered within the context or environment in which an individual would be expected to apply the knowledge and skills. For FSIOs, the appropriate training environment is one that mirrors the actual experience of inspecting retail food, restaurant, and/or institutional foodservice establishments. When developing the FSIO training plan, every effort should be made to provide the FSIO with opportunities to demonstrate a competency during actual field training inspections.

In an ideal training environment, the selection of establishments used for training will provide adequate opportunity to demonstrate all competencies. However, for a variety of reasons, it may not always be possible for the trainee to demonstrate all competencies during joint field training inspections. Should this occur, other training options will need to be considered and implemented.

Some of the performance elements that comprise the *CFP Training Plan and Log* include competencies that frequently occur as part of the inspection process and give multiple opportunities for the trainer to observe the trainee demonstrating these job tasks during joint field training inspections. These performance elements include:

- Has the required equipment and forms to conduct the inspection;
- Reviews establishment file for previous inspection report, complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance;

- Provides identification as a regulatory official to the person in charge, confirming agency authority for the inspection and stating the purpose of the visit;
- Uses inspection equipment correctly during the inspection;
- Conducts the exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations;
- Presents the inspection report and, when necessary, cross-referenced documents, to the person in charge; and
- Maintains a professional appearance that is consistent with jurisdiction's policy (e.g., clean outer clothing, hair restraints).

Some of the performance elements, though they frequently occur during field inspections, **will have competencies that the FSIO will need to successfully demonstrate throughout the course of the joint field training process.** These performance elements represent competencies for which the trainer will observe a trainee's continued development and improvement with each subsequent training inspection. Most of the performance elements fall into this category and include:

- Has knowledge of the jurisdiction's laws, rules, and regulations required for conducting retail food/foodservice inspections;
- Uses a risk-based inspection method to assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food;
- Obtains immediate corrective actions for out of compliance employee practices and management procedures essential to the safe storage, preparation, and service of food;
- Verifies correction of out of compliance observations identified during the previous inspection;
- Asks questions and engages in a dialogue with the person in charge/employees to obtain information relevant to the inspection;
- Provides the operator with accurate answers to inspection-related questions or admits not knowing the answer;
- Uses available means (e.g. interpreter, drawings, demonstrations, diagrams, international food safety icons) to overcome language or communication barriers;
- Completes inspection form per the jurisdiction's administrative procedures (e.g., observations, corrective actions, public health reasons, applicable code reference, compliance dates);
- Includes with the inspection report any compliance or regulatory documents identified or cross-referenced in written statements (e.g., exhibits, attachments, sample forms, embargo forms, destruction forms, suspension notices);
- Demonstrates proper sanitary practices as expected from a food service employee; and
- Only reports substantiated findings as violations.

There are, however, some performance elements that are important inspection responsibilities but **may seldom or rarely occur during the FSIO field training process**. Due to the variable nature of inspections, the trainee may not be presented with an opportunity to demonstrate these competencies as part of the joint field training process. Although less frequently encountered, these performance elements include knowledge and skills integral to enhancing the effectiveness of the inspection process and include:

- Follows the jurisdiction's policy in regard to disclosure of confidential information;
- Uses effective communication and conflict resolution techniques to overcome inspection barriers; and
- Uses an aseptic food or water sample collection method consistent with criteria established by the laboratory serving the jurisdiction.

Whenever possible, competencies are to be assessed in the field inspection environment. If this is not feasible **laboratory, classroom, or office exercises** may be used to assess performance elements difficult to observe in the field. Examples of such training exercises may include:

- Trainee photographing a specific object in the office, field, or laboratory;
- Trainee explaining to the trainer the jurisdiction's policy in regard to disclosure of confidential information;
- Trainee explaining to the trainer the jurisdiction's policy in regard to conflict resolution (the trainer may develop scenarios for the trainee to review and discuss appropriate conflict resolution techniques); or
- Trainee demonstrating aseptic food and/or water sampling in the office, laboratory, or during a designated field training inspection.

The graphic below provides an illustration to document alternative training methods.

III. Oral Communication (continued)

	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<input checked="" type="checkbox"/> 3. Uses available means (e.g., interpreter, drawings, diagrams demonstrations, international food safety icons) to overcome language or communication barriers.				
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>				
<input checked="" type="checkbox"/> Avoided using jargon and acronyms, without explanation.	JFT			
<input checked="" type="checkbox"/> Used interpreter, drawings, demonstrations, or diagrams to overcome language or communication barriers.	CE And/or JFT			
<input checked="" type="checkbox"/> Checked the person in charge's understanding of information/instructions by asking the operator to paraphrase or demonstrate the information/instructions.	JFT			
<input type="checkbox"/> <u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>				
Comments:				
Trainee has demonstrated acceptable performance for all competencies listed				
Date:	Trainee's Initials:	Trainer's Signature:		
<input checked="" type="checkbox"/> 4. Follows jurisdiction's policy in regard to disclosure of confidential information.				
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>				
<input checked="" type="checkbox"/> Explained confidentiality laws, policies and procedures to the person in charge when necessary. (If the need to explain confidentiality laws did not occur during the joint field training inspections, the FSIO explained confidentiality laws, policies and procedures to the trainer).				
<input checked="" type="checkbox"/> Applied the confidentiality policy per the jurisdictional requirements				

In this example, the types of establishments selected for the joint training process did not present an inspection environment that required the trainee to overcome language barriers. An opportunity for the trainee to demonstrate these competencies was addressed by incorporating a classroom exercise as an alternative training method.

V. Preparing for Joint Field Training Inspections

STEP 1 – IDENTIFY SOURCE DOCUMENTS FOR ORIENTATION

Information that a regulatory jurisdiction should review as part of the FSIO's orientation to the retail food protection program includes but is not limited to:

- The jurisdiction's FSIO training plan that identifies the specific performance element competencies that a FSIO will need to successfully demonstrate during joint field training inspections;
- The jurisdiction's current statutes, regulations, code, or ordinances governing foodservice and/or retail food under its inspection authority;
- Any written policies or interpretations implemented by the jurisdiction that carry the same weight as their prevailing statutes, rules, and ordinances;
- The jurisdiction's current retail food protection program inspection form;
- Any marking instructions that the jurisdiction may have developed to assist staff with documenting inspection findings;
- The prerequisite curriculum posted on FDA's ORA U web site and the web address for obtaining an access password; and
- Other documents specific to the jurisdiction that the trainer has determined are integral to the retail food protection training program.

The inclusion of the above list of source documents is not meant to imply that all material must be reviewed during a single dedicated FSIO orientation session. The documents are included here to provide a starting point for a checklist of materials a trainer will likely need to review with the FSIO the first weeks of employment or assignment to the retail food protection program.

STEP 2 – REVIEW LIST OF PREREQUISITE CURRICULUM WITH TRAINEE

The courses listed as part of the prerequisite curriculum should be reviewed with the FSIO. The trainer or food program manager needs to make a determination whether a candidate has met any or all of the prerequisite curriculum requirements and has documentation indicating successful completion. If the FSIO needs to complete coursework, the trainer should assist him/her with obtaining an access password to the FDA ORA U web site, or make a determination as to whether equivalent courses are a more viable option.

Reserving designated blocks of time each week for the FSIO to devote to this curriculum often facilitates timely completion of the prerequisite coursework. Keep in mind that the FSIO can participate and even take the lead in conducting joint field training inspections while they are in the process of completing the prerequisite coursework.

NOTE: *The prerequisite coursework includes a listing for the FDA 2005 Food Code. While most jurisdictions use the FDA Food Code as the foundation for their own rules and regulations, there will be some differences unless the jurisdiction has adopted the entire FDA Food Code by reference. Jurisdictions should use their own Food Code as the prerequisite course for training FSIOs. State, local, and tribal jurisdictions are strongly encouraged to*

conduct a frequent review of their existing Food Code provisions against the current version of the FDA Food Code to ensure that it provides a scientifically sound technical and legal basis for regulating the retail food segment of the industry.

STEP 3 – REVIEW TRAINING PLAN WITH TRAINEE

A review of the jurisdiction's retail food protection training plan should include a discussion of:

- The performance elements, how they were determined, and their impact on conducting effective food safety inspections;
- The specific competencies that comprise each performance element so the trainee has a clear understanding of what job tasks they will be expected to successfully demonstrate during the course of the field training process;
- Training methods and approaches that will be offered to facilitate a trainee's demonstration of the competencies;
- How field training objectives will be determined and communicated to the trainee;
- How the trainer will observe the trainee perform competencies during field training inspections and share feedback on their observations;
- How progress and accomplishments will be documented on the training plan; and
- The jurisdiction's criteria for determining a trainee's readiness to conduct independent inspections of retail food and/or foodservice facilities.

VI. Conducting Field Training Inspections

Field training inspections are a core component for preparing a FSIO to perform their job responsibilities independently. There are two types of field training inspections: demonstration (trainer-led) and those where the trainee takes the lead (trainee-led).

Field training will initially be comprised of demonstration (trainer-led) inspections. Providing an opportunity for the FSIO to observe experienced staff conducting food safety inspections is an essential step in preparing a trainee for taking the lead during field training inspections.

Trainee-led inspections provide the opportunity for the jurisdiction's trainer to observe the trainee build their skills and successfully demonstrate competencies. Inspections led by a trainee are ***not*** part of an examination or audit process. They are intended to be part of a structured training process where learning is still occurring, where trainers are providing feedback, and where correct demonstration of competencies is continually being re-enforced.

A sufficient number of field training inspections led by the trainee are to be conducted to allow the demonstration of ***all*** competencies identified in the jurisdiction's training plan. Upon completion of the field training process, the trainee should have successfully demonstrated all competencies in the training plan and be ready to conduct independent inspections of retail food and/or foodservice facilities.

STEP 1 – SELECTING APPROPRIATE TRAINERS

The manager of the regulatory retail food protection program has the discretion of deciding who will serve as trainers. In making this decision, available training resources (e.g., personnel, time, funding) and overall program objectives will need to be considered when selecting staff to oversee and conduct the FSIO field training.

A trainee can garner important knowledge and perspective from observing different inspection approaches from experienced staff. During the course of these joint inspections, it is expected that a trainee will observe experienced staff demonstrate all performance element competencies that are part of the jurisdiction's training plan.

STEP 2 – CONDUCTING DEMONSTRATION (TRAINER-LED) INSPECTIONS

When selecting staff for trainer-led inspections, management should consider experienced staff with a solid command of all the competencies the FSIO will be expected to demonstrate in the training process. These experienced staff members will lay the foundation for the trainee's assimilation of the knowledge and skills needed to conduct food safety inspections as they will be initially demonstrating how to correctly perform specific job tasks.

If possible, management should consider pairing the trainee with several different FSIOs during demonstration inspections to allow exposure to different inspection approaches and techniques. Moreover, these trainer-led inspections should be conducted in a variety of establishments that cover the spectrum of retail food and foodservice operations that the FSIO will eventually be inspecting on their own.

The level of preparedness and time needed to assimilate knowledge from observations made during demonstration inspections will vary with each trainee. When a determination has been made that the trainee is ready to take the lead during an inspection, it is important to keep in mind that training has not stopped. Trainees will still need trainers to demonstrate competencies and provide feedback. The CFP training process is designed to facilitate a continuous improvement learning experience.

STEP 3 – PREPARING FOR INSPECTIONS LED BY THE TRAINEE

Inspections led by the trainee consist of two inter-related but separate activities: one is specific to the role of the jurisdiction's trainer, the other relates to the role and responsibilities of the trainee.

- The trainer is responsible for observing the trainee as he/she demonstrates competencies identified in the jurisdiction's training plan.
- The trainee is responsible for conducting the inspection in the presence of the trainer, per the jurisdiction's administrative procedures and policies.

Even though there is a relationship between these activities, it is important to recognize the need to view them separately.

Trainer's Role

During trainee-led inspections, the trainer observes the trainee conducting the inspection and demonstrating the competencies. The trainer participates *only* when the inspection process dictates their assistance or intervention.

No single field training inspection will provide an opportunity for the trainee to demonstrate all the competencies listed in the training plan. The trainer should allow the inspection process to unfold as it normally would; in other words, the jurisdiction's training plan should *not* be used as a checklist for structuring the inspection to accommodate observations of a trainee demonstrating competencies. Requesting that a trainee demonstrate a competency that is not integral to the inspection that is occurring may be disruptive and create unwanted confusion and stress for the trainee.

As the field training process progresses, the trainer may note that the selection of establishments has not provided the trainee an opportunity to demonstrate some competencies. The trainer can try to remedy this situation by selecting establishments that may provide appropriate environments where the trainee can demonstrate the job tasks. If this is not feasible, the trainer can set up field exercises during inspections led by the trainee; however, the exercise should be conducted at a time that will not disrupt the flow of the inspection and the trainer should discuss these exercises with the trainee prior to the inspection so expectations are clear.

Trainee's Role

Since the trainee will be taking the lead during these field training inspections, their focus should be on observations of food safety practices and procedures within the establishment. During these inspections the trainee is responsible for:

- Initiating contact with the person in charge;
- Explaining the purpose of the inspection;
- Directing the inspection process;
- Establishing a dialogue with management and employees;
- Making the observations of food safety practices;
- Obtaining corrective actions for out-of-compliance foodborne illness risk factors;
- Preparing the inspection report; and
- Facilitating and conducting the exit discussion of the report.

The trainee's inspection approach, communication techniques, and food safety priorities should be reflective of those they would implement if inspecting independently. The inspection should *not* be structured solely around the demonstration of competencies. The trainee should concentrate on conducting an effective food safety inspection. Providing an appropriate variety of establishments will help ensure the competencies listed on the jurisdiction's training plan do not drive the inspection approach.

STEP 4 – SELECTING ESTABLISHMENTS FOR INSPECTIONS LED BY TRAINEE

The ideal establishment for conducting a food safety inspection led by the trainee is one that will provide an opportunity for the trainee to successfully demonstrate the greatest number of competencies. The majority of these inspections should be completed in establishments that are representative of the highest risk categories within the jurisdiction or the FSIO's assigned training area.

Jurisdictions can use their own system for grouping establishments into categories based on potential or inherent food safety risks. Annex 5, Table 1 of the *2005 FDA Food Code* can also be used as a reference for assigning risk categories.

STEP 5 – DETERMINING THE NUMBER OF INSPECTIONS LED BY TRAINEE

There is no definitive number of inspections led by the trainee that can be used as a standard for all newly hired employees. The number of inspections necessary is one that provides adequate opportunity for all competencies to be demonstrated. Some of the competencies, such as those related to conducting a risk-based inspection, must be continually demonstrated throughout the course of the field training process.

NOTE: *For jurisdictions enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards, staff conducting food safety inspections must conduct a minimum of 25 joint field inspections comprised of both "demonstration" (trainer-led) and trainee-led inspections, and include a variety of establishment types available within the jurisdiction.*

The CFP field training process is *not* intended to be part of an audit or evaluation process, therefore a “scoring system” has not been included. The primary objective of this process is to ensure that the FSIO has received training for all the competencies that are part of the job responsibilities within that jurisdiction. As part of this training, the FSIO is to successfully demonstrate their ability to perform each of these competencies. No single inspection or observation should be used by the trainer(s) as the standard of measurement; the jurisdiction’s trainer(s) need to evaluate the trainee’s ability to demonstrate competencies throughout the entire process.

NOTE: *FSIOs should successfully complete the field training process prior to conducting independent inspections and re-inspections of retail food establishments equivalent to Risk Categories 2, 3, and 4 as noted in Annex 5, Table 1 of the 2005 FDA Food Code. However a jurisdiction’s trainer or food program manager can make a determination as to the FSIO’s readiness to conduct independent inspections of Risk Category 1 establishments at any time during the training process.*

STEP 6 – OBSERVING TRAINEE DEMONSTRATE COMPETENCIES

NOTE: *For jurisdictions enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards, the trainer or designated staff member responsible for documenting the FSIOs demonstration of a competency must have completed all the training elements in Steps 1-3 required in Standard 2 – Trained Regulatory Staff. It is highly recommended that this trainer be standardized in a process similar to the “FDA Standardization Procedures” (See FDA Procedures for Standardization of Retail Food Inspection/Training Officers at <http://www.cfsan.fda.gov/~ear/rfi-toc.html>).*

There is no single “correct” method for making a determination as to when a trainee has successfully demonstrated a competency during field training inspections. Throughout the series of training inspections, the trainer will observe the trainee demonstrate many competencies. For some competencies, the trainer will be able to ascertain relatively quickly whether a trainee has demonstrated the job task correctly. For example, once a trainee successfully demonstrates the proper use of inspection equipment, he/she generally will maintain that skill throughout the training process.

Almost all of the competencies listed, however, should be demonstrated by the trainee several times. The trainer should observe the trainee successfully demonstrate a consistent pattern of behavior for each competency. As defined in this document, a “**consistent pattern of behavior**” means:

- The trainee can explain the purpose/objective of the job task and the steps necessary to carry it out effectively;
- The demonstration of a clear understanding of a given competency; and
- A collective set of trainer observations which predominately indicate that the trainee can successfully demonstrate the competency correctly and repeatedly.

Trainees will be on a continuous learning curve throughout the training process;

inconsistencies in their inspection approach from one facility to another should be expected. Trainers will need to determine whether these inconsistencies are due to a lack of understanding, an inability to successfully demonstrate a competency, or simply inexperience.

In some cases a trainee may be capable of successfully demonstrating a competency but fails to do so during an inspection. For example, he/she may not address an important food safety risk (such as employee health) with the person in charge. The trainee may understand and can demonstrate the proper approach to assessing an employee health policy within an establishment, but forgets to do so because they may have become distracted by other risk related observations and the need to work with management to obtain corrective actions. This is an example of a trainee who is still in the process of developing his/her own organized risk-based inspection approach.

It is important for trainers to recognize that during the training process, trainees are not only learning competencies but are also becoming acclimated to their working environment. Trainer's decisions regarding a trainee demonstrating a competency should be based on a collective set of observations which predominately indicate the job task is being performed correctly.

When the trainee successfully demonstrates a competency, the jurisdiction's trainer or designated staff person documents the completion of the skill on the training plan. Some options and forms for tracking the trainee's progress and accomplishments are presented in Section VII of this document.

VII. Documenting Training Progress and Accomplishments

Each regulatory retail food protection program will need to develop a system to track a FSIO’s training progress and accomplishments. A jurisdiction can customize the forms provided in this manual or develop their own. Any system for documenting training should provide a method for:

- Recording competencies that have been demonstrated by a FSIO;
- Determining competencies a FSIO has not yet demonstrated;
- Identifying the trainer(s) responsible for observing a FSIO demonstrating a competency;
- Providing feedback to the FSIO on training objectives; and
- Obtaining confirmation from both the FSIO and trainer that competencies have been demonstrated correctly.

CFP TRAINING PLAN AND LOG USED AS A SINGLE SOURCE DOCUMENT

The *CFP Training Plan and Log* (Attachment A) can be used as a single source document for recording a FSIO’s training progress and accomplishments.

The graphic below provides an illustration of how a FSIO’s training status can be tracked with documentation entered for the four competencies listed under this performance element.

II. Inspection Observations and Performance(continued)

<input checked="" type="checkbox"/>		Training Method	Date Demonstrated by the Trainee	Trainee's Initials	Training Officer
<input checked="" type="checkbox"/>	4. Obtains immediate corrective action for out of compliance employee practices and management procedures (listed in Item 3 above) essential to the safe storage, preparation, and service of food				
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input checked="" type="checkbox"/>	Notified the person in charge/employee(s) of the out of compliance observations.	JFT	5-21-07	R.T.	Mary Jones
<input checked="" type="checkbox"/>	Reviewed corrective actions with the person in charge/employee(s).	JFT	5-21-07	R.T.	Mary Jones
<input checked="" type="checkbox"/>	Observed the person in charge/employee(s) immediately take corrective action for out of compliance observations (e.g., movement of food to ensure product temperature or prevent contamination; reconditioning food; restriction/exclusion of ill employees; discarding of food product) in accordance with local jurisdiction's procedures.	JFT	7-18-07	R.T.	Mary Jones
<input checked="" type="checkbox"/>	Identified conditions requiring issuance of an embargo/stop sale/food destruction order per jurisdiction's administrative procedures.	OD	8-2-07	R.T.	John Smith
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					

Comments: Trainee did not observe a condition during the joint field training inspections that required issuance of an embargo/stop sale/food destruction order. Office scenarios were set up. Trainee demonstrated steps that would be implemented for the issuance of an embargo/stop sale/food destruction order and completed required forms per the jurisdiction's administrative protocol. (John Smith)

Trainee has demonstrated acceptable performance for all competencies listed

Date: 8-2-07	Trainee's Initials: R.T.	Trainer's Signature: John Smith
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For each of the competencies, the trainer records the date a determination was made that the trainee successfully demonstrated the competency. The trainee's initials (represented by "R.T." in the graphic on the previous page), indicate his/her agreement with the date recorded (represented as 5-21-07). The training officer's name or signature indicates confirmation that the trainee successfully demonstrated the competency. When the trainee has demonstrated all the competencies for a performance element, the bottom row is completed as indicated with the arrow in the graphic.

Documentation on the *CFP Training Plan and Log* does not have to follow this format exactly. For example, a jurisdiction that has only one trainer may find it redundant to record the trainee's initials and trainer's name for all competencies within each performance element. In scenarios like this, a trainer may choose to simply record the date when each competency was demonstrated under the "Date Demonstrated by the Trainee" column. Then, when the trainee has demonstrated all the performance element competencies, he/she places their initials in the bottom row (indicated with the arrow in the graphic), and the trainer signs confirming completion.

However, if multiple trainers are used, competencies demonstrated by the trainee may be confirmed by different individuals. In this case, in order to ensure open communication between the training staff and the trainee throughout the field training process, it may be important to know which trainer actually observed that the trainee demonstrated a specific competency.

A "comment" section is provided at the bottom of each of the performance element tables. This area can be used to describe future training objectives or to provide a method of communicating training observations among multiple trainers. It can also be used to describe changes to the training plan to ensure opportunity to demonstrate a competency that may be difficult to observe during field training inspections.

From the example presented on the previous page, the comment section includes the following note:

Trainee did not observe a condition during the joint field training inspections that required issuance of an embargo/stop sale/food destruction order. Office scenarios were set up. Trainee demonstrated steps that would be implemented for the issuance of an embargo/stop sale/food destruction order and completed the required forms per the jurisdiction's administrative protocol. (John Smith)

In this example, the scheduled field training inspections were coming to an end. The field inspections had not provided an opportunity for the trainee to demonstrate the jurisdiction's procedure for issuance of an embargo/stop sale/food destruction order. The trainer set up an office exercise for the trainee to demonstrate this competency and the "OD" designation under training method in the graphic indicates "Office Demonstration."

OPTIONAL TRAINING LOGS

Two optional training logs are included at the end of the *CFP Training Plan and Log* that can be used to track a FSIO’s progress and achievements:

- FSIO Training Log
- Joint Field Training Inspections – Establishment Log

A determination on whether to use these optional training logs should be made by the manager of the regulatory retail food protection program before initiating field training so their intended use and purpose can be communicated to FSIOs in training and staff who will serve as trainers.

FSIO Training Log

The optional *FSIO Training Log* provides a method for tracking a FSIO’s progress and accomplishments from one week to another by noting competencies demonstrated each week. Training objectives for the upcoming week can be established and communicated with the trainee to clarify expectations and assist in focusing on specific competencies. This weekly training log can also be an important means of sharing information in situations where multiple trainers are working with a FSIO.

OPTIONAL - FSIO TRAINING LOG

Trainee's Name: Richard Thompson

Week: 6 Date Ending: 4-6-07

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
Provides name /agency to the person in charge	Observe use of all inspection equipment (see items noted in additional comments)	Training focus on the use of the Maximum Registering Thermometer, Flashlight, PH meter. Use of inspection forms
Presents regulatory ID prior to inspection	Continue to observe communication with operator (focus areas described in additional comments)	Dialog with manager/employees to understand operation; response to questions asked by management and employees; how exit interview is conducted
States the purpose of the inspection	Continue training on preparing the written inspection report	Focus on correctly writing the observation; citing the correct provision of the Food Code; completeness of the report
Confirms authorization to conduct inspection with person in charge before proceeding	Observe process for review and establishment file prior to inspection	Review of past inspection report; follow-up actions noted on report; complaints.
Demonstrated use of Thermcouple / Alcohol Swabs		
Demonstated use of Chemical Test Kits		
Trainee's Initials: R.T.	Trainer's Signature: Mary Jones	

Week: 7 Date Ending: 4-13-07

Joint Field Training Inspections – Establishment Log

The optional *Joint Field Training Inspections – Establishment Log* provides a method of tracking the number and type of establishments within which training has been conducted. A “Risk Category” column provides a quick reference as to the complexity of food preparation processes that have been included in the FSIO’s training and assists in determining what types of establishments to include in future field training inspections.

OPTIONAL
JOINT FIELD TRAINING INSPECTIONS - ESTABLISHMENT LOG

#	Date	Permit #	Establishment Name	Establishment Address	Risk Category	Demonstration (Trainer-led) Inspection	FSIO-led (Trainee-led) Inspection
1	4-2-07	07896	Dig These Dogs	6437 Oak Street, Pepperoni, AZ	3	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2	4-2-07	07912	Try R Food	1919 Park Place, Monopoly, AZ	3	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3	4-3-07	07485	Ultimate Dining	2100 3 rd Street, Cactus, AZ	4	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4	4-3-07	07020	Can You Say Cheese?	739 N. Main Street, Cheddar, AZ	2	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5	4-4-07	08923	No Place Like Home	881 S. Prairie Lane, Cactus, AZ	4	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6	4-4-07	08237	Only The Finest Meats	23 N. Main St., Cactus, AZ	2	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7	4-6-07	07654	Happy Feet Day Care	34 Tender Care Road, Cactus, AZ	5	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8	4-6-07	07345	St. John's Medical Ctr.	421 W. Desert Avenue Cactus, AZ	5	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9	4-9-07	08787	Zesty Delights	971 Center Avenue, Cactus, AZ	4	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10	4-9-07	07001	Survival Foods	699 Desert Avenue, Cactus, AZ	1	<input type="checkbox"/>	<input checked="" type="checkbox"/>
11	4-9-07	07492	Tasty Treats	567 Illinois Avenue, Monopoly, AZ	1	<input type="checkbox"/>	<input checked="" type="checkbox"/>
12	4-10-07	07113	Big Pizzas	23 Pizza Place, Pepperoni, AZ	2	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13	4-10-07	07222	Make Your Own Sandwich	1 Elm Street, Monopoly, AZ	3	<input type="checkbox"/>	<input checked="" type="checkbox"/>
14	4-12-07	07555	Anytime Food	1 Ocean Drive, Ocean Park, AZ	3	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15	4-18-07	07639	Just Packaged Goods	538 Broadway, Ocean Park, AZ	1	<input type="checkbox"/>	<input checked="" type="checkbox"/>
16	4-18-07	07777	Leafy Greens	679 West Olive Avenue, Ocean Park, AZ	3	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17	4-18-07	07184	Hungry Horses	972 E. West Street, Ocean Park, AZ	3	<input type="checkbox"/>	<input checked="" type="checkbox"/>
18	4-19-07	07014	You Don't Leave Hungry	871 W. Mushroom Boulevard, Cactus, AZ	4	<input type="checkbox"/>	<input checked="" type="checkbox"/>
19	4-19-07	07296	We Make What You Like	43 N. Madison, Monopoly, AZ	4	<input type="checkbox"/>	<input checked="" type="checkbox"/>
20	4-20-07	07666	Shamrock Casino & Resort	3030 Big Bucks Lane, Monopoly, AZ	5	<input type="checkbox"/>	<input checked="" type="checkbox"/>

In addition, the establishment log provides a quick method for distinguishing trainer-led (demonstration) inspections from those that are trainee-led. An “X” is placed in the appropriate column to denote the type of field training inspection conducted. In the above graphic, the first 9 inspections were trainer-led, and the trainee first took the lead during joint field training inspections when Establishment #10 was visited.

SUPPLEMENTAL FIELD TRAINING WORKSHEET FOR TRAINERS

Some jurisdictions who field tested the CFP training process requested optional *Field Training Worksheets* that trainers could use during trainee-led inspections to record observations that will aid in determining when a competency has been consistently demonstrated. The *Field Training Worksheet* also provides a means for identifying competencies that the trainee has not had the opportunity to successfully demonstrate.

Two versions of such a worksheet have been developed:

- Field Training Worksheet, a distilled version of the *CFP Training Plan and Log*
- Abbreviated Field Training Worksheet, a version listing only the performance elements.

Either version can be used in conjunction with the *CFP Training Plan and Log* to track a FSIO's progress and accomplishments. The manager of the regulatory retail food protection program has the discretion of determining whether to use a *Field Training Worksheet* as part of their training process.

Field Training Worksheet

The *Field Training Worksheet*, included as Attachment B, is a distilled version of the *CFP Training Plan and Log*.

In this worksheet, all **performance element competencies** for which the most appropriate training method is “Joint Field Training Inspections – JFT” have been included.

Conference for Food Protection

→ **FIELD TRAINING WORKSHEET**
(Performance Elements and Competencies)

**Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer**

NOTE: The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers (FSIOs) should be reviewed prior to using the CFP Field Training Worksheet. The manual provides jurisdictions with information that will be helpful in customizing the CFP Field Training Worksheet and implementing a training process that meets the specific needs of the jurisdiction.

Establishment Name:	Establishment Address:
Food Safety Inspection Officer's (FSIO) Name:	Food Safety Inspection Officer's (FSIO) Agency:
Trainer's Name:	Trainer's Agency:
Date of Inspection led by Trainee:	Time IN: Time OUT:

The Conference for Food Protection (CFP) has conducted a national research study and identified the basic minimum competencies that are needed to perform regulatory retail food and/or foodservice inspections. The CFP Field Training Worksheet has been designed as a trainer's tool to be used in conjunction with the CFP Training Plan and Log. It provides a method for keeping track of the Food Safety Inspection Officer's (FSIOs) progress and accomplishment in demonstrating performance element

For each of the competencies included in the jurisdiction's *Field Training Worksheet*, the trainer:

- Determines whether or not there was an opportunity to demonstrate a competency; and
- Determines when a FSIO consistently demonstrates a competency correctly.

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input checked="" type="checkbox"/>	3. Uses available means (e.g., interpreter, drawings, diagrams, demonstrations, international food safety icons) to overcome language or communication barriers.				
<input checked="" type="checkbox"/>	Avoided using jargon and acronyms, without explanation.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Used interpreter, drawings, demonstrations, or diagrams to overcome language or communication barriers.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Checked the person in charge's understanding of information/instructions by asking the operator to paraphrase or demonstrate the information/instructions.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Reviewed techniques with the FSIO for asking open ended questions when checking food employees understanding of information presented during the inspection. Discussed the importance of demonstrating, when possible, a procedure when it appears that management or food employees may not clearly understand a verbal explanation. For example, setting up the wash, rinse, and sanitize bins of a 3 compartment sink, then checking for understanding by having the food employees demonstrate the procedure. I will continue to work with the FSIO on this competency during the field training inspections scheduled for next week. (Mary Jones)					
<input checked="" type="checkbox"/>	4. Follows jurisdiction's policy in regard to disclosure of confidential information.				

The *Field Training Worksheet* contains two major columns for recording observations:

- *Opportunity occurred for FSIO to demonstrate competency during field training inspection.*

YES – An “X” is placed in this box if the trainee had an opportunity to successfully demonstrate the listed competency during the inspection. In the graphic above, the trainee had opportunity to demonstrate competencies pertaining to “avoiding the use of acronyms/jargon” and “checking the person in charge’s understanding of information.”

NO – An “X” is placed in this box if the inspection environment did not require or present an opportunity for the trainee to successfully demonstrate the competency. Using the graphic above, an opportunity did not occur during the field training for the trainee to demonstrate “the use of interpreters/drawings/demonstrations, etc., to overcome language or communication barriers.” If this pattern continues throughout the field training inspections, an alternative training method may need to be considered.

- *Competency demonstrated during field training inspections.*

YES – An “X” is placed in this box if the trainee successfully demonstrates the competency during the inspection. When possible, a trainer should observe a trainee demonstrating a competency several times. In the graphic displayed on the previous page, the trainer has indicated that the trainee has successfully demonstrated the ability to avoid acronyms/jargon when providing explanations to food employees during inspections.

NO – An “X” is placed in this box if the trainee has an opportunity to demonstrate a competency during the inspection but does not do so correctly or does not act correctly in the inspection situation. It is important to emphasize that a “NO” determination for the competency does *not in any way* denote or indicate that the trainee has failed. It is simply part of the continuous learning process and is intended to identify areas where additional training is needed. When a “NO” determination is made regarding a specific competency, the trainer should take immediate steps to review or demonstrate the correct procedure or protocol with the trainee. In the graphic on the previous page, the trainer has indicated that the trainee needs additional training related to communication techniques for determining the person in charge’s level of understanding for the information presented during the inspection.

Comments – The trainer can provide detailed descriptions of observations made during joint training inspections in the “comments” section at the bottom of each performance element table, as well as additional training provided and future training objectives. In the example used for this discussion, the trainer has provided the following statements in the comment section:

Reviewed techniques with the FSIO for asking open-ended questions when checking food employees understanding of information presented during the inspection. Discussed the importance of demonstrating, when possible, a specific procedure when it appears that management or food employees may not clearly understand a verbal explanation. For example, setting up the wash, rinse, and sanitize bins of a 3 compartment sink, then checking for understanding by having the food employees demonstrate the procedure. I will continue to work with the FSIO on this competency during the field training inspections scheduled for next week. (Mary Jones)

The *Field Training Worksheet* is a method for trainers to organize and record their notes from observations made of the trainee demonstrating competencies during training inspections.

As indicated in the graphic at the top of the next page, information from the *Field Training Worksheet* can be transferred to the *CFP Training Plan and Log* when a trainee has demonstrated a competency.

CFP Model Training Plan Worksheet DRAFT 10-15-07.doc - Microsoft Word

File Edit View Insert Format Tools Table Window Help Adobe PDF Acrobat Comments Type a question for help

II. Inspection Observations and Performance(continued)

	4. Obtains immediate corrective action for out of compliance employee practices and management procedures (listed in Item 3 above) essential to the safe storage, preparation, and service of food	Training Method	Date Demonstrated by the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input checked="" type="checkbox"/>	Notified the person in charge/employee(s) of the out of compliance observations.	JFT	5-21-07	R.T.	Mary Jones
<input checked="" type="checkbox"/>	Reviewed corrective actions with the person in charge/employee(s).	JFT	5-21-07	R.T.	Mary Jones
<input checked="" type="checkbox"/>	Observed the person in charge/employee(s) immediately take corrective action for out of compliance observations (e.g., movement of food to ensure product temperature or prevent contamination, reconditioning food, restriction/exclusion of ill employees, discarding of food product) in accordance with local jurisdiction's procedures.	JFT	7-18-07	R.T.	Mary Jones
<input checked="" type="checkbox"/>	Identified conditions requiring issuance of an embargo/stop sale/food destruction order per jurisdiction's administrative procedures.	OD	8-2-07	R.T.	John Smith
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments: Trainee did not observe a condition during the joint field training inspections that required issuance of an embargo/stop sale/food destruction order. Office scenarios were set up. Trainee demonstrated steps that would be implemented for the issuance of an embargo/stop sale/food destruction order and completed required forms per the jurisdiction's administrative protocol. (John Smith)					
Trainee has demonstrated acceptable performance for all competencies listed					
Date: 8-2-07		Trainee's Initials: R.T.		Trainer's Signature: John Smith	

Page 6 Sec 1 6/21 At 4.8" Ln 42 Col 1 REC TRK EXT OVR

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In this example, the trainee has demonstrated the first 3 competencies during “Joint Field Training Inspections – JFT.” The trainer, “Mary Jones” has recorded the date the trainee demonstrated each of the competencies in the *CFP Training Plan and Log*.

Abbreviated Field Training Worksheet

The *Abbreviated Field Training Worksheet*, included as Attachment C, lists only the performance elements and is an even shorter version of the worksheet just discussed.

The use of this worksheet is intended for experienced trainers with a strong working knowledge of the competencies that FSIOs are expected to successfully demonstrate during field training inspections.

Conference for Food Protection
ABBREVIATED - FIELD TRAINING WORKSHEET
(Performance Elements Only)
Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer

Establishment Name:		Establishment Address:	
Food Safety Inspection Officer's (FSIO) Name:		Food Safety Inspection Officer's (FSIO) Agency:	
Trainer's Name:		Trainer's Agency:	
Date of Inspection led by the Trainee:	Time IN:	Time OUT:	

I. Pre-Inspection

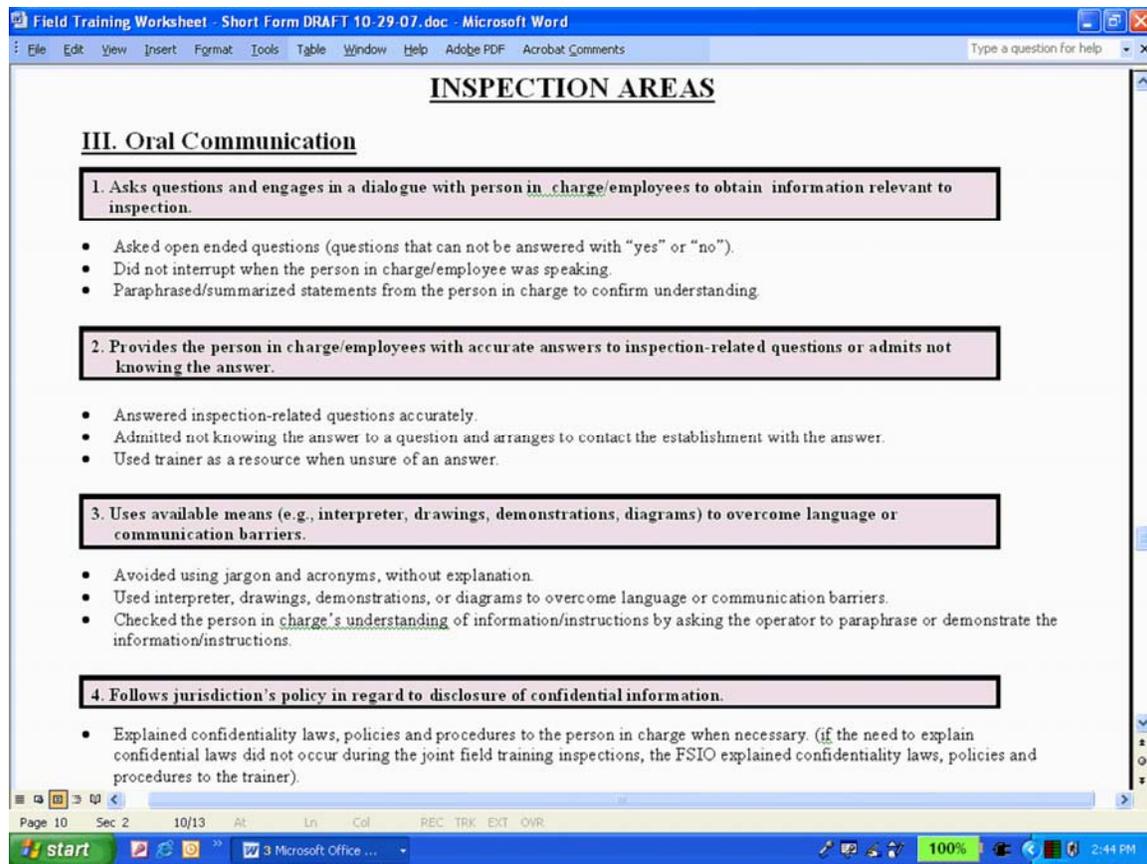
PERFORMANCE ELEMENTS	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
	YES	NO	YES	NO
<input type="checkbox"/> 1. Has required equipment and forms to conduct inspection.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

As an example, the abbreviated worksheet segment that lists the performance elements pertaining to oral communication is displayed in the graphic below. All six (6) of the performance elements for the “Oral Communication” inspection area are included. None of the competencies (job tasks), however, are listed for these performance elements. The two column format and comment section for documenting training observations is the same as for the longer *Field Training Worksheet*.

PERFORMANCE ELEMENTS		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input checked="" type="checkbox"/>	1. Asks questions and engages in a dialogue with person in charge/employees to obtain information relevant to the inspection.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	2. Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	3. Uses available means (e.g., interpreter, drawings, diagrams, demonstrations, international food safety icons) to overcome language or communication barriers.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	4. Follows jurisdiction's policy in regard to disclosure of confidential information.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	5. Uses effective communication and conflict resolution techniques to overcome inspection barriers.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	6. Conducts exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction Specific Performance Elements)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: Reviewed techniques with the FSIO for asking open ended questions when checking food employees understanding of information presented during the inspection. Discussed the importance of demonstrating, when possible, a procedure when it appears that management or food employees may not clearly understand a verbal explanation. For example, setting up the wash, rinse, and sanitize bins of a 3 compartment sink, then checking for understanding by having the food employees demonstrate the procedure. I will continue to work with the FSIO on this competency during the field training inspections scheduled for next week. (Mary Jones)

A reference list of example competencies for each performance element is provided at the end of the *Abbreviated Field Training Worksheet* for trainers to use during trainee-led inspections. The graphic that appears at the top of the next page displays competencies for some of the oral communication performance elements used as examples throughout this discussion.



It is important to keep in mind that using either of the worksheets is a determination to be made by the regulatory jurisdiction's management. These documents have been included with this manual to support a jurisdiction's effort to ensure a FSIO has received training and demonstrated all competencies needed to conduct effective independent food safety inspections.

USING A SUPPLEMENTAL FIELD TRAINING WORKSHEET

In determining how to integrate a supplemental *Field Training Worksheet* into the training process, two approaches are generally considered:

- Using a worksheet during every trainee-led inspection; or
- Using a worksheet at set interval points during the trainee-led field training process.

These two approaches are only examples and are not intended to restrict the use of other formats by a jurisdiction. The following summary of strengths and challenges for each approach provides some guidance to regulatory retail food protection programs on ways to integrate a *Field Training Worksheet* into their training process.

Approach #1: During every inspection led by a trainee

Strengths: This approach provides continual feedback to the trainee on the competencies they have demonstrated and those for which more focused training is still needed. In the early stages of the training process, the *Field Training Worksheet* can be an important tool in determining whether more demonstration (trainer-led) inspections need to be performed. In later stages, the worksheet will help focus training on competencies the trainee is having difficulty performing.

In addition, using the *Field Training Worksheet* with every inspection will provide important feedback on the jurisdiction's training and orientation program. The *Field Training Worksheet* can assist trainers with identifying potential gaps in the orientation/training program, coursework requirements, or administrative materials used to prepare staff to take the lead during field training inspections.

Challenges: Using the *Field Training Worksheet* during every inspection may cause trainers to focus too much on completing the form rather than on the training of the FSIO. The *Field Training Worksheet* is simply a tool to assist the trainer to track competencies as demonstrated during inspections led by a trainee.

Competing program priorities and limited resources may impede a jurisdiction's ability to use a *Field Training Worksheet* during every trainee-led inspection. Jurisdictions will need to track the training process and communicate results effectively with the time commitment associated with completing forms used to support the training process.

Approach #2: At set interval points

Strengths: A trainer may choose to use the *Field Training Worksheet* at set interval points during trainee-led inspections. For example, a *Field Training Worksheet* could be completed after every fifth inspection (i.e., inspections 5, 10, 15, 20 and 25). This process provides set checkpoints for determining when training observations indicate the trainee has successfully demonstrated a competency.

The trainer can set achievable objectives for the trainee using the interval process, focusing on a few competencies at a time. Trainee-led inspections conducted between each use of the *Field Training Worksheet* can enhance a trainee's knowledge and skills for competencies or provide additional training when needed.

Challenges: The interval process requires trainers to work from notes or inspection reports to determine competencies that have been observed and/or demonstrated over a period of time. The primary objective during trainee-led inspections is for the trainer to observe a consistent pattern of behavior in the trainee's ability to successfully demonstrate a competency. Depending on how frequently a competency is observed, an interval approach could reveal fluctuations in a trainee's ability to demonstrate a job task. The interval process

may not provide as structured a method for providing continuous feedback to the trainee as that provided if the *Field Training Worksheet* is used during every trainee-led inspection.

The “Joint Field Training Inspection – Establishment Log” can be an important tool for documenting the use of the *Field Training Worksheet* when using the interval approach. The establishment log provides a means to note the point in time when the worksheet was completed and the time frame covered during the training period. In the illustration below, the trainer completed a *Field Training Worksheet* after the inspection of Establishment #15 and Establishment #20.

#	Date	Permit #	Establishment Name	Establishment Address	Risk Category	Demonstration (Trainer-led) Inspection	FSIO-led (Trainee-led) Inspection	Field Training Worksheet Completed	
								Yes	Training Period
1	4-2-07	07896	Dig These Dogs	647 Oak Street, Pepperson, AZ	3	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2	4-2-07	07912	Try R Food	1919 Park Place, Monopoly, AZ	3	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3	4-3-07	07485	Ultimate Dining	2100 3 rd Street, Cactus, AZ	4	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4	4-3-07	07020	Can You Say Cheese?	739 N. Main Street, Cheddar, AZ	2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5	4-4-07	08923	No Place Like Home	881 S. Prairie Lane, Cactus, AZ	4	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6	4-4-07	08237	Only The Finest Meats	23 N. Main St., Cactus, AZ	2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7	4-6-07	07654	Happy Feet Day Care	34 Tender Care Road, Cactus, AZ	5	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8	4-6-07	07345	St. John's Medical Ctr	421 W. Desert Avenue Cactus, AZ	5	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9	4-9-07	08787	Zesty Delights	971 Center Avenue, Cactus, AZ	4	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10	4-9-07	07001	Survival Foods	699 Desert Avenue, Cactus, AZ	1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11	4-9-07	07492	Tasty Treats	567 Illinois Avenue, Monopoly, AZ	1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12	4-10-07	07113	Big Pizzas	23 Pizza Place, Pepperson, AZ	2	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13	4-10-07	07222	Make Your Own Sandwich	1 Elm Street, Monopoly, AZ	3	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
14	4-12-07	07555	Anytime Food	1 Ocean Drive, Ocean Park, AZ	3	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15	4-18-07	07639	Juni Packaged Goods	538 Broadway, Ocean Park, AZ	1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4/9 through 4/12, 2007
16	4-18-07	07777	Leafy Greens	679 West Olive Avenue, Ocean Park, AZ	3	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
17	4-18-07	07184	Hungry Homes	972 E. West Street, Ocean Park, AZ	3	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
18	4-19-07	07014	You Don't Leave Hungry	871 W. Mushroom Boulevard, Cactus, AZ	4	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
19	4-19-07	07296	We Make What You Like	43 N. Madison, Monopoly, AZ	4	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
20	4-20-07	07666	Shamrock Casino & Resort	3030 Big Buckle Lane, Monopoly, AZ	5	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4/9 through 4/20, 2007

In the above example, the trainee-led inspections began with Establishment #10. The first *Field Training Worksheet* was completed after Establishment #15 and contains a collective set of observations of the trainee demonstrating competencies for Establishments #10 through #15, encompassing the period, April 9 through 12, 2007.

In this example, the jurisdiction’s training staff completes a *Field Training Worksheet* using establishment inspection intervals of five. The second *Field Training Worksheet* was completed after Establishment #20 and the trainer’s observations again represented observations over a cumulative period of time. The notes from one *Field Training Worksheet* build on observations made on previous documents. The observations on the second *Field Training Worksheet*, therefore, represents the period when the trainee began taking the lead during the training process on April 9, 2007 until the date the second *Field Training Worksheet* was completed on April 20, 2007.

The *Field Training Worksheet* is ***not*** intended to be used as a checklist during inspections nor should it drive the inspection approach used by the trainee. Continuous instruction is encouraged during each of the inspections led by a trainee. Trainers should take the opportunity to demonstrate and/or review correct procedures and skills for competencies that are not understood or properly performed by the trainee during each inspection.

REVIEWING FIELD TRAINING

Consistent and on-going feedback regarding inspection competencies is the cornerstone of the FSIO field training process presented in this manual. The trainer should share his/her observations with the trainee during each of the inspections. Discussions should include competencies successfully demonstrated by the trainee, as well as those where additional training is needed. Trainers should provide continuous positive reinforcement for competencies correctly demonstrated by the trainee.

For areas where additional training is needed, the trainer should demonstrate the competency to the trainee during joint inspections and determine if other training methods may benefit the trainee's understanding and application of the competency. Field training objectives should continually be reviewed with the trainee and updated as needed during the field training process.

Equally as important, the field training process provides critical feedback to managers and trainers on the effectiveness of their retail food training and orientation programs. Competencies (job tasks) that are not consistently performed well by trainees may be an indication that the regulatory jurisdiction has significant gaps in their training program, coursework, or materials used to prepare staff for field inspections. Field training, where observations are made of a trainee demonstrating specific competencies, provides a framework for evaluating and enhancing the effectiveness of a jurisdiction's existing regulatory retail food training programs.

DOCUMENTATION OF COMPLETION

The trainer's and trainee's signature in the header of the *CFP Training Plan and Log* indicates they both concur that all prerequisite coursework has been completed and competencies listed on the jurisdiction's training plan have been demonstrated.

**Conference for Food Protection
TRAINING PLAN and LOG
Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer**

NOTE: The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers (FSIOs) should be reviewed prior to using the CFP Training Plan and Log. The manual provides jurisdictions with information that will be helpful in customizing the FSIO training plan and implementing a field training process that meets the specific needs of the jurisdiction.

Food Safety Inspection Officer's (FSIO) Name:	Start Date of the Training Process:
Food Safety Inspection Officer's (FSIO) Agency:	
Trainer's Name (if multiple trainers list all):	Trainer's Agency:
1.	
2.	
3.	
4.	
(Signatures below indicate FSIO has completed all curriculum and field training elements and is ready to conduct independent retail food and/or foodservice inspections.)	
Completion Date of Pre-requisite Coursework: OPTION 1: <input type="checkbox"/> or OPTION 2: <input type="checkbox"/>	
Completion Date - (Performance Elements & Competencies):	
Food Safety Inspection Officer's (FSIO) Signature:	Trainer's or Food Program Manager's Signature:

When a FSIO has completed all the prerequisite coursework and demonstrated all the competencies identified in the jurisdiction's training plan, the retail food protection program managers has a basis for determining the FSIO's readiness to conduct independent food safety inspections. The completed and signed *CFP Training Plan and Log* should be placed in the FSIO's training file and a copy of the completed document given to the FSIO for their records.

VIII. Continuing Training

The prerequisite coursework, training plan, and field training inspection process presented in this manual are based on the minimum performance competencies a FSIO should be able to successfully demonstrate *prior* to conducting independent food safety inspections. This process should be considered but a first step in the development of inspection staff in a regulatory retail food protection program. Additional training opportunities and standardization should be provided on a continual basis to advance the development of a FSIO's ability to implement a risk-based inspection approach and communicate food safety principles to the regulated industry and the public.

Additional Food Safety Courses

Over 100 food safety related courses are accessible from the FDA ORA U web site. The Conference for Food Protection has worked with FDA to identify courses that a FSIO should complete within the first 18 months of hire or assignment to the retail food program. It is expected that most FSIOs would complete this second phase of coursework *after* they have started to conduct independent inspections.

This additional coursework is part of the criteria contained in *Standard 2 – Trained Regulatory Staff, FDA Voluntary National Retail Food Regulatory Program Standards* and includes:

MICRIBIOLOGY

Food Microbiological Control (series):

- 7C. Control by Retorting (90) MIC10
8. Technology-Based Food Processes (120) MIC11
9. Natural Toxins (90) MIC12

HACCP

Basics of HACCP (series):

1. Overview of HACCP (60) FDA16
2. Prerequisite Programs & Preliminary Steps (60) FDA 17
3. The Principles (60) FDA18

EPIDEMIOLOGY

Foodborne Illness Investigation (series):

1. Collecting Surveillance Data (90) F101
2. Beginning the Investigation (90) F102
3. Expanding the Investigation (90) F103
4. Conducting a Food Hazard Review (90) F104
5. Epidemiological Statistics (90) F105
6. Final Report (30) F106

Note: the estimated amount of time (in minutes) to complete each module is indicated in parenthesis followed by the course number.

The jurisdiction should also conduct or provide an opportunity for FSIOs to attend an *Application of the Basics of Inspection/Investigations Course*. This course addresses all retail food program inspection areas in which a FSIO should receive training and contains a practicum that provides an opportunity to demonstrate inspection techniques and procedures. The *Application Course* provides an important confirmation that retail food safety program training objectives have been achieved.

A fully developed *Application Course* is available on CD through FDA's Division of Human Resource Development's lending library. A jurisdiction's trainer can conduct their own *Application Course* using these materials or develop one that addresses at least 80% of the learning objectives and exercises contained in the course. In addition, the Association of Food and Drug Officials (AFDO) at www.afdo.org/ has, upon request,

conducted the course for state and local retail food protection programs.

Standardization

Managers of regulatory retail food protection programs are encouraged to implement a standardization process similar to what is included in “*FDA’s Standardization Procedures*” for FSIOs to complete within 18 months of hire. A copy of FDA’s standardization process can be obtained from the following web link:

www.cfsan.fda.gov/~ear/rfi-toc.html.

Conference for Food Protection
Attachment A: TRAINING PLAN and LOG
Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer

NOTE: The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers (FSIOs) should be reviewed prior to using the *CFP Training Plan and Log*. *The manual provides jurisdictions with information that will be helpful in customizing a FSIO training plan and implementing a training process that meets the specific needs of the jurisdiction.*

Food Safety Inspection Officer's (FSIO) Name:		Start Date of the Training Process:
Food Safety Inspection Officer's (FSIO) Agency:		
Trainer's Name (if multiple trainers list all):	Trainer's Agency:	
1.		
2.		
3.		
4.		
Signatures below indicate FSIO has completed all curriculum and field training elements and is ready to conduct independent retail food and/or foodservice inspections		
Completion Date of Pre--requisite Coursework:		
OPTION 1: <input type="checkbox"/> or OPTION 2: <input type="checkbox"/>		
Completion Date - (Performance Elements & Competencies):		
Food Safety Inspection Officer's (FSIO) Signature:	Trainer's or Food Program Manager's Signature:	

*The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers includes two components. One includes completion of prerequisite coursework outlined in Program Standard 2 – Trained Regulatory Staff, FDA Voluntary National Retail Food Regulatory Program Standards. The second component focuses on the FSIO's ability to demonstrate performance element competencies that are needed to conduct effective regulatory food safety inspections. A FSIO should successfully complete both components **prior** to conducting independent inspections.*

PREREQUISITE COURSEWORK

The CFP Field Training Manual outlines the courses included in the prerequisite curriculum and provides options for completing this component of the CFP training process. A jurisdiction can begin the field training process with FSIOs while they are still in the process of completing their prerequisite coursework. The jurisdiction's trainers and/or food program managers are given the discretion to determine the appropriate time frame within which FSIOs are to complete prerequisite course work during the field training process.

TRAINING METHODS

The CFP Training Plan and Log is designed to incorporate a variety of training methods appropriate for each of the performance element competencies. A sufficient number of field training inspections should be conducted to provide an opportunity for the FSIO to successfully demonstrate the applicable competencies. The jurisdiction’s trainer can use the table below to identify the training methods that will be used.

JURISDICTION’S TRAINING METHODS	
Code	Training Method

INSPECTION TRAINING AREAS

The CFP Training Plan and Log is divided into six (6) inspection training areas:

- I. Pre-Inspection
- II. Inspection Observations and Performance
- III. Oral Communication
- IV. Written Communication
- V. Professionalism
- VI. Additional Inspection Areas (Jurisdictions can add performance elements and competencies not contained in the CFP Training Plan and Log)

The Conference for Food Protection (CFP) has conducted a national research study and identified the minimum performance elements and competencies for each of the specified inspection training areas needed to perform regulatory retail safety inspections. The CFP Training Plan and Log contains a national model that regulatory retail food protection programs can readily integrate into their existing field training of Food Safety Inspection Officers (FSIOs).

The CFP Training Plan lists the basic performance elements (in BOLD font in the shaded areas of the Worksheet). Under each performance element is a list of competencies provided as examples of job tasks a jurisdiction should ensure the FSIO receives training on in order to perform their job responsibilities effectively. The jurisdiction’s trainer should identify those performance element competencies that are applicable to the FSIO’s job responsibilities within their jurisdiction. A small box appears adjacent to each of the performance elements and competencies on the worksheet. If the performance element and/or competency is applicable to the jurisdiction, it is to be checked and included as part of the training process.

INSPECTION TRAINING AREAS

I. Pre-Inspection

<input type="checkbox"/>	1. Has required equipment and forms to conduct inspection.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Necessary inspection forms and administrative materials.				
<input type="checkbox"/>	Lab coat or equivalent protection to cover street clothes.				
<input type="checkbox"/>	Head cover: baseball cap; hair net; or equivalent.				
<input type="checkbox"/>	Calibrated thermocouple temperature measuring device.				
<input type="checkbox"/>	Maximum registering thermometer or temperature sensitive tapes for verifying hot water warewashing final rinse temperature.				
<input type="checkbox"/>	Chemical test kits for chlorine, iodophor, and quaternary ammonia sanitizers.				
<input type="checkbox"/>	Flashlight.				
<input type="checkbox"/>	Alcohol swabs.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

<input type="checkbox"/>	2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance by the agency.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Reviewed previous inspection report noting documented out of compliance observations.				
<input type="checkbox"/>	Reviewed establishment file for complaint reports.				
<input type="checkbox"/>	Reviewed establishment file for documentation indicating a need for a HACCP Plan.				
<input type="checkbox"/>	Reviewed establishment file for documentation of food production or processes operating under a variance issued by the jurisdiction.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

II. Inspection Observations and Performance

<input type="checkbox"/>	1. Provides identification as a regulatory official to person in charge, confirming agency authority for inspection, and stating the purpose of visit.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Verbally provided name and agency to the person in charge.				
<input type="checkbox"/>	Presented regulatory identification or business card.				
<input type="checkbox"/>	Stated the purpose of the visit.				
<input type="checkbox"/>	Requests and confirmed permission to conduct inspection from the person in charge prior to initiating the inspection.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

<input type="checkbox"/>	2. Has knowledge of jurisdiction's laws, rules, and regulations required for conducting retail food/foodservice inspections.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Verified the correct critical limit and or standard specified in the jurisdiction's rules/regulations to the observation made.				
<input type="checkbox"/>	Correctly cited the rule/regulation for each out of compliance observation.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

II. Inspection Observations and Performance (continued)

<input type="checkbox"/> 3. Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>				
<input type="checkbox"/> Verified Demonstration of Knowledge of the person in charge. <input type="checkbox"/> Verified approved food sources (e.g., food from regulated food processing plants; shellfish documentation; game animal processing; parasite destruction for certain species of fish intended for raw consumption; receiving temperatures). <input type="checkbox"/> Verified food safety practices for preventing cross-contamination of ready-to-eat food. <input type="checkbox"/> Verified food contact surfaces are clean and sanitized, protected from contamination from soiled cutting boards, utensils, aprons, etc., or raw animal foods. <input type="checkbox"/> Verified the restriction or exclusion of ill employees. <input type="checkbox"/> Verified no bare hand contact with ready-to-eat foods (or use of a pre-approved, alternative procedure). <input type="checkbox"/> Verified employee handwashing. <input type="checkbox"/> Verified cold holding temperatures of foods requiring time/temperature control for safety (TCS food), or when necessary, verified that procedures are in place to use time alone to control bacterial growth and toxin production. <input type="checkbox"/> Verified date marking of ready-to-eat foods TCS food held for more than 24 hours. <input type="checkbox"/> Verified cooking temperatures to destroy bacteria and parasites. <input type="checkbox"/> Verified hot holding temperatures of TCS food or when necessary, that procedures were in place to use time alone to prevent the outgrowth of spore-forming bacteria. <input type="checkbox"/> Verified cooling temperatures of TCS food to prevent the outgrowth of spore-forming or toxin-forming bacteria. <input type="checkbox"/> Verified reheating temperatures of TCS food for hot holding. <input type="checkbox"/> Verified the availability of a consumer advisory for foods of animal origin served raw or undercooked. <input type="checkbox"/> Identified food processes and/or procedures that require a HACCP Plan per the jurisdiction's regulations. <u>ADDITIONAL (Jurisdiction specific competencies)</u> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				
Comments:				
Trainee has demonstrated acceptable performance for all competencies listed				
Date:	Trainee's Initials:	Trainer's Signature:		

II. Inspection Observations and Performance (continued)

<input type="checkbox"/>	4. Obtains immediate corrective action for out of compliance employee practices and management procedures (listed in Item 3 above) essential to the safe storage, preparation, and service of food.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Notified the person in charge/employee(s) of the out of compliance observations.				
<input type="checkbox"/>	Reviewed corrective actions with the person in charge/employee(s).				
<input type="checkbox"/>	Observed the person in charge/employee(s) immediately take corrective action for out of compliance observations (e.g., movement of food to ensure product temperature or prevent contamination; reconditioning food; restriction/exclusion of ill employees; discarding of food product) in accordance with local jurisdiction's procedures.				
<input type="checkbox"/>	Identified conditions requiring issuance of an embargo/stop sale/food destruction order per jurisdiction's administrative procedures.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:	Trainee's Initials:	Trainer's Signature:			

<input type="checkbox"/>	5. Correctly assesses compliance status of other regulations (not included in Item 4 – Good Retail Practices) that are included in jurisdiction's prevailing statutes, regulations and/or ordinances.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Correctly assessed compliance status of other regulations (not included in Item 4 above - Good Retail Practices) that are included in jurisdiction's prevailing statutes, regulations and/or ordinances.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:	Trainee's Initials:	Trainer's Signature:			

II. Inspection Observations and Performance (continued)

<input type="checkbox"/>	6. Verifies correction of out of compliance observations identified during previous inspection.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Verified correction of out of compliance observations identified during previous inspection				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

<input type="checkbox"/>	7. Correctly uses inspection equipment during joint inspections.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Used temperature measuring devices/probes in accordance with manufacturer's instructions.				
<input type="checkbox"/>	Cleaned and sanitized (alcohol swabs) temperature measurement probes to prevent food contamination.				
<input type="checkbox"/>	Used infrared thermometer in accordance with manufacturer's instructions. Verified any out of compliance product temperatures registered on the infrared with a thermocouple.				
<input type="checkbox"/>	Used maximum registering thermometer or heat sensitive tapes in accordance with manufacturer's instructions to verify final rinse dishwasher temperature.				
<input type="checkbox"/>	Used chemical test strips in accordance with manufacturer's instructions to measure sanitizer concentrations in manual and mechanical dishwashing operations; wiping cloth solutions; and spray bottle applicators.				
<input type="checkbox"/>	Used flashlight to assess observations in areas with no or low light.				
<input type="checkbox"/>	Photographs taken support regulatory findings or conditions observed.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

III. Oral Communication

<input type="checkbox"/>	1. Asks questions and engages in a dialogue with person in charge/employees to obtain information relevant to inspection.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Asked open ended questions (questions that can not be answered with "yes" or "no").				
<input type="checkbox"/>	Did not interrupt when the person in charge/employee was speaking.				
<input type="checkbox"/>	Paraphrased/summarized statements from the person in charge to confirm understanding.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

<input type="checkbox"/>	2. Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Answered inspection-related questions accurately.				
<input type="checkbox"/>	Admitted not knowing the answer to a question and arranges to contact the establishment with the answer.				
<input type="checkbox"/>	Used trainer as a resource when unsure of an answer.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

III. Oral Communication (continued)

<input type="checkbox"/>	3. Uses available means (e.g., interpreter, drawings, diagrams demonstrations, international food safety icons) to overcome language or communication barriers.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Avoided using jargon and acronyms, without explanation.				
<input type="checkbox"/>	Used interpreter, drawings, demonstrations, or diagrams to overcome language or communication barriers.				
<input type="checkbox"/>	Checked the person in charge's understanding of information/instructions by asking the operator to paraphrase or demonstrate the information/instructions.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

<input type="checkbox"/>	4. Follows jurisdiction's policy in regard to disclosure of confidential information.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Explained confidentiality laws, policies and procedures to the person in charge when necessary. (If the need to explain confidential laws did not occur during the joint field training inspections, the FSIO explained confidentiality laws, policies and procedures to the trainer).				
<input type="checkbox"/>	Applied the confidentiality policy per the jurisdictional requirements (e.g., FSIO did not reveal confidential information to the operator during the inspection).				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

III. Oral Communication (continued)

<input type="checkbox"/>	5. Uses effective communication and conflict resolution techniques to overcome inspection barriers.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Identified challenges faced by the person in charge and offered possible solution(s).				
<input type="checkbox"/>	Did not become argumentative (e.g., remained calm and focused).				
<input type="checkbox"/>	Removed himself/herself from a confrontation or threat that may impact personal safety.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

<input type="checkbox"/>	6. Conducts exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Explained the public health significance of the inspection observations.				
<input type="checkbox"/>	Reviewed all findings with the person in charge with emphasis on contributing factors to foodborne illness and Food Code Interventions (listed in Section II, Item 3).				
<input type="checkbox"/>	Used foodborne illness data to highlight contributing factors.				
<input type="checkbox"/>	Answered all questions or concerns pertaining to items on the inspection report.				
<input type="checkbox"/>	Provided contact information to the person in charge for follow up questions or additional guidance.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

IV. Written Communication

<input type="checkbox"/> 1. Completes inspection form per jurisdiction’s administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).	Training Method	Date Demonstrated By the Trainee	Trainee’s Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>				
<input type="checkbox"/> Used correct inspection form. <input type="checkbox"/> Completed a legible report. <input type="checkbox"/> Accurately documented observations made during inspection. <input type="checkbox"/> Completed inspection form in accordance with jurisdiction’s administrative procedures. <input type="checkbox"/> Cited correct code provisions/rules/regulations. <input type="checkbox"/> Documented immediate corrective action for out-of-compliance foodborne illness contributing factors and Food Code Interventions (listed in Section II, Item 3). <input type="checkbox"/> Documented time frames for correcting each out of compliance observation. <input type="checkbox"/> <u>ADDITIONAL (Jurisdiction specific competencies)</u> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				
Comments:				
Trainee has demonstrated acceptable performance for all competencies listed				
Date:	Trainee’s Initials:	Trainer’s Signature:		

<input type="checkbox"/> 2. Includes 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).	Training Method	Date Demonstrated By the Trainee	Trainee’s Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>				
<input type="checkbox"/> Referenced attached documents in inspection report. <input type="checkbox"/> Referenced documents are legible. <input type="checkbox"/> Referenced documents are accurate and reflect observations made during the inspection. <input type="checkbox"/> Attached referenced document(s) to the inspection report per jurisdiction’s administrative procedures. <input type="checkbox"/> <u>ADDITIONAL (Jurisdiction specific competencies)</u> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				
Comments:				
Trainee has demonstrated acceptable performance for all competencies listed				
Date:	Trainee’s Initials:	Trainer’s Signature:		

IV. Written Communication (continued)

<input type="checkbox"/>	3. Presents inspection report, and when necessary cross-referenced documents, to person in charge.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Presented complete inspection report, with referenced documents when necessary, to person in charge during exit interview. Followed jurisdiction's administrative procedures for delivering written inspection report. Obtained signature of person in charge on inspection report. <u>ADDITIONAL (Jurisdiction specific competencies)</u> 				
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:	Trainer's Signature:		

V. Professionalism

<input type="checkbox"/>	1. Maintains a professional appearance consistent with jurisdiction’s policy (e.g., clean outer clothing, hair restraint).	Training Method	Date Demonstrated By the Trainee	Trainee’s Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Maintained a professional appearance consistent with jurisdiction’s policy (e.g., clean outer clothing, hair restraint). <u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee’s Initials:		Trainer’s Signature:	

<input type="checkbox"/>	2. Demonstrates proper sanitary practices as expected from a food service employee.	Training Method	Date Demonstrated By the Trainee	Trainee’s Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>	Washed hands as needed (e.g., prior to conducting inspection, after using restroom, after touching dirty surfaces, after touching face/body, after sneezing/coughing).				
<input type="checkbox"/>	Protected bandages on hands, when necessary, to prevent contamination of food or food contact surfaces.				
<input type="checkbox"/>	Did NOT contact ready-to-eat foods with bare hands.				
<input type="checkbox"/>	Did NOT show any obvious signs of illness in accordance with jurisdiction’s employee health policy and/or current food code.				
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>				
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee’s Initials:		Trainer’s Signature:	

V. Professionalism (continued)

<input type="checkbox"/> 3. Only reports substantiated findings as violations.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>				
<input type="checkbox"/> Only reported findings that were directly observed or substantiated in accordance with jurisdiction's policies and procedures. <input type="checkbox"/> Findings are supported by fact (e.g., are NOT based on hunch or suspicion; are witnessed, are investigated). <input type="checkbox"/> Did NOT note violations without visiting the establishment. <input type="checkbox"/> Did NOT exaggerate details related to findings to support report conclusions. <input type="checkbox"/> Did NOT modify report after leaving the establishment except as allowed by jurisdiction's administrative procedures. <u>ADDITIONAL (Jurisdiction specific competencies)</u> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				
Comments: 				
Trainee has demonstrated acceptable performance for all competencies listed				
Date:	Trainee's Initials:	Trainer's Signature:		

VI. Additional Performance Elements – Jurisdiction Specific

<input type="checkbox"/>	1. Uses an aseptic food sample collection method consistent with criteria established by laboratory serving jurisdiction.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/> <input type="checkbox"/>	<p>Used proper hygiene before and during sample process (e.g., washed hands prior to sampling; did not touch sample container opening, inside lip, inside cap or did not blow into the bag to open it up.)</p> <p>Used sample collection method specified by the jurisdiction (e.g., original container if available; collection of a representative sample from a large quantity or container).</p> <p>Used sterile, leak-proof lidded container or zipper-lock type bags.</p> <p>Used a separate sterile utensil to collect each different sample item.</p> <p>Labeled all containers with required information (e.g., date, time, location, product name, FSIO initials) with corresponding information noted on inspection report or laboratory forms.</p> <p>Initiated written chain of custody including use of evidence seal.</p> <p>Stored and transported sample in a clean, refrigerated unit (e.g., ice chest with ice) within the prescribed time period.</p> <p>Maintained sample refrigerated or frozen until transport or shipping to laboratory.</p> <p>Sample packed and shipped in sterile, leak-proof, insulated container with refrigerant (wet or dry ice) via the most rapid and convenient means available (e.g., courier, bus, express mail).</p> <p><u>ADDITIONAL (Jurisdiction specific competencies)</u></p>				
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:	Trainer's Signature:		

VI. Additional Performance Elements – Jurisdiction Specific (continued)

<input type="checkbox"/>		Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	
<input type="checkbox"/>		Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	
<input type="checkbox"/>		Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer
<i>(Training method and selected competencies for this performance element are to be indicated below)</i>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
Comments:					
Trainee has demonstrated acceptable performance for all competencies listed					
Date:		Trainee's Initials:		Trainer's Signature:	

OPTIONAL - FSIO TRAINING LOG

Trainee's Name: _____

Week: 1 Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials: _____

Trainer's Signature: _____

Week: 2 Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials: _____

Trainer's Signature: _____

Week: 3 Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials: _____

Trainer's Signature: _____

OPTIONAL - FSIO TRAINING LOG

Trainee's Name: _____

Week: 4 Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials:

Trainer's Signature:

Week: 5 Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials:

Trainer's Signature:

Week: 6 Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials:

Trainer's Signature:

OPTIONAL - FSIO TRAINING LOG

Trainee's Name: _____

Week: _____ Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials:

Trainer's Signature:

Week: _____ Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials:

Trainer's Signature:

Week: _____ Date Ending: _____

Training Areas Demonstrated	Planned Training Areas for Upcoming Week	Additional Comments
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Trainee's Initials:

Trainer's Signature:

OPTIONAL
JOINT FIELD TRAINING INSPECTIONS - ESTABLISHMENT LOG

#	Date	Permit #	Establishment Name	Establishment Address	Risk Category	Demonstration (Trainer-led) Inspection	FSIO-led (Trainee-led) Inspection	Field Training Worksheet Completed	
								Yes	Training Period
1						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

OPTIONAL
JOINT FIELD TRAINING INSPECTIONS – ESTABLISHMENT LOG

#	Date	Permit #	Establishment Name	Establishment Address	Risk Category	Demonstration (Trainer-led) Inspection	FSIO-led (Trainee-led) Inspection	Field Training Worksheet Completed	
								Yes	Training Period
21						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
26						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
27						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
28						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
29						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
30						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
31						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
32						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
33						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
34						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
35						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
36						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
37						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
38						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
39						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
40						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Conference for Food Protection
Attachment B: FIELD TRAINING WORKSHEET
(Performance Elements and Competencies)
Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer

NOTE: *The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers (FSIOs) should be reviewed prior to using the Field Training Worksheet. The manual provides jurisdictions with information that will be helpful in customizing the Field Training Worksheet and implementing a training process that meets the specific needs of the jurisdiction.*

Establishment Name:	Establishment Address:	
Food Safety Inspection Officer's (FSIO) Name:	Food Safety Inspection Officer's (FSIO) Agency:	
Trainer's Name:	Trainer's Agency:	
Date of Inspection led by Trainee:	Time IN:	Time OUT:

The Conference for Food Protection (CFP) conducted a national research study and identified the basic minimum competencies needed to perform effective regulatory food safety inspections. The Field Training Worksheet has been designed as a trainer's tool to be used in conjunction with the CFP Training Plan and Log. It provides a method for tracking a FSIO's progress and accomplishments in successfully demonstrating performance element competencies during field training inspections.

There is no single correct way to use the worksheet. The CFP Field Training Manual provides examples of ways to incorporate the worksheet into existing retail food protection training programs.

The Field Training Worksheet lists the basic performance elements (in BOLD font in the shaded areas of the Worksheet). Under each performance element is a list of competencies provided as examples of job tasks that a jurisdiction should ensure a FSIO has received adequate training on in order to perform their job responsibilities effectively. The jurisdiction's trainer should identify those performance elements and/or competencies that are applicable to the FSIOs job responsibilities within their jurisdiction. A small box appears adjacent to each of the performance element competencies on the worksheet; if the performance element and/or competency is applicable to the jurisdiction, it is to be checked and included as part of the training process.

*Trainers should review with the FSIO the competencies that will be included as part of the field training inspections. FSIOs are expected to successfully demonstrate these minimum competencies correctly **prior** to conducting independent food safety inspections.*

I. Pre-Inspection

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	1. Has required equipment and forms to conduct inspection.				
<input type="checkbox"/>	Necessary inspection forms and administrative materials.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Lab coat or equivalent protection to cover street clothes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Head cover: baseball cap; hair net; or equivalent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Calibrated thermocouple temperature measuring device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Maximum registering thermometer or temperature sensitive tapes for verifying hot water warewashing final rinse temperature.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Chemical test kits for chlorine, iodophor, and quaternary ammonia sanitizers.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Flashlight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Alcohol swabs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance.				
<input type="checkbox"/>	Reviewed previous inspection report noting documented out of compliance observations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Reviewed establishment file for complaint reports.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Reviewed establishment file for documentation indicating a need for a HACCP Plan.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Reviewed establishment file for documentation of food production or processes operating under a variance issued by the jurisdiction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

II. Inspection Observations and Performance

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	1. Provides identification as a regulatory official to person in charge, confirming agency authority for inspection, and stating the purpose of visit.				
<input type="checkbox"/>	Verbally provided name and agency to the person in charge.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Presented regulatory identification or business card.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Stated the purpose of the visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Requests and confirmed permission to conduct inspection from the person in charge prior to initiating the inspection.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	2. Has knowledge of jurisdiction’s laws, rules, and regulations required for conducting retail food/foodservice inspections.				
<input type="checkbox"/>	Verified the correct critical limit and or standard specified in the jurisdiction’s rules/regulations to the observation made.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Correctly cited the rule/regulation for each out of compliance observation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

II. Inspection Observations and Performance (continued)

<input type="checkbox"/>	3. Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Verified Demonstration of Knowledge of the person in charge.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified approved food sources (e.g., food from regulated food processing plants; shellfish documentation; game animal processing; parasite destruction for certain species of fish intended for raw consumption; receiving temperatures).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified food safety practices for preventing cross-contamination of ready-to-eat food.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified food contact surfaces are clean and sanitized, protected from contamination from soiled cutting boards, utensils, aprons, etc., or raw animal foods.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified the restriction or exclusion of ill employees.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified no bare hand contact with ready-to-eat foods (or use of a pre-approved, alternative procedure).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified employee handwashing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified cold holding temperatures of foods requiring time/temperature control for safety (TCS food), or when necessary, verified that procedures are in place to use time alone to control bacterial growth and toxin production.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified date marking of ready-to-eat foods TCS food held for more than 24 hours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified cooking temperatures to destroy bacteria and parasites.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified hot holding temperatures of TCS food or when necessary, that procedures were in place to use time alone to prevent the outgrowth of spore-forming bacteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified cooling temperatures of TCS food to prevent the outgrowth of spore-forming or toxin-forming bacteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified reheating temperatures of TCS food for hot holding.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Verified the availability of a consumer advisory for foods of animal origin served raw or undercooked.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Identified food processes and/or procedures that require a HACCP Plan per the jurisdiction's regulations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

II. Inspection Observations and Performance (continued)

<input type="checkbox"/>	4. Obtains immediate corrective action for out of compliance employee practices and management procedures (listed in Item 3 above) essential to the safe storage, preparation, and service of food	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Notified the person in charge/employee(s) of the out of compliance observations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Reviewed corrective actions with the person in charge/employee(s).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Observed the person in charge/employee(s) immediately take corrective action for out of compliance observations (e.g., movement of food to ensure product temperature or prevent contamination; reconditioning food; restriction/exclusion of ill employees; discarding of food product) in accordance with local jurisdiction’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Identified conditions requiring issuance of an embargo/stop sale/food destruction order per jurisdiction’s administrative procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

<input type="checkbox"/>	5. Correctly assesses compliance status of other regulations (not included in Item 4 – Good Retail Practices) that are included in jurisdiction’s prevailing statutes, regulations and/or ordinances.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Correctly assessed compliance status of other regulations (not included in Item 4 above - Good Retail Practices) that are included in jurisdiction’s prevailing statutes, regulations and/or ordinances.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

II. Inspection Observations and Performance (continued)

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	6. Verifies correction of out of compliance observations identified during previous inspection.				
<input type="checkbox"/>	Verified correction of out of compliance observations identified during previous inspection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	7. Correctly uses inspection equipment during joint inspections.				
<input type="checkbox"/>	Used temperature measuring devices/probes in accordance with manufacturer’s instructions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Cleaned and sanitized (alcohol swabs) temperature measurement probes to prevent food contamination.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used infrared thermometer in accordance with manufacturer’s instructions. Verified any out of compliance product temperatures registered on the infrared with a thermocouple.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used maximum registering thermometer or heat sensitive tapes in accordance with manufacturer’s instructions to verify final rinse dishwasher temperature.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used chemical test strips in accordance with manufacturer’s instructions to measure sanitizer concentrations in manual and mechanical dishwashing operations; wiping cloth solutions; and spray bottle applicators.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used flashlight to assess observations in areas with no or low light.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Photographs taken support regulatory findings or conditions observed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

III. Oral Communication

	1. Asks questions and engages in a dialogue with person in charge/employees to obtain information relevant to the inspection.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Asked open ended questions (questions that can not be answered with “yes” or “no”).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Did not interrupt when the person in charge/employee was speaking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Paraphrased/summarized statements from the person in charge to confirm understanding.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

	2. Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Answered inspection-related questions accurately.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Admitted not knowing the answer to a question and arranges to contact the establishment with the answer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used trainer as a resource when unsure of an answer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

III. Oral Communication (continued)

	3. Uses available means (e.g., interpreter, drawings, diagrams, demonstrations, international food safety icons) to overcome language or communication barriers.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Avoided using jargon and acronyms, without explanation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used interpreter, drawings, demonstrations, or diagrams to overcome language or communication barriers.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Checked the person in charge’s understanding of information/instructions by asking the operator to paraphrase or demonstrate the information/instructions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

	4. Follows jurisdiction’s policy in regard to disclosure of confidential information.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Explained confidentiality laws, policies and procedures to the person in charge when necessary. (if the need to explain confidential laws did not occur during the joint field training inspections, the FSIO explained confidentiality laws, policies and procedures to the trainer).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Applied the confidentiality policy per the jurisdictional requirements (e.g., FSIO did not reveal confidential information to the operator during the inspection).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

III. Oral Communication (continued)

	5. Uses effective communication and conflict resolution techniques to overcome inspection barriers.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Identified challenges faced by the person in charge and offered possible solution(s).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Did not become argumentative (e.g., remained calm and focused).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Removed himself/herself from a confrontation or threat that may impact personal safety.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

	6. Conducts exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Explained the public health significance of the inspection observations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Reviewed all findings with the person in charge with emphasis on contributing factors to foodborne illness and Food Code Interventions (listed in Section II, Item 3).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used foodborne illness data to highlight contributing factors.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Answered all questions or concerns pertaining to items on the inspection report.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Provided contact information to the person in charge for follow up questions or additional guidance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

IV. Written Communication

	<input type="checkbox"/> 1. Completes inspection form per jurisdiction’s administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Used correct inspection form.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Completed a legible report.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Accurately documented observations made during inspection.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Completed inspection form in accordance with jurisdiction’s administrative procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Cited correct code provisions/rules/regulations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Documented immediate corrective action for out-of-compliance foodborne illness contributing factors and Food Code Interventions (listed in Section II, Item 3).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Documented time frames for correcting each out of compliance observation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

	<input type="checkbox"/> 2. Includes 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).	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Referenced attached documents in inspection report.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Referenced documents are legible.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Referenced documents are accurate and reflect observations made during the inspection.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Attached referenced document(s) to the inspection report per jurisdiction’s administrative procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

IV. Written Communication (continued)

<input type="checkbox"/>	3. Presents inspection report, and when necessary cross-referenced documents, to person in charge.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Presented complete inspection report, with referenced documents when necessary, to person in charge during exit interview.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Followed jurisdiction’s administrative procedures for delivering written inspection report.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Obtained signature of person in charge on inspection report.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

V. Professionalism

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	1. Maintains a professional appearance consistent with jurisdiction’s policy (e.g., clean outer clothing, hair restraint).				
<input type="checkbox"/>	Maintained a professional appearance consistent with jurisdiction’s policy (e.g., clean outer clothing, hair restraint).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	2. Demonstrates proper sanitary practices as expected from a food service employee.				
<input type="checkbox"/>	Washed hands as needed (e.g., prior to conducting inspection, after using restroom, after touching dirty surfaces, after touching face/body, after sneezing/coughing).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Protected bandages on hands, when necessary, to prevent contamination of food or food contact surfaces.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Did NOT contact ready-to-eat foods with bare hands.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Did NOT show any obvious signs of illness in accordance with jurisdiction’s employee health policy and/or current food code.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

V. Professionalism (continued)

<input type="checkbox"/>	3. Only reports substantiated findings as violations.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Only reported findings that were directly observed or substantiated in accordance with jurisdiction's policies and procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Findings are supported by fact (e.g., are NOT based on hunch or suspicion; are witnessed, are investigated).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Did NOT note violations without visiting the establishment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Did NOT exaggerate details related to findings to support report conclusions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Did NOT modify report after leaving the establishment except as allowed by jurisdiction's administrative procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

VI. Additional Performance Elements – Jurisdiction Specific

<input type="checkbox"/>	1. Uses an aseptic food sample collection method consistent with criteria established by the laboratory serving the jurisdiction.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Used proper hygiene before and during sample process (e.g., washed hands prior to sampling; did not touch sample container opening, inside lip, inside cap or did not blow into the bag to open it up.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used sample collection method specified by the jurisdiction (e.g., original container if available; collection of a representative sample from a large quantity or container).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used sterile, leak-proof lidded container or zipper-lock type bags.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used a separate sterile utensil to collect each different sample item.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Labeled all containers with required information (e.g., date, time, location, product name, FSIO initials) with corresponding information noted on inspection report or laboratory forms.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Initiated written chain of custody including use of evidence seal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Stored and transported sample in a clean, refrigerated unit (e.g., ice chest with ice) within the prescribed time period.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Maintained sample refrigerated or frozen until transport or shipping to laboratory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Sample packed and shipped in sterile, leak-proof, insulated container with refrigerant (wet or dry ice) via the most rapid and convenient means available (e.g., courier, bus, express mail).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

VI. Additional Performance Elements – Jurisdiction Specific (continued)

<input type="checkbox"/>	2. Uses an aseptic water sample collection method consistent with criteria established by laboratory serving jurisdiction.	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	Used proper hygiene before and during sample process (e.g., washed hands prior to sampling; did not touch sample container opening, inside lip, inside cap or did not blow into the bag to open it up.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Sample taken at site closest to source of water (prior to any treatment) if possible, or at a site (post treatment) per jurisdiction’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Sample taken from operational fixed type faucet – no swing type or leaking faucets.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Removed aerator (if present) from faucet prior to sampling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Disinfected faucet with bleach or flame.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Ran water through faucet for several minutes to clear line.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Used a sterile, leak-proof lidded container, “whirl-pak” or zipper-lock type bag.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Sample taken from midstream of the flowing faucet.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Labeled all containers with required information (e.g., date, time, location, product name, FSIO initials) with corresponding information noted on inspection report or laboratory forms.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Initiated written chain of custody including use of evidence seal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Stored and transported sample in a clean, refrigerated unit (e.g., ice chest with ice) within the prescribed time period.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Maintained sample refrigerated until transport or shipping to the laboratory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Sample packed and shipped in sterile, leak-proof, insulated container with refrigerant via the most rapid and convenient means available (e.g., courier, bus, express mail).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction specific competencies)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

VI. Additional Performance Elements – Jurisdiction Specific (continued)

<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction Specific Performance Element)</u>	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	<u>(Jurisdiction specific competencies for Performance Element listed above)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

<input type="checkbox"/>	<u>ADDITIONAL (Jurisdiction Specific Performance Element)</u>	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
<input type="checkbox"/>	<u>(Jurisdiction specific competencies for Performance Element listed above)</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

Conference for Food Protection

**Attachment C: ABBREVIATED - FIELD TRAINING WORKSHEET
(Performance Elements Only)**

**Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer**

The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers (FSIOs) should be reviewed prior to using the Abbreviated Field Training Worksheet. The manual provides jurisdictions with information that will be helpful in customizing the Field Training Worksheet and implementing a training process that meets the specific needs of the jurisdiction.

The Conference for Food Protection (CFP) has conducted a national research study and identified the basic minimum competencies that are needed to perform effective regulatory food safety inspections. The Abbreviated Field Training Worksheet has been designed to be used in conjunction with the CFP Training Plan and Log as a trainer's tool during field training inspections. It provides a method for tracking a FSIO's progress and accomplishments in successfully demonstrating performance element competencies specific to their job responsibilities.

There is no single correct way to use the worksheet. The Field Training Manual provides examples of ways to incorporate the worksheet into existing retail food protection training programs.

This abbreviated version of the Field Training Worksheet provides another option for regulatory retail food protection program trainers. It simply lists the performance elements for each of the inspection areas. It is intended to be used in conjunction with the CFP reference document – "Competencies for Each Performance Element" included at the end of this Attachment. It is intended for experienced trainers who have a solid command of the FSIO competencies that comprise each of the performance elements. The jurisdiction should determine the specific performance elements that apply to the FSIOs within their jurisdiction prior to initiating the field training process

*Included with this Abbreviated Field Training Worksheet is a reference document that lists examples of competencies for each performance elements. Trainers should review with the FSIO the competencies that will be included as part of the field training inspections. FSIOs are expected to successfully demonstrate these minimum competencies correctly **prior** to conducting independent food safety inspections.*

Conference for Food Protection
ABBREVIATED - FIELD TRAINING WORKSHEET
(Performance Elements Only)
Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer

Establishment Name:	Establishment Address:	
Food Safety Inspection Officer's (FSIO) Name:	Food Safety Inspection Officer's (FSIO) Agency:	
Trainer's Name:	Trainer's Agency:	
Date of Inspection led by the Trainee:	Time IN:	Time OUT:

<u>I. Pre-Inspection</u> PERFORMANCE ELEMENTS	Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
	YES	NO	YES	NO
<input type="checkbox"/> 1. Has required equipment and forms to conduct inspection.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 2. Reviews establishment file for previous inspection report, complaints of file, and if applicable, required HACCP Plans or documents supporting the issuance of variance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>ADDITIONAL (Jurisdiction Specific Performance Elements)</u>				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:				

<u>II. Inspection Observations and Performance</u>		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
PERFORMANCE ELEMENTS					
<input type="checkbox"/>	1. Provides identification as a regulatory official to person in charge, confirming agency authority for inspection, and stating the purpose of visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. Has knowledge of jurisdiction’s laws, rules, and regulations required for conducting retail food/foodservice inspections.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	4. Obtains immediate corrective action for out of compliance employee practices and management procedures (listed in Item 3 above) essential to the safe storage, preparation, and service of food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	5. Correctly assesses compliance status of other regulations (not included in Item 4 – Good Retail Practices) that are included in jurisdiction’s prevailing statutes, regulations and/or ordinances.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	6. Verifies correction of out of compliance observations identified during previous inspection.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	7. Correctly uses inspection equipment during joint inspections.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>ADDITIONAL (Jurisdiction Specific Performance Elements)</u>					
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

<u>III. Oral Communication</u>		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
PERFORMANCE ELEMENTS					
<input type="checkbox"/>	1. Asks questions and engages in a dialogue with person in charge/employees to obtain information relevant to the inspection.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. Uses available means (e.g., interpreter, drawings, diagrams, demonstrations, international food safety icons) to overcome language or communication barriers.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	4. Follows jurisdiction’s policy in regard to disclosure of confidential information.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	5. Uses effective communication and conflict resolution techniques to overcome inspection barriers.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	6. Conducts exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>ADDITIONAL (Jurisdiction Specific Performance Elements)</u>					
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

<u>IV. Written Communication</u>		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
PERFORMANCE ELEMENTS					
<input type="checkbox"/>	1. Completes inspection form per jurisdiction’s administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. Includes 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).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. Presents inspection report, and when necessary cross-referenced documents, to person in charge.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>ADDITIONAL (Jurisdiction Specific Performance Elements)</u>					
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

<u>V. Professionalism</u>		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
PERFORMANCE ELEMENTS					
<input type="checkbox"/>	1. Maintains a professional appearance consistent with jurisdiction’s policy (e.g., clean outer clothing, hair restraint).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. Demonstrates proper sanitary practices as expected from a food service employee.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. Only reports substantiated findings as violations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>ADDITIONAL (Jurisdiction Specific Performance Elements)</u>					
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

<u>VI. Additional Inspection Area– Sample Collection and Evidence Development</u>		Opportunity occurred for FSIO to demonstrate competency during joint field training inspection		Competency demonstrated during joint field training inspection	
		YES	NO	YES	NO
PERFORMANCE ELEMENTS					
<input type="checkbox"/>	1. Uses an aseptic food sample collection method consistent with criteria established by laboratory serving jurisdiction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. Uses an aseptic water sample collection method consistent with criteria established by laboratory serving jurisdiction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>ADDITIONAL (Jurisdiction Specific Performance Elements)</u>					
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					

Conference for Food Protection REFERENCE DOCUMENT Competencies for Each Performance Element

PREREQUISITE TRAINING COURSES

Food Safety Inspection Officer (FSIO) has successfully completed prerequisite training courses as specified in FDA Voluntary National Retail Food Regulatory Program Standards: Standard #2 – Trained Regulatory Staff.

- OPTION 1: Completed the FDA ORA-U prerequisite (“Pre”) courses/examinations AND training on the jurisdiction’s prevailing statutes, regulations, and/or ordinances.
- OPTION 2: Submitted documentation of completing coursework equivalent to the FDA-ORA prerequisite (“Pre”) curriculum, AND training on the jurisdiction’s prevailing statutes, regulations, and/or ordinances, AND has certificate or documentation of successfully passing one of the written examination options in Program Standard #2.

NOTE: *A jurisdiction can begin the field training process with FSIOs while they are still in the process of completing their prerequisite coursework. However, the prerequisite coursework should be completed prior to conducting any independent inspections of foodservice or retail food facilities.*

INSPECTION AREAS

The Food Safety Inspection Officer *Field Training Worksheet* is divided into (six) 6 inspection areas:

- I. Pre-Inspection;
- II. Inspection Observations and Performance;
- III. Oral Communication;
- IV. Written Communication;
- V. Professionalism; and
- VI. Additional Inspection Areas (*The Field Training Worksheet includes as an additional area Sample Collection and Evidence Development for those jurisdiction where Food Safety Inspection Officers are expected to take aseptic food and/or water samples.*)

The performance elements for each of the 6 inspection categories were derived from research of current regulatory retail food protection program training curriculums and competency areas. Flexibility has been built into the training process to allow regulatory jurisdictions the ability to customize training so that it reflects a jurisdiction’s administrative policies, procedures, and inspection protocol. If a performance element competency is part of the FSIO’s job responsibility it should be included in the training plan. Competencies that are applicable to the FSIO’s job should not be arbitrarily removed or deleted from the *Field Training Worksheet*.

The competencies listed under each performance element are intended to serve as examples of job tasks that should be successfully demonstrated by the FSIO during field training inspections. Some of the competencies listed for a performance element may not be applicable to a FSIO within a given jurisdiction. For example, infrared thermometers may not be part of the standard issued equipment for inspection staff. The FSIO would not, therefore, be responsible for using this type of equipment. In such cases this competency is not included as part of the training.

Conversely, there may be competencies not listed under the performance element that are important for a jurisdiction to include. The trainer should review these additional competencies with the FSIO and include him/her as part of the field training process.

INSPECTION AREAS

I. Pre-Inspection

1. Has required equipment and forms to conduct inspection.

- Necessary inspection forms and administrative materials.
- Lab coat or equivalent protection to cover street clothes.
- Head cover: baseball cap; hair net; or equivalent.
- Calibrated thermocouple temperature measuring device.
- Maximum registering thermometer or temperature sensitive tapes for verifying hot water warewashing final rinse temperature.
- Chemical test kits for chlorine, iodophor, and quaternary ammonia sanitizers.
- Flashlight.
- Alcohol swabs.

2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance.

- Reviewed previous inspection report noting documented out of compliance observations.
- Reviewed establishment file for complaint reports.
- Reviewed establishment file for documentation indicating a need for a HACCP Plan.
- Reviewed establishment file for documentation of food production or processes operating under a variance issued by the jurisdiction.

II. Inspection Observations and Performance

1. Provides identification as a regulatory official to person in charge, confirming agency authority for inspection, and stating the purpose of visit.

- Verbally provided name and agency to the person in charge.
- Presented regulatory identification or business card.
- Stated the purpose of the visit.
- Requests and confirmed permission to conduct inspection from the person in charge prior to initiating the inspection.

2. Has knowledge of jurisdiction's laws, rules, and regulations required for conducting retail food/foodservice inspections.

- Verified the correct critical limit and or standard specified in the jurisdiction's rules/regulations to the observation made.
- Correctly cited the rule/regulation for each out of compliance observation.

3. Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.

- Verified Demonstration of Knowledge of the person in charge.
- Verified approved food sources (e.g., food from regulated food processing plants; shellfish documentation; game animal processing; parasite destruction for certain species of fish intended for raw consumption; receiving temperatures).
- Verified food safety practices for preventing cross-contamination of ready-to-eat food.

- Verified food contact surfaces are clean and sanitized, protected from contamination from soiled cutting boards, utensils, aprons, etc., or raw animal foods.
- Verified the restriction or exclusion of ill employees.
- Verified no bare hand contact with ready-to-eat foods (or use of a pre-approved, alternative procedure).
- Verified employee handwashing.
- Verified cold holding temperatures of foods requiring time/temperature control for safety (TCS food), or when necessary, verified that procedures are in place to use time alone to control bacterial growth and toxin production.
- Verified date marking of ready-to-eat foods TCS food held for more than 24 hours.
- Verified cooking temperatures to destroy bacteria and parasites.
- Verified hot holding temperatures of TCS food or when necessary, that procedures were in place to use time alone to prevent the outgrowth of spore-forming bacteria.
- Verified cooling temperatures of TCS food to prevent the outgrowth of spore-forming or toxin-forming bacteria.
- Verified reheating temperatures of TCS food for hot holding.
- Verified the availability of a consumer advisory for foods of animal origin served raw or undercooked.
- Identified food processes and/or procedures that require a HACCP Plan per the jurisdiction's regulations.

4. Obtains immediate corrective action for out of compliance employee practices and management procedures (listed in Item 3 above) essential to the safe storage, preparation, and service of food.

- Notified the person in charge/employee(s) of the out of compliance observations.
- Reviewed corrective actions with the person in charge/employee(s).
- Observed the person in charge/employee(s) immediately take corrective action for out of compliance observations (e.g., movement of food to ensure product temperature or prevent contamination; reconditioning food; restriction/exclusion of ill employees; discarding of food product) in accordance with local jurisdiction's procedures.
- Identified conditions requiring issuance of an embargo/stop sale/food destruction order per jurisdiction's administrative procedures.

5. Correctly assesses compliance status of other regulations (not included in Item 4 – Good Retail Practices) that are included in jurisdiction's prevailing statutes, regulations and/or ordinances.

- Correctly assessed compliance status of other regulations (not included in Item 4 above - Good Retail Practices) that are included in jurisdiction's prevailing statutes, regulations and/or ordinances.

6. Verifies correction of out of compliance observations identified during previous inspection.

- Verified correction of out of compliance observations identified during previous inspection

7. Correctly uses inspection equipment during joint inspections.

- Used temperature measuring devices/probes in accordance with manufacturer's instructions.
- Cleaned and sanitized (alcohol swabs) temperature measurement probes to prevent food contamination.
- Used infrared thermometer in accordance with manufacturer's instructions. Verified any out of compliance product temperatures registered on the infrared with a thermocouple.
- Used maximum registering thermometer or heat sensitive tapes in accordance with manufacturer's instructions to verify final rinse dishwasher temperature.
- Used chemical test strips in accordance with manufacturer's instructions to measure sanitizer concentrations in manual and mechanical dishwashing operations; wiping cloth solutions; and spray bottle applicators.
- Used flashlight to assess observations in areas with no or low light.
- Photographs taken support regulatory findings or conditions observed.

III. Oral Communication

1. Asks questions and engages in a dialogue with person in charge/employees to obtain information relevant to inspection.

- Asked open ended questions (questions that can not be answered with “yes” or “no”).
- Did not interrupt when the person in charge/employee was speaking.
- Paraphrased/summarized statements from the person in charge to confirm understanding.

2. Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.

- Answered inspection-related questions accurately.
- Admitted not knowing the answer to a question and arranges to contact the establishment with the answer.
- Used trainer as a resource when unsure of an answer.

3. Uses available means (e.g., interpreter, drawings, demonstrations, diagrams, international food safety icons) to overcome language or communication barriers.

- Avoided using jargon and acronyms, without explanation.
- Used interpreter, drawings, demonstrations, or diagrams to overcome language or communication barriers.
- Checked the person in charge’s understanding of information/instructions by asking the operator to paraphrase or demonstrate the information/instructions.

4. Follows jurisdiction’s policy in regard to disclosure of confidential information.

- Explained confidentiality laws, policies and procedures to the person in charge when necessary. (if the need to explain confidential laws did not occur during the joint field training inspections, the FSIO explained confidentiality laws, policies and procedures to the trainer).
- Applied the confidentiality policy per the jurisdictional requirements (e.g., FSIO did not reveal confidential information to the operator during the inspection).

5. Uses effective communication and conflict resolution techniques to overcome inspection barriers.

- Identified challenges faced by the person in charge and offered possible solution(s).
- Did not become argumentative (e.g., remained calm and focused).
- Removed himself/herself from a confrontation or threat that may impact personal safety.

6. Conducts exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.

- Explained the public health significance of the inspection observations.
- Reviewed all findings with the person in charge with emphasis on contributing factors to foodborne illness and Food Code Interventions (listed in Section II, Item 3).
- Used foodborne illness data to highlight contributing factors.
- Answered all questions or concerns pertaining to items on the inspection report.
- Provided contact information to the person in charge for follow up questions or additional guidance.

IV. Written Communication

1. Completes inspection form per jurisdiction's administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).

- Used correct inspection form.
- Completed a legible report.
- Accurately documented observations made during inspection.
- Completed inspection form in accordance with jurisdiction's administrative procedures.
- Cited correct code provisions/rules/regulations.
- Documented immediate corrective action for out-of-compliance foodborne illness contributing factors and Food Code Interventions (listed in Section II, Item 3).
- Documented time frames for correcting each out of compliance observation.
- Signed completed inspection report.

2. Includes 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).

- Referenced attached documents in inspection report.
- Referenced documents are legible.
- Referenced documents are accurate and reflect observations made during the inspection.
- Attached referenced document(s) to the inspection report per jurisdiction's administrative procedures.

3. Presents inspection report, and when necessary cross-referenced documents, to person in charge.

- Presented complete inspection report, with referenced documents when necessary, to person in charge during exit interview.
- Followed jurisdiction's administrative procedures for delivering written inspection report.
- Obtained signature of person in charge on inspection report.

V. Professionalism

1. Maintains a professional appearance consistent with jurisdiction's policy (e.g., clean outer clothing, hair restraint).

- Maintained a professional appearance consistent with jurisdiction's policy (e.g., clean outer clothing, hair restraint).

2. Demonstrates proper sanitary practices as expected from a food service employee.

- Washed hands as needed (e.g., prior to conducting inspection, after using restroom, after touching dirty surfaces, after touching face/body, after sneezing/coughing).
- Protected bandages on hands, when necessary, to prevent contamination of food or food contact surfaces.
- Did **NOT** contact ready-to-eat foods with bare hands.
- Did **NOT** show any obvious signs of illness in accordance with jurisdiction's employee health policy and/or current food code.

3. Only reports substantiated findings as violations.

- Only reported findings that were directly observed or substantiated in accordance with jurisdiction's policies and procedures.
- Findings are supported by fact (e.g., are **NOT** based on hunch or suspicion; are witnessed, are investigated).
- Did **NOT** note violations without visiting the establishment.
- Did **NOT** exaggerate details related to findings to support report conclusions.
- Did **NOT** modify report after leaving the establishment except as allowed by jurisdiction's administrative procedures.

ADDITIONAL INSPECTION AREAS

VII. Sample Collection and Evidence Development

1. Uses an aseptic food sample collection method consistent with criteria established by laboratory serving jurisdiction.

- Used proper hygiene before and during sample process (e.g., washed hands prior to sampling; did not touch sample container opening, inside lip, inside cap or did not blow into the bag to open it up.)
- Used sample collection method specified by the jurisdiction (e.g., original container if available; collection of a representative sample from a large quantity or container).
- Used sterile, leak-proof lidded container or zipper-lock type bags.
- Used a separate sterile utensil to collect each different sample item.
- Labeled all containers with required information (e.g., date, time, location, product name, FSIO initials) with corresponding information noted on inspection report or laboratory forms.
- Initiated written chain of custody including use of evidence seal.
- Stored and transported sample in a clean, refrigerated unit (e.g., ice chest with ice) within the prescribed time period.
- Maintained sample refrigerated or frozen until transport or shipping to laboratory.
- Sample packed and shipped in sterile, leak-proof, insulated container with refrigerant (wet or dry ice) via the most rapid and convenient means available (e.g., courier, bus, express mail).

2. Uses an aseptic water sample collection method consistent with criteria established by laboratory serving jurisdiction.

- Used proper hygiene before and during sample process (e.g., washed hands prior to sampling; did not touch sample container opening, inside lip, inside cap or did not blow into the bag to open it up.)
- Sample taken at site closest to source of water (prior to any treatment) if possible, or at a site (post treatment) per jurisdiction's procedures.
- Sample taken from operational fixed type faucet – no swing type or leaking faucets.
- Removed aerator (if present) from faucet prior to sampling.
- Disinfected faucet with bleach or flame.
- Ran water through faucet for several minutes to clear line.
- Used a sterile, leak-proof lidded container, "whirl-pak" or zipper-lock type bag.
- Sample taken from midstream of the flowing faucet.
- Labeled all containers with required information (e.g., date, time, location, product name, FSIO initials) with corresponding information noted on inspection report or laboratory forms.
- Initiated written chain of custody including use of evidence seal.
- Stored and transported sample in a clean, refrigerated unit (e.g., ice chest with ice) within the prescribed time period.
- Maintained sample refrigerated until transport or shipping to the laboratory.
- Sample packed and shipped in sterile, leak-proof, insulated container with refrigerant via the most rapid and convenient means available (e.g., courier, bus, express mail).

2005 FDA Food Code – Annex 5
Table 1
Appendix B-3: Risk Categorization of Food Establishments

RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, nonpotentially hazardous foods (non time/temperature control for safety (TCS) foods). Establishments that prepare only nonpotentially hazardous foods (nonTCS foods). Establishments that heat only commercially processed, potentially hazardous foods (TCS foods) for hot holding. No cooling of potentially hazardous foods (TCS foods). Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.	1
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of potentially hazardous foods (TCS foods) after preparation or cooking. Complex preparation of potentially hazardous foods (TCS foods) requiring cooking, cooling, and reheating for hot holding is limited to only a few potentially hazardous foods (TCS foods). Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.	2
3	An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many potentially hazardous foods (TCS foods). Variety of processes require hot and cold holding of potentially hazardous food (TCS food). Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.	3
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

APPENDIX C - SUPPLEMENT TO STANDARD 3 - INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

TABLE C- 1 – INSPECTION PROGRAM WORKSHEET

Criteria	YES	NO
1. The inspection form in use is designed to: a. identify risk factors and interventions b. document in, out, not observed, and not applicable status c. document compliance and enforcement activities		
	1a.	
	1b.	
	1c.	
2. Your jurisdiction uses a written process that groups food establishments into at least three categories based on potential and inherent food safety risks.	2.	
3. Your jurisdiction assigns an annual inspection frequency to each food establishment based on its assigned food safety risk category.	3.	
4. Your jurisdiction has an implemented, written policy that requires: a. On-site corrective actions b. Discussion of long-term control options c. Follow-up activities		
	4a.	
	4b.	
	4c.	
5. Your jurisdiction has an implemented written policy that addresses code variance requests related to risk factors and interventions.	5.	
6. Your jurisdiction has an implemented written policy for the verification and validation of HACCP plans when a plan is required by the code.	6.	

A “yes” affirmation to each statement is required to meet Standard 3. The source documents specified as quality records in Standard 3 must be maintained in good order by the regulatory authority to support this summary record and must be made available for purposes of a verification audit.

I affirm that the information represented on this record is true and correct. This jurisdiction meets all the requirements for Standard 3, _____ YES _____ NO

 Printed Name and Signature of Self-Assessor

 Date

 Name and Address of the Jurisdiction

APPENDIX D - SUPPLEMENT TO STANDARD 4 – UNIFORM INSPECTION PROGRAM

Use Table D-2 or a similar manual or automated form to document the success of a jurisdiction's quality assurance program in meeting Standard 4. In the first column, identify the inspector by name or by a code. In the Establishment ID column, identify the establishment by name or by code. In the "DATE" column, record the dates of the field visit and file review. Items 1 through 10 below summarize the desired activities and competencies of an inspector. Note that some items (such as 5, 6, 8, and 9) cannot be verified without a review of the file for the establishment visited. Place a check mark in the corresponding column of Table D-2 when the activity or competency is verified.

1. Determines and documents the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable is noted on the inspection form) through observation and investigation;
2. Completes an inspection report that is clear, legible, concise, and accurately records findings and observations;
3. Interprets and applies laws, regulations, policies and procedures correctly;
4. Cites the proper local code provisions for CDC-identified risk factors and Food Code interventions;
5. Reviews past inspection findings and acts on repeated or unresolved violations;
6. Follows through with compliance and enforcement actions;
7. Obtains on-site corrective action;
8. Discusses and documents discussion of options for implementing food safety systems, when required;
9. Confirms that the facility is assigned to the correct risk category and inspection frequency; and
10. Files reports and other documentation in a timely manner.

NOTE TO AGENCIES HAVING LESS THAN 10 INSPECTORS: When dealing with samples this small, it is statistically necessary to group all the item ratings together, disregarding the score for each individual Item (1) – (10). Agencies having less than 4 inspectors 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 inspections large enough to statistically measure the uniformity of your inspection program fairly. Therefore, do not calculate the "% compliance" row for each item at the bottom of Table D-2. Instead use Chart D-1 and Table D-1 to determine the program's rating.

CHART D-1 METHOD OF CALCULATION FOR JURISDICTIONS WITH LESS THAN TEN INSPECTORS		
# of inspectors	# inspections needed	# of items needed to be marked in compliance in order to pass
<4	8 minimum	65 (out of 80 possible Items)
4-9	2 per inspector	4 inspectors = 65 (out of 80 possible Items) 5 inspectors = 82 (out of 100 possible Items) 6 inspectors = 99 (out of 120 possible Items) 7 inspectors = 116 (out of 140 possible Items) 8 inspectors = 133 (out of 160 possible Items) 9 inspectors = 150 (out of 180 possible Items)

Example: For 6 inspectors, there will be 2 field visits per inspector = 12 visits
 12 visits X 10 Items per visit = 120 Total Possible Items

These minimum passing scores are comparable to the 75% per aspect passing rate for jurisdictions with 10 or more inspectors.

TABLE D-1 CALCULATION OF UNIFORMITY FOR JURISDICTIONS WITH LESS THAN TEN INSPECTORS	
Period from _____ to _____	
1. Number of inspectors in the jurisdiction	
2. Number of inspections used in the calculation (minimum of 8)	
3. Total number of items marked as correct during joint field visits and corresponding file reviews and recorded on Table D-2.	
4. Total number of possible items based on the number of inspections (10 items times the # of inspections – see Chart D-1, column 3)	
Indicate Pass or Fail as determined by chart D-1, column 3	

TABLE D-2 CALCULATION OF UNIFORMITY FOR JURISDICTIONS WITH TEN OR MORE INSPECTORS
 Period from _____ to _____

INSPECTOR ID.	Establishment ID	Date	ITEM (1)	ITEM (2)	ITEM (3)	ITEM (4)	ITEM (5)	ITEM (6)	ITEM (7)	ITEM (8)	ITEM (9)	ITEM (10)
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10												
% In Compliance												

A check mark indicates the inspector complies with the item. Conduct at least two field visits and file reviews per inspector during each three-year self-assessment period. For each item, compute the Percent In Compliance by dividing the number of checks in each column by the number of field inspections observed and multiplying the result by 100. Each column must show at least a 75% In Compliance rate for the program to conform to the Standard. See instructions on page D-1 for jurisdictions with less than ten inspectors.

EXPLANATION OF THE STATISTICAL MODEL

This is an explanation of the thinking that determined the statistical model relating to the criteria used for evaluating the inspection performance of jurisdictions. The FDA Program Standards Workgroup and the Retail Food Steering Committee agreed this model to, with guidance from the CFSAN Division of Mathematics.

Evaluation of the performance of large jurisdictions

For large jurisdictions (jurisdictions with 10 or more inspectors) the evaluation is based on direct oversight of two inspections per inspector, with respect to 10 items of performance. If 10 or more inspectors are being evaluated in the program, then we will see 20 or more scores of satisfactory or unsatisfactory for each item. The standard for approval of the inspection performance is a passing score of 75% on each of the 10 items. An individual item receives a passing score if at least 75 percent of the instances of observation are completed in a satisfactory manner. For example, with 10 inspectors, we must have at least 15 (that is 75 percent of 20 inspections) completed correctly for item number 1. Similarly, for item number 2, we would need to see at least 15 inspections done correctly. In order for the program to pass the evaluation successfully with respect to inspection performance, all of the 10 items would be required to show satisfactory completion of at least 15 out of the 20 ratings. For those jurisdictions with more than 10 inspectors, we simply apply the 75 percent rule as we did for the jurisdiction with 10 inspectors. Using two overseen inspections for each inspector, record the observations for each item, figure the percent correct for each item, and round up to the next higher whole number when the percent is not a whole number.

The 75 percent per item rule was determined by the consensus of several highly experienced individuals working in the retail food safety team. We view the set of overseen inspections as a sample from a much larger set of total inspections performed. In this approach to program evaluation, the statistical measure does not evaluate any individual inspector. The emphasis is on the overall performance of the team, with respect to any item. Even if an inspection were observed in which one inspector fails all 10 items, the program would not necessarily fail.

The jurisdiction's quality assurance program, however, must address individual inspector's performance to ensure a standard of uniformity among the team. If each inspection were successful only 75 percent of the time for each item, the team as a whole would almost always fail. This is because they would almost always dip below 75 percent on at least one of the 10 items. For example, a team that scored 70, 70, 70, 75, 75, 75, 75, 80, 80, and 80 on each of the 10 items would be successful 75 percent of the time, but they would fail three times over since three items scored below 75. However, for a team with 10 inspectors exactly, if their chance of getting each item right improved to 88 percent at each inspection, then they would have a much better chance of keeping all 10 results at 75 percent or higher. Under the simple statistical assumption of independent sampling, a team achieving 88 percent at each inspection would pass the evaluation 75 percent of the time. Therefore, this 88 percent level of performance was used as a simple representation of a team that is good enough that we want them to have a good chance of passing, but not so good that they would not find it advantageous to improve.

Evaluation of performance of small jurisdictions

A statistical issue was to determine a reasonable standard for those jurisdictions with less than 10 inspectors. When the sample gets this small, the relative error in the estimated fractions gets so large that the “each of 10 items rule” will fail good programs too frequently. Therefore, the 88 percent level of performance at each inspection was the feature of the standard that was kept constant in designing the sample sizes for the smaller jurisdictions

In jurisdictions with less than 10 inspectors, the statistical solution is to group all of the individual ratings, disregarding the individual items. For 5 inspectors we would review $5 \times 2 = 10$ inspections, with respect to all 10 items combined. This gives 100 observations. It is not possible to make a total observation test mimic exactly a 10 item test, but the minimum passing rates will be about as stringent as the 75 percent for each of 10 aspects test.

For 4 to 9 inspectors, conduct two co-inspections for each inspector. Chart D-1 shows the lowest total passing score out of the complete set of combined items that would give at least a 75 percent chance of passing for a team with an 88 percent chance of getting any particular observation correct. For a team of three or less, it is recommended that extra oversight inspections be performed to produce a total of 8 inspections. This is an intuitive judgment call that any set smaller than 8 could randomly turn out to be odd enough to produce an unfair rating.

APPENDIX E - SUPPLEMENT TO STANDARD 5 - FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

Criteria	YES	NO
1. INVESTIGATION PROCEDURES		
a. The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and food-related injury* that clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. (The procedures may be contained in a single source document or in multiple documents.)	a.	
b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.	b.	
c. The program maintains a written operating procedure or a memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.	c.	
d. The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, food-related injury or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is files in or linked to the establishment record for retrieval purposes.	d.	
e. Program procedures describe the disposition, action or follow-up and reporting requirement for each type of complaint or referral report.	e.	
f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.	f.	
g. The program has established procedures and guidance for collecting information on the suspect foods' preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.	g.	
h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.	h.	

<p>i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency’s jurisdiction or has been shipped interstate.</p>	<p>i.</p>	
<p>2. REPORTING PROCEDURES</p>		
<p>a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.</p>	<p>a.</p>	
<p>b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks* with CDC.</p>	<p>b.</p>	
<p>3. LABORATORY SUPPORT DOCUMENTATION</p>		
<p>a. The program has a letter of understanding, written procedures, contract or MOU acknowledging that a laboratory(s) is willing and able to provide analytical support to the jurisdiction’s food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.</p>	<p>a.</p>	
<p>b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction’s primary laboratory(s).</p>	<p>b.</p>	
<p>4. TRACE-BACK PROCEDURES</p>		
<p>a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The track-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.</p>	<p>a.</p>	
<p>5. RECALLS</p>		
<p>a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.</p>	<p>a.</p>	

<p>b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFP, Part 7 are followed.</p>	<p>b.</p>	
<p>c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.</p>	<p>c.</p>	
<p>6. MEDIA MANAGEMENT</p>		
<p>a. The program has a written policy and procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.</p>	<p>a.</p>	
<p>7. DATA REVIEW AND ANALYSIS</p>		
<p>a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.</p>	<p>a.</p>	
<p>b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:</p> <ul style="list-style-type: none"> i. Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment; ii. Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type; iii. Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food; iv. Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food preparation processes; v. Number of confirmed foodborne disease outbreaks*; vi. Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*; vii. Contributing factors most often identified; viii. Number of complaints involving real and alleged threats of intentional food contamination; and ix. Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified. 	<p>b.</p>	

<p>c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no illness outbreak investigations occur.</p>	<p>c.</p>	
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*Note: See the Standards Definitions for the meaning of these defined terms.

A “yes” affirmation to each statement is required to meet Standard 5. If an appendix item contains multiple questions, then all questions must be answered in the affirmative in order to meet that element of the Standard.

The source documents, such as the various policies and procedures, that support this summary record must be maintained in good order by the regulatory authority and must be made available upon request for purposes of a verification audit.

I affirm that the information represented on this record is true and correct. This jurisdiction meets all the requirements for Standard 5, _____ Yes _____ NO

 Signature of Self-assessor

 Date

 Printed Name of Self-assessor and Title

 Name and Address of Jurisdiction

APPENDIX F - SUPPLEMENT TO STANDARD 6 - COMPLIANCE AND ENFORCEMENT

WORK SHEET INSTRUCTIONS

This Standard applies to all voluntary and regulatory activities used by a jurisdiction to achieve compliance with regulatory requirements. The desired outcome is an effective compliance and enforcement program that consistently follows through on documented violations and achieves compliance. The sequence and type of follow-up activity a particular jurisdiction elects to use may vary. However, when an out-of-control risk factor or intervention is documented on an inspection report, the expectation is that actions taken to correct the violation will also be documented in the establishment file. For the purposes of self-assessment, follow-up actions have been divided into three types.

- On-site corrective action that occurs at the time of a routinely scheduled inspection,
- Follow-up action that occurs after the routine inspection, such as re-inspections, training, risk control plans, and informal conferences, and
- Enforcement activities such as fines, permit suspension, hearings, mandated training, restriction of operations, embargo, etc.

The measure of success for a compliance and enforcement program under Standard 6 is based on a review of randomly selected establishment files to determine whether documented violations have been resolved satisfactorily in the establishment.

In order to track documented violations through the compliance and enforcement process for a period of time long enough to determine resolution, a fixed point in time must be chosen as the starting point. It is expected that follow-up or subsequent inspections of that facility should show correction of the violations documented at the starting point. The Standard 6 measure uses a concept called the ‘start-point inspection.’

The ‘start-point inspection’ will be the third oldest routine inspection in the establishment’s file if it shows a violation of one of the risk factors or *Food Code* interventions. If no risk factor or *Food Code* intervention violation is shown on that inspection, then the fourth oldest routine inspection may be used if it shows a risk factor or *Food Code* intervention violation. The third oldest routine inspection is determined by starting from the most recent routine inspection in the establishment’s file and working backward chronologically. The fourth oldest routine inspection would be the one prior to the third oldest. If no violation of a risk factor or *Food Code* intervention is documented on the third or fourth oldest routine inspection, then no ‘start-point inspection’ exists for that establishment.

A sampling of files will be reviewed for compliance and enforcement performance based on the ‘start-point inspection’ concept. The following section provides instructions for the proper construction of a list of sample files and a required alternate list of sample files.

SELECTING THE SAMPLE

Jurisdictions with less than 400 total establishments will select at least 20 files for review. Jurisdictions with over 400 establishments will select a sample equal to 5% of the total establishments up to a maximum of 70 files. This initial selection of sample files will be the initial sample and will be the first files reviewed. Sample selection using a table of random numbers or a random number generator is the preferred method of sample selection and can be used with a card file, ledger, list, or automated data system. However, two alternative sample selection techniques acceptable for retail food program self-assessments are presented here.

1. Method 1. The first alternative technique to the use of a random number generator requires that each establishment be identified by a card or strip of paper having the establishment's name and address, permit number, file number, or other means of positive identification. These identifying cards or slips of paper are thoroughly mixed and the establishment files to be reviewed are drawn one at a time until the required number is obtained.
2. Method 2. The second alternative technique to the use of a random number generator utilizes a card file, ledger, list or data processing record system. When this procedure is used, all the establishments in the program must be subject to sampling. The frequency interval may be determined by dividing the total number of retail food establishments by the number of files needed in the sample. [For example, if there are 800 establishments within the jurisdiction, a sample of 40 would be needed (5% of 80). The frequency interval would be 800 divided by 40, or 20. Thus every 20th establishment shall be selected to make up the initial sample.] To establish a starting point when using a frequency interval of 20, write numbers 1 – 20, inclusive, on separate strips of paper and draw one slip at random. The number appearing on that strip of paper represents the first establishment to be drawn. If a ledger or list is being used for sampling and the number drawn is 7, then the seventh entry in the ledger or list would be the first establishment in the sample. The second establishment would be the 27th entry, the third would be the 47th entry and so forth, until the sample of 40 is drawn.

ALTERNATE SAMPLE LIST

Deletion of an establishment from the sample of files to be reviewed will be limited to those establishments which have not been in business long enough to have at least three regularly scheduled inspections or those files where no risk factor or *Food Code* intervention violation is documented on the "start-point inspection."

When an establishment file is eliminated from the initial random draw, a new establishment file will be drawn from a pre-determined alternate sample list. Alternate files will be drawn in the same manner as the original sample and at the same time as the original sample selection. It is suggested that the number of alternate files selected be at least 30 percent of the original sample size. If a large number of files selected in the initial draw do not have risk factor or *Food Code* intervention violations on the "start-point inspection," then a larger

alternate sample will be needed.

The sample list of alternate files shall be kept separate from the original sample list. When an original selected file cannot be rated because it has not been in business long enough to have received at least three routine inspections or because it has no risk factor/intervention violation on the start-point inspection, a substitute file from the pre-selected alternate list will be reviewed. Substitute files from the alternate list will be used in the order in which the files were drawn.

If a random number generator or a table of random numbers is used for the initial sample selection, then this same method should be used to select the appropriate number of files for the alternate sample list. Again, this is the easiest and preferred method of sample selection.

If method 1 is used for the random selection, the alternate sample files will be the last files drawn. For example, if the sample size required is 20, then 26 files will be selected, and the last 6 files drawn will be designated as alternative files.

If method 2 is used for the random selection, a separate drawing of the alternate files will be made using an interval determined as follows: the number of establishments in the inventory, minus the number of files drawn for the original sample, divided by the number of alternate files needed. Using our example from method 2 above:

$$800 \text{ (inventory)} - 40 \text{ (files drawn in the original sample)} / 12 \text{ (30\% of the original sample)} = 63$$

To establish a starting point for the new interval of 63, write the numbers 1 – 63 inclusively on separate slips of paper and draw one at random. The number drawn will be the first file selected for the alternate sample and every 63rd file afterward until 12 files are drawn.

REVIEWING AND RATING THE FILES

Step 1. Identify the items on the local inspection report that correspond to each of the risk factors and interventions on the worksheet. Record the local item numbers on the “reference key” line of the worksheet. If there is no corresponding local requirement for a particular *FDA Code* risk factor or intervention, record “NA” for not applicable. You may find the Standard No. 1, Appendix A Worksheets, helpful in making this comparison. Note that the program is not penalized under Standard No. 6 for sections of the *Food Code* that have not been adopted.

Step 2. Open the first establishment inspection file that was randomly selected in Step 1 above. Identify the third oldest routine inspection report in the file, starting at the current date and working back chronologically. This inspection will be the “start-point inspection” for the review of this file. Using the reference key line on the worksheet, determine which risk factors and interventions were out of compliance at the time of this “start-point inspection.” Place a check under each item that is out of compliance on the horizontal status line. If there is no risk factor/intervention that was out of compliance on the third oldest

inspection in the file, you may move to the fourth oldest inspection in the file and use it for the “start-point inspection” if it contains a risk factor/intervention that was out of compliance. If there is no risk factor/intervention that was out of compliance on the third or fourth oldest inspection, eliminate this file from the review and select a substitute file from the alternate list. ***JNOTE: Be sure to indicate the date of the start-point inspection on the Appendix F worksheet for each reviewed file. This will aid the reviewer during a validation audit.***

Step 3. Review all of the documentation in the establishment file from the start-point inspection forward to the current date and determine whether follow-up action was taken and documented for each of the out-of-compliance risk factors and interventions that were out of compliance on the start-point inspection. Determine whether there was at least one type of follow-up activity for each item that was marked out of compliance. Place “Yes” in the appropriate line and column to indicate that follow-up action was documented in the establishment file. Make a notation below each “Yes” to indicate the type of action taken such as “RH” for Reheat, “WL” for warning letter or “RCP” for risk control plan. If there is no documentation in the establishment file to indicate that follow-up action was taken for each specific risk factor or intervention that was out of compliance, the presumption is that follow up did not occur. Indicate by “yes” or “no” in the last column whether follow-up actions complied with the jurisdiction's written step-by-step procedure for compliance and enforcement.

In order for an individual establishment file to pass, each column marked with a violation at the start-point inspection must have a subsequent “yes” answer to indicate that at least one type of follow-up action was taken. Actions must have complied with the jurisdiction's written step-by-step procedure for compliance and enforcement. A single start-point violation without a final resolution, either correction or a compliance/enforcement activity causes the file to fail. A single failure to follow the jurisdiction’s written procedures also causes the file to fail. Circle the appropriate “pass” or “fail” notation at the bottom of the work sheet.

Repeat Steps 2 and 3 with each of the randomly selected establishment files. When all of the files have been reviewed, total the number of files that passed and divide by the total number of files that met the sample selection criteria that were reviewed. To meet Standard No. 6, eighty percent (80%) of the files must pass.

See the following example and blank Worksheet.

EXAMPLE:

SAMPLE WORK SHEET -COMPLIANCE AND ENFORCEMENT

File No: 1

Risk Factors and Food Code Interventions											
Establishment Name Seafood Palace	Unsafe Source	Inadequate Cooking	Improper holding Temperatures Hot & Cold	Time/Temperature Parameters not met. (Time as a control, date marking, rapid cooling)	Bare hand contact with ready-to-eat PHF	Poor Personal Hygiene	Contaminated Food Contact Surfaces & Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control system or policy implemented.	Was the Written Procedure Followed?
Permit Number 339											
Inspection Date (start point) 3 May 2000											
Reference Key to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16	Circle One <u>YES</u> or NO
Start Point Inspection Violations		X		X	X	X					
Was on site corrective action taken ?		Yes RH		YES EM	Yes Glove						
Was follow up corrective action taken?				Yes RCP		Yes TR					
Was enforcement action taken?		Yes WL									
Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed.											Circle One <u>PASS/FAIL</u>

In this example, the file passes because each of the violations noted on the start point inspection, dated 3 May 2000, has documented follow-up action in the file. The "NA" under Consumer Advisory indicates that the jurisdiction does not have a requirement for this intervention. The "yes" in the last column indicates that the compliance and enforcement procedure of the jurisdiction was followed.

*Define the acronyms and notations used to reflect follow-up action. **RH**= Reheat to safe temperature, **RCP**= risk control plan successfully completed, **WL**= warning letter sent, **EM**= embargo, **TR** = training required

APPENDIX G - SUPPLEMENT TO STANDARD 7 - INDUSTRY AND COMMUNITY RELATIONS

It is necessary to maintain records of the Industry and Consumer Interaction forums and of the Educational Outreach activities over the last 24-month period. The following chart is used to document that status. Meeting minutes, agendas, by-laws, charters, membership criteria and lists, frequency of meetings, roles, performed actions and documentation of food safety educational efforts are to be maintained by the regulatory authority.

INDUSTRY AND CONSUMER INTERACTION FORUMS

Forum Title	Regulatory Participants by Organization	Industry Participants by Organization	Consumer Participants by Organization	Meeting Dates	Summary of Activities Related to Control of Risk Factors

EDUCATIONAL OUTREACH

Dates	Summary of Activities

OTHER OUTREACH ACTIVITIES

Please list any additional outreach activities of note below.

Dates	Summary of Activities

APPENDIX H - SUPPLEMENT TO STANDARD 8- PROGRAM SUPPORT AND RESOURCES

PROGRAM SUPPORT AND RESOURCES WORKSHEET

Do you have sufficient funds, staff, equipment, and resources necessary to meet the following Standards? Answer “yes” or “no” in each block. A “no” answer requires an explanation. Use additional pages as needed. Disclosure and analysis only is required for Standards 1 through 7 and 9. Standard 8 requires a positive response to the three identified items. ****The row at the bottom for “other shared resources” provides a place for you to identify needs that may not be easily attached to a specific Standard (i.e. copy machines, data lines, etc.)

Standard #	Funding	Staffing	Equipment	Other resources needed
1				
2				
3				
4				
5				
6				
7				
8		*	**	***
9				
****Other shared resources				

Do you meet the full-time equivalent (FTE) staff to inspection ratio as required in Standard 8? **Do your inspectors have the equipment provided and available as required in Standard 8? *Does your department have the equipment and supplies necessary to maintain the records and reports system that supports the program as required in Standard 8?*

The requirements of Standard 8 are met. _____ Yes _____ No

Signature: _____ Title: _____ Date: _____

APPENDIX I – FDA NATIONAL REGISTRY REPORT FDA FORM 3519

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION FDA National Registry Report	FORM APPROVED: OMB NUMBER: EXPIRATION DATE:
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Jurisdiction Reporting	Address	City	State	Zip
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To: FDA Regional Retail Food Specialist	Date
---	-------------

Enrollment Only: <input type="checkbox"/>	Self Assessment: <input type="checkbox"/>	Verification Audit: <input type="checkbox"/>	Baseline Survey: <input type="checkbox"/>
Standard #	Standard Met (✓ all that apply & add the date met)	Verification Audit Confirmed	Original: <input type="checkbox"/> Update: <input type="checkbox"/>
	Date: (required)	Date: (required)	Date:
1.	<input type="checkbox"/>	<input type="checkbox"/>	Date:
2.	<input type="checkbox"/>	<input type="checkbox"/>	
3.	<input type="checkbox"/>	<input type="checkbox"/>	
4.	<input type="checkbox"/>	<input type="checkbox"/>	
5.	<input type="checkbox"/>	<input type="checkbox"/>	
6.	<input type="checkbox"/>	<input type="checkbox"/>	
7.	<input type="checkbox"/>	<input type="checkbox"/>	Survey Audit Confirmed: <input type="checkbox"/>
8.	<input type="checkbox"/>	<input type="checkbox"/>	Date:
9.	<input type="checkbox"/>	<input type="checkbox"/>	
Risk Reduction Confirmed			Yes: <input type="checkbox"/> No: <input type="checkbox"/>

Self Assessment Completed by:			
Name (printed)	Signature	Title	Agency

Verification Audit Completed by:			
Name (printed)	Signature	Title	Agency

Baseline Survey Completed by:			
Name (printed)	Signature	Title	Agency

Baseline Survey-Update Completed by:			
Name (printed)	Signature	Title	Agency

Action Plan Completed by:			
Name	Signature	Title	Agency

Public reporting burden for this collection of information is estimated to average 92 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration, Office of Food Safety, Retail Food and Cooperative Programs Coordination Staff (HFS – 320), CFSAN, 5100 Paint Branch Parkway, College Park, Maryland 20740. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Signed Affidavit of Permission to Publish in National Registry transmitted with this report? Yes: <input type="checkbox"/> No: <input type="checkbox"/>	
---	--

Program Manager Name: (print)	Signature of Program Manager:	Date
--------------------------------------	--------------------------------------	-------------

RELEASE RECORD AND AGREEMENT – PERMISSION TO PUBLISH IN NATIONAL REGISTRY

I, the undersigned, am enrolling _____ as participant in the Voluntary National Retail Food Regulatory Program Standards.

I, the undersigned, confirm, that a *Self-Assessment* of the _____ Retail Food Program, has been completed in accordance with the *U.S. Food and Drug Administration (FDA) Voluntary National Retail Food Regulatory Program Standards* on _____ (date).

I, the undersigned, confirm that _____ (Name of Jurisdiction) has completed a baseline survey on the occurrence of foodborne illness risk factors.

I, the undersigned, confirm, that I have:

- Requested _____ (Auditor) perform a *Verification Audit* of the above-named Retail Food Program *Self-assessment*.
- Reviewed and agree with the findings of the *Verification Audit* report dated _____.
- Requested that the *Auditor* forward the *Verification Audit* report, dated _____, to the FDA.

On behalf of the state or local regulatory agency, permission is hereby granted to publish the following in the FDA National Registry of Retail Food Protection Programs via the Internet:

- Enrollment information
- Self-assessment findings
- Baseline survey completion date and trend, if applicable
- Verification audit findings

Public reporting burden for this collection of information is estimated to average less than 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration, Food and Drug Administration, Office of Food Safety, Retail Food and Cooperative Programs Coordination Staff (HFS – 320), CFSAN, 5100 Paint Branch Parkway, College Park, Maryland 20740. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Signed: _____ Title: _____

Jurisdiction: _____ Date: _____

**APPENDIX J - SUPPLEMENT TO STANDARD 9 – PROGRAM
ASSESSMENT**
Retail Food Program Database of Foodborne Illness Risk Factors
BASELINE DATA COLLECTION FORM

Date: _____
Time In: _____ Time Out: _____ Inspector: _____
Data Collected During: _____
Establishment: _____ Manager: _____
Physical Address: _____
City: _____ Industry Segment: _____
State: _____ Zip: _____ County: _____ Facility Type: _____

Certified Food Protection Manager: **YES NO**

_____ 41°F (5°C) or _____ 45°F (7°C) or _____ 41°F (5°C) + 45°F (7°C) is the cold holding requirement for this jurisdiction.

STATUS OF OBSERVATIONS:

- IN** = Item found in compliance (**IN** Compliance marking must be based on actual observations)
OUT = Item found out of compliance (**OUT** of Compliance marking must be based on actual observations)
NO = Not observable (**NO** marking is made when the data item is part of the establishment's operation or procedures, OR is seasonal and is not occurring at the time of the inspection)
NA = Not applicable (**NA** marking is made when the data item is NOT part of the establishment's operation or procedures)

CDC RISK FACTORS

****CDC RISK FACTOR - FOODS FROM UNSAFE SOURCE****

FOOD SOURCE

STATUS 1. Approved Source

- IN OUT** A. All food from Regulated Food Processing Plants/ No home prepared/canned foods
IN OUT NA B. All Shellfish from NSSP listed sources. No recreationally caught shellfish received or sold
IN OUT NA NO C. Game, wild mushrooms harvested with approval of Regulatory Authority

STATUS 2. Receiving / Sound Condition

- IN OUT** A. Food received at proper temperatures/ protected from contamination during transportation and receiving/food is safe, unadulterated
-
-
-

STATUS 3. Records

- IN OUT NA NO** A. Shellstock tags/labels retained for 90 days from the date the container is emptied
IN OUT NA NO B. As required, written documentation of parasite destruction maintained for 90 days for Fish products
IN OUT NA C. CCP monitoring records maintained in accordance with HACCP plan when required
-
-
-

****CDC RISK FACTOR-INADEQUATE COOK****

PATHOGEN DESTRUCTION

STATUS 4. Proper Cooking Temperature Per Potentially Hazardous Food (PHF)

(NOTE: Cooking temperatures must be taken to make a determination of compliance or non-compliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or non-compliance. If one food item is found out of temperature, that PHF category must be marked as OUT of compliance.)

- IN OUT NA NO** A. Raw shell eggs broken for immediate service cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds
IN OUT NA NO B. Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for 15 seconds
IN OUT NA NO C. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specified and according to oven parameters per Chart *(NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).*
IN OUT NA NO D. Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds
IN OUT NA NO E. Wild game animals cooked to 165°F (74°C) for 15 seconds
IN OUT NA NO F. Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165°F (74°C). Food is allowed to stand covered for 2 minutes after cooking
IN OUT NA NO G. Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds. Specify product and temperature in the space below. *(NOTE: Pork observed cooked between 145° F (63°C) and 155° F (68°C), would be marked OUT here, but marked IN under Supplemental Item 17 A. Please make notes in the comment section.)*
IN OUT NA NO H. All other PHF cooked to 145°F (63°C) for 15 seconds
-
-
-

STATUS 5. Rapid Reheating For Hot Holding

- IN OUT NA NO** A. PHF that is cooked and cooled on premises is rapidly reheated to 165°F (74°C) for 15 seconds for hot holding
- IN OUT NA NO** B. Food reheated in a microwave is heated to 165°F (74°C) or higher
- IN OUT NA NO** C. Commercially processed ready to eat food, reheated to 140°F (60°C.) or above **for hot holding**
- IN OUT NA NO** D. Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters
-
-
-

CDC RISK FACTOR - IMPROPER HOLD

LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

STATUS 6. Proper Cooling Procedure

(NOTE: Record any temperature above 41°F (5°C) on blank lines. Production documents as well as statements from managers, person- in-charge (PIC), and employees, regarding the time the cooling process was initiated, may be used to supplement actual observations.)

- IN OUT NA NO** A. Cooked PHF is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours **and** from 140°F (60°C) to 41°F (5°C) or below within 6 hours
- IN OUT NA NO** B. PHF (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
- IN OUT NA NO** C. Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours
-
-
-

STATUS 7. Cold Hold (41°F (5°C))

*(NOTE: For the purposes of this Baseline, 41° F (5°C) or below will be used as the criteria for assessing all PHF that are maintained/held cold.) If one product is found out of temperature the item is marked **OUT** of compliance.)*

- IN OUT** A. PHF is maintained at 41°F (5°C) or below, except during preparation, cooking, cooling or when time is used as a public health control. *(Record products and temperatures in the space below.)*
-
-
-

STATUS 8. Hot Hold (140° F (60°C))

IN OUT NA NO A. PHF is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control. *(NOTE: Products held between 135° F (57°C) and 140° F (60°C) should be marked OUT in 8A, but IN under supplemental item number 18A. Record actual product and measured temperatures in the space below.)*

IN OUT NA NO B. Roasts are held at a temperature of 130°F (54°C) or above

STATUS 9. Time

IN OUT NA NO A. Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)

IN OUT NA NO B. Discard RTE PHF and/or opened commercial container exceeding 7 days at ≤ 41°F (5°C) or 4 days at ≤ 45°F (7°C)

IN OUT NA NO C. Opened Commercial container of prepared ready-to-eat PHF is date marked as required

IN OUT NA NO D. When time only is used as a public health control, food is cooked and served within 4 hours as required

****CDC RISK FACTOR-CONTAMINATED EQUIPMENT****

PROTECTION FROM CONTAMINATION

STATUS 10. Separation / Segregation / Protection

IN OUT NA NO A. Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food

IN OUT NA NO B. Raw animal foods are separated from each other during storage, preparation, holding, and display

IN OUT C. Food is protected from environmental contamination – critical items

IN OUT NA NO D. After being served or sold to a consumer, food is not re-served

STATUS 11. Food-Contact Surfaces

(NOTE: This item will require some judgment to be used when marking this item IN or OUT of compliance. This item should be marked OUT of compliance if observations are made that supports a pattern of non-compliance with this item. One dirty utensil, food contact surface or one sanitizer container without sanitizer would not necessarily support an OUT of compliance mark. You must provide notes concerning an OUT of compliance mark on this item.)

IN OUT A. Food-contact surfaces and utensils are clean to sight and touch and sanitized before use

****CDC RISK FACTOR-POOR PERSONAL HYGIENE****

PERSONNEL

STATUS 12. Proper, Adequate Handwashing

IN OUT NO A. Hands are clean and properly washed when and as required

STATUS 13. Good Hygienic Practices

IN OUT NO A. Food Employees eat, drink, and use tobacco only in designated areas / do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service or single-use articles

STATUS 14. Prevention of Contamination From Hands

IN OUT NA NO A. Employees do not contact exposed, ready-to-eat food with their bare hands. *(NOTE: In determining the status of this data item, an assessment of alternative methods when otherwise approved is to be made to determine implementation in accordance with the guidelines contained in Annex 3, 2001 Food Code, page 289.)*

STATUS 15. Handwash Facilities

- IN OUT** A. Handwash facilities conveniently located and accessible for employees
IN OUT B. Handwash facilities supplied with hand cleanser / sanitary towels / hand drying devices
-
-
-

****CDC RISK FACTOR - OTHER****

FOREIGN SUBSTANCES

STATUS 16. Chemicals

- IN OUT NA** A. If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw consumption
IN OUT B. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are properly identified, stored and used
IN OUT NA C. Poisonous or toxic materials held for retail sale are properly stored
-
-
-

SUPPLEMENTAL ITEMS

(NOTE: The following items will be included as part of FDA's 2003 Baseline. These are additional items to the original 42 data items (contained in Section 1 – 16) that were assessed as part of the original baseline.)

STATUS 17. Proper Cooking Temperature (Supplement to Item 4G)

- IN OUT NA NO** A. Pork is cooked to 145°F (63°C) or above for 15 seconds. *(NOTE: Final cooking temperatures of Pork Roasts are recorded under data item 4C.)*
IN OUT NA NO B. Ratites and injected meats are cooked to 155°F (68°C) for 15 seconds
-
-
-

STATUS 18. Hot Hold (135°F (57°C)) – (Supplement to Item 8A)

- IN OUT NA NO** A. PHF is maintained at 135°F (57° C) or above, except during preparation, cooking, or Cooling or when time is used as a public health control. *(NOTE: Products held between 135° F (57° C) and 140° F (60° C) should be marked OUT in 8A. Record actual product and measured temperatures.)*
-
-
-

STATUS 19. Employee Health Policy

IN OUT A. Facility has a **written policy** that is consistent with 2-201 of the Food Code for excluding and restricting employees on the basis of their health and activities as they relate to diseases that are transmissible through food. **Written policy** includes a statement regarding employee responsibility to notify management of symptoms and illnesses identified in the Food Code

STATUS 20. Treating Juice

IN OUT NA NO A. When packaged in a food establishment, juice is treated under a HACCP Plan to reduce pathogens or be labeled as specified in the Food Code

STATUS 21. Cooling – Raw Shell Eggs

IN OUT NA NO A. After receiving, raw shell eggs are immediately placed under refrigeration that maintains ambient air temperature of 45°F (7°C) or less

STATUS 22. Cold Holding – Raw Shell Eggs

IN OUT NA NO A. After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45°F (7°C) or less

STATUS 23. Food & food preparation for highly susceptible populations

(NOTE: These items pertain specifically to those facilities that serve Highly Susceptible Populations as defined in the Food Code. Establishments would include such facility types as Hospitals, Nursing Homes and Elementary Schools.)

IN OUT NA NO A. Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served

IN OUT NA NO B. Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this Baseline Form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls Salmonella Enteritidis

IN OUT NA NO C. Raw or partially cooked animal food and raw seed sprouts not served

SHEET-MARKING INSTRUCTIONS
Retail Food Program Database of Foodborne Illness Risk Factors
Data Collection Form

Date: _____
Time In: _____ Time Out: _____ Inspector: _____
Data Collected During: _____
Establishment: _____ Manager: _____
Physical Address: _____
City _____ Industry Segment: _____
State: _____ Zip: _____ County: _____ Facility Type: _____

Certified Food Protection Manager: **YES NO**

YES marking indicates that there is a food protection manager present at the time of inspection who has been certified through a CFP recognized program.

NO marking indicates that there are NO certified food protection managers in the establishment at the time of inspection OR certification has been obtained through a program **NOT** recognized by the Conference for Food Protection.

_____ 41°F (5°C) or _____ 45°F (7°C) or _____ 41°F (5°C) + 45°F (7°C) is the cold holding requirement for this jurisdiction.

STATUS OF OBSERVATIONS:

- IN** = Item found in compliance (**IN** Compliance marking must be based on actual observations)
- OUT** = Item found out of compliance (**OUT** of Compliance marking must be based on actual observations)
- NO** = Not observable (**NO** marking is made when the data item is part of the establishment's operation or procedures, **OR** is seasonal and is not occurring at the time of the inspection)
- NA** = Not applicable (**NA** marking is made when the data item is NOT part of the establishment's operation or procedures)

CDC RISK FACTORS

****CDC RISK FACTOR - FOODS FROM UNSAFE SOURCE****

FOOD SOURCE

STATUS 1. Approved Source

_____ **A. All food from Regulated Food Processing Plants/ No home prepared/canned foods**

IN / OUT This item should be marked either IN or OUT. If it is marked OUT of compliance make notes as to why it is OUT of compliance.

_____ **B. All Shellfish from NSSP listed sources. No recreationally caught shellfish received or sold**

IN / OUT This item may be marked either **IN** or **OUT**. If it is marked **OUT** of compliance make notes as to why it is **OUT** of compliance.

NA This item is marked **NA** if no shellfish are sold at the establishment.

_____ **C. Game, wild mushrooms harvested with approval of Regulatory Authority**

IN / OUT This item may be marked either **IN** or **OUT**. If it is marked **OUT** of compliance make notes as to why it is **OUT** of compliance.

NA This item is marked **NA** if no game or wild mushrooms are sold at the establishment.

NO This item is marked **NO** if no game or wild mushrooms are in the facility at the time. Mark **NO** if game/ wild mushrooms are a seasonal or an occasional menu item but are not being used at the time of inspection.

STATUS **2. Receiving / Sound Condition**

_____ **A. Food received at proper temperatures/ protected from contamination during transportation and receiving/food is safe, unadulterated.**

IN / OUT This item may be marked **IN** or **OUT** of compliance on any one of the listed items. If the food is safe and unadulterated, but you are not able to check any temperatures of food during receiving or are not able to determine the condition of foods transported, mark the item **IN** compliance with an explanation on the lines below as to what the **IN** represents. If one or all the listed items are **OUT** of compliance, make appropriate notes as to why the item is marked out of compliance.

STATUS **3. Records**

_____ **A. Shellstock tags/labels retained for 90 days from the date the container is emptied.**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason it is marked **OUT** of compliance.

NA This item is marked **NA** if shell stock is not used in the establishment.

NO This item is marked **NO** when shellstock is a seasonal or occasional item and has not been sold or used within the establishment within the past 90 days or you were unable to determine from invoices or purchases records whether shellstock was used or sold within the past 90 days.

-
- B. As required, written documentation of parasite destruction maintained for 90 days for fish products.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if these types of fish products are not used in the establishment.
- NO** This item may be marked **NO** if fish products of this type are a seasonal or occasional item and no fish products of this type are in the facility during visit and you are unable to determine compliance through purchase records, on-site documentation or invoices.

-
- C. CCP monitoring records maintained in accordance with HACCP plan when required.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if these types of records are not required for the operation of the establishment.

****CDC RISK FACTOR – INADEQUATE COOK****

PATHOGEN DESTRUCTION

- STATUS 4. Proper Cooking Temperature Per Potentially Hazardous Food (PHF)**
- (NOTE: Cooking temperatures must be taken to make a determination of compliance or non-compliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or non-compliance. If one food item is found out of temperature, that PHF category must be marked as OUT of compliance.)*
-
- A. Raw shell eggs broken for immediate service cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** when raw shell eggs are not used in the establishment, including raw shell eggs not used in recipes.
- NO** This item is marked **NO** if raw shell eggs are used in the establishment, but you are unable to determine the cooking temperature.

	<u>B. Comminuted Fish, Meats, Game Animals (commercially raised) cooked to 155°F (68°C) for 15 seconds</u>
IN / OUT	This item may be marked IN or OUT of compliance for one or all of the types of meat, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA if no comminuted meats are used in the establishment.
NO	This item is marked NO if one or more types of meat are used, but you are unable to determine the cooking temperature for any of them.
	<u>C. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as chart specified and according to oven parameters per chart. (NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).</u>
IN / OUT	This item may be marked IN or OUT of compliance for one or all of the types of meat, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA when roasts or formed roasts are not cooked in the establishment
NO	This item is marked NO if one or more of these meat items are used, but you are unable to determine the cooking temperature for any of them.
	<u>D. Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing these items cooked to 165°F (74°C) for 15 seconds</u>
IN / OUT	This item may be marked IN or OUT of compliance for one or all of the types of stuffed items or stuffing containing these items with notes made concerning the reason it is OUT of compliance.
NA	This item is marked NA if none of the types of stuffed items or stuffing containing these items are used in the establishment.
NO	This item is marked NO if one or more of these food items are used, but you are unable to determine the cooking temperature for any of them.
	<u>E. Wild game animals cooked to 165°F (74°C) for 15 seconds</u>
IN / OUT	This item may be marked IN or OUT of compliance with notes made concerning the reason it is OUT of compliance.
NA	This item is marked NA if no wild game animals are used in the establishment.
NO	This item is marked NO if wild game animals are used, but you are unable to determine the cooking temperature for any of them.

_____ **F. Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165°F (74° C). Food is allowed to stand covered for 2 minutes after cooking.**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if raw animal foods are not cooked in a microwave.

NO This item is marked **NO** if raw animal foods are cooked in a microwave but you are unable to determine the cooking temperatures during your inspection.

_____ **G. Pork, Ratites and injected meats are cooked to 155°F (68° C) for 15 seconds.**

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the foods listed, with notes made concerning the reason it is marked **OUT** of compliance. *(NOTE: Pork observed cooked between 145°F (63°C) and 155°F (68°C), would be marked OUT here, but marked IN under supplemental item number 17. Please Make notes in the comment section.)*

NA This item is marked **NA** if NONE of the listed foods are cooked in the establishment

NO This item is marked **NO** if one or more of the listed foods are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

_____ **H. All other PHF cooked to 145°F (63°C) for 15 seconds.**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if no other PHF foods are cooked in the establishment

NO This item is marked **NO** if one or more of the food types for this category are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

STATUS **5. Rapid Reheating For Hot Holding**

_____ **A. PHF that is cooked and cooled on premises is rapidly reheated to 165°F (74°C) for 15 seconds for hot holding**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if foods are not held over for a second service.

NO This item is marked **NO** if foods are held over for a second service, but you are unable to check the reheating procedure. Do not depend solely on discussions with management or cooks to make a determination on this item.

- _____ **B. Food reheated in a microwave is heated to 165°F (74° C) or higher.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if foods are not reheated in a microwave in the establishment.
- NO** This item is marked **NO** if foods are reheated in a microwave but you were unable to make a determination of compliance.

- _____ **C. Commercially processed ready to eat food reheated to 140°F (60°C) or above for hot holding.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if commercially processed ready to eat foods are not reheated in the establishment.
- NO** This item is marked **NO** if commercially processed ready to eat foods are reheated in the establishment but you were unable to make a determination of compliance.

- _____ **D. Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if remaining unsliced portions of beef roasts are not used or reheated in the establishment.
- NO** This item is marked **NO** if remaining unsliced portions of beef roasts are reheated in the establishment, but you were unable to make a determination of compliance.

****CDC RISK FACTOR - IMPROPER HOLD****

LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

(NOTE: Record any temp above 41°F (5°C) on blank lines. Production documents as well as statements from managers, person-in-charge (PIC), and employees regarding the time the cooling process was initiated may be used to supplement actual observations.)

STATUS	6. Proper Cooling Procedure
_____	<u>A. Cooked PHF is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA if the establishment is a cook-serve establishment type or does not cool or reheat food.
NO	This item is marked NO if the establishment does cool PHF for a second service, but you were unable to make a determination of compliance.
_____	<u>B. PHF is cooled to 41°F (5°C) or below within 4 hours (prepared from ingredients at ambient temperature)</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA if the establishment has no PHF that are prepared from ingredients at ambient temperature.
NO	This item is marked NO if these types of foods are prepared, but you were unable to make a determination of compliance.
_____	<u>C. Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA if the establishment does not receive raw shell eggs, shellstock, milk or other products that have a transport temperature above 41°F (5°C).
NO	This item is marked NO if the establishment does receive raw shell eggs, shellstock, milk or other products that have a transport temperature above 41°F (5°C), but you were unable to determine if these products were cooled down as described above.

STATUS 7. Cold Hold

(NOTE: For the purposes of this Baseline, 41° F (5°C) or below will be used as the criteria for assessing all PHF that are maintained/held cold.) If one product is found out of temperature the item is marked OUT of compliance.)

_____ **A. PHF is maintained at 41°F (5°C) or below, except during preparation, cooking, cooling or when time is used as a public health control.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

STATUS 8. Hot Hold

(NOTE: If one product is found out of temperature the item is marked OUT of compliance. Record all temperatures taken.)

_____ **A. PHF is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.**

(NOTE: Products held between 135°F (57°C) and 140°F (60° C) should be marked OUT in 8.A. but IN under supplemental item number 18A. Record actual product and measured temperatures taken.)

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there is no PHF hot holding in the establishment.

NO This item is marked **NO** only in rare instances when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.

_____ **B. Roasts are held at a temperature of 130°F (54°C) or above**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if roast is not a menu item.

NO This item is marked **NO** only when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.

STATUS 9. Time

_____ **A. Ready-to- eat PHF held for more than 24 hours is date marked as required (prepared on site)**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there are no RTE PHF held for more than 24 hours

NO This item is marked **NO** when RTE PHF are held for more than 24 hours and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

_____ **B. Discard RTE PHF and/or opened commercial container exceeding 7 days at < 41°F (5°C) or 4 days at < 45°F (7°C).**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA**, such as when there is no RTE PHF prepared-on-premises, or opened commercial container held for more than 24 hours.

NO This item is marked **NO** if no date marking is done in the establishment and you are unable to determine compliance based on other information provided by PIC, manager or employees.

_____ **C. Opened commercial container of prepared ready-to-eat PHF is date marked as required.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there are no commercially prepared RTE PHF held.

NO This item is marked **NO** when commercially prepared RTE PHF are date marked and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

_____ **D. When time only is used as a public health control, food is cooked and served within 4 hours as required.**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if time is not used as a public health control.

NO This item is marked **NO** when time is used for a public health control and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

****CDC RISK FACTOR-CONTAMINATED EQUIPMENT****

PROTECTION FROM CONTAMINATION

STATUS	10. Separation / Segregation / Protection
_____	<u>A. Food is protected from cross-contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA , such as when there is a vegetarian menu or only commercially pre-cooked animal foods are used.
NO	This item is marked NO when raw animal foods are used or served seasonally and you are unable to determine compliance.
_____	<u>B. Raw animal foods are separated from each other during storage, preparation, holding, and display.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA when there are NO raw animal foods used or only one raw animal species is used
NO	This item is marked NO when raw animal foods are used or served seasonally and you are unable to determine compliance.
_____	<u>C. Food is protected from environmental contamination – critical items.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
_____	<u>D. After being served or sold to a consumer, food is not re-served.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance. <i>(NOTE: Actual observation of the disposition of unwrapped/unprotected, served food being returned to the kitchen must be made.)</i>
NA	This item may be marked NA for retail operations for which there is no opportunity for re-service of foods, such as carry-out service only in restaurants or meat, produce and seafood depts. within retail food stores.
NO	This item may be marked NO if you are not able to observe the disposition of unwrapped/unprotected foods after they have been served to the public and returned to the kitchen or food preparation area.

STATUS 11. Food Contact Surfaces

(NOTE: This item will require some judgment to be used when marking this item IN or OUT of compliance. This item should be marked OUT of compliance if observations are made that supports a pattern of non-compliance with this item. One dirty utensil, food contact surface or one sanitizer container without sanitizer would not necessarily support an OUT of compliance mark. You must provide notes concerning an OUT of compliance mark on this item.)

_____ **A. Food contact surfaces and utensils are clean to sight and touch and sanitized before use**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

****CDC RISK FACTOR-POOR PERSONAL HYGIENE****

PERSONNEL

STATUS 12. Proper, Adequate Handwashing

(NOTE: Maximum effort must be made to observe all sections of PERSONNEL.)

_____ **A. Hands are clean and properly washed when and as required.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. This item must be marked **OUT** of compliance if one person is observed with dirty hands or hands that have not been properly washed as required.

NO This item may be marked **NO** for retail operations only in the case where no food workers are present to observe, such as a retail food store produce section where the display aisle has been fully stocked prior to the inspection.

STATUS 13. Good Hygienic Practices

_____ **A. Food Employees eat, drink, and use tobacco only in designated areas / do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service or single-use articles**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. This item must be marked **OUT** of compliance if one person is observed to be out of compliance with this item.

NO This item may be marked **NO** for retail operations only in the case where no food workers are present.

STATUS	14. Prevention of Contamination From Hands
_____	<u>A. Employees do not contact exposed, ready-to-eat food with their bare hands.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance. This item must be marked OUT of compliance if one person is observed to be out of compliance with this item. <i>(NOTE: In determining the status of this data item, an assessment of alternative methods when otherwise approved is to be made to determine implementation in accordance with the guidelines contained in Annex 3, 2001 Food Code, page 289.)</i>
NA	This item may be marked NA for facilities that do not prepare ready-to-eat foods, such as retail meat or seafood department.
NO	This item may be marked NO for retail operations that prepare ready-to-eat foods only in the case where no food workers are present.

STATUS	15. Handwash Facilities
_____	<u>A. Handwash facilities conveniently located and accessible for employees.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if marked OUT of compliance.
_____	<u>B. Handwash facilities supplied with hand cleanser / sanitary towels / hand drying devices</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.

****CDC RISK FACTOR - OTHER****

FOREIGN SUBSTANCES

STATUS	16. CHEMICAL
_____	<u>A. If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw consumption.</u>
IN	This item is marked IN compliance if no unapproved additives are on site; or if sulfites are on the premises, but they are used properly.
OUT	This item is marked OUT of compliance if unapproved additives are found on premises or approved additives are improperly used, i.e. on fresh fruits & vegetables.
NA	This item is marked NA if the food establishment does not use any additives.

_____ **B. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items properly identified, stored and used.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance. It may be marked **OUT** of compliance for improper storage or use of any one of the listed items.

_____ **C. Poisonous or toxic materials held for retail sale are properly stored.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. It may be marked **OUT** of compliance for improper storage or use of any one of the items.

NA This item may be marked **NA** if the establishment does not hold “poisonous or toxic materials for retail sale.”

SUPPLEMENTAL ITEMS

(NOTE: The following items will be included as part of FDA’s 2003 Baseline. These are additional items to the original 42 data items (contained in Section 1 – 16) that were assessed as part of the original baseline.)

STATUS 17. Proper Cooking Temperature (Supplement to Item 4G)

_____ **A. Pork is cooked to 145°F (63°C) or above for 15 seconds.** *(NOTE: Final cooking temperatures of Pork Roasts are recorded under data item 4C.)*

IN / OUT This item may be marked **IN** or **OUT** of compliance for pork, with notes made concerning the reason it is marked **OUT** of compliance. Please make note of actual temperature in the comment section.

NA This item may be marked **NA** if pork is not cooked in the establishment

NO This item may be marked **NO** if pork is cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

_____ **B. Ratites and injected meats are cooked to 155°F (68°C) or above for 15 seconds.**

IN / OUT This item may be marked **IN** or **OUT** of compliance for ratites or injected meats, with notes made concerning the reason it is marked **OUT** of compliance. Make notes of actual temperatures in the comments section.

NA This item may be marked **NA** if no ratites or injected meats are prepared in the establishment.

NO This item may be marked **NO** if ratites or injected meats are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

STATUS	18. Hot Hold (135°F (57°C)) – (Supplement to Item 8A.)
_____	<u>A. PHF is maintained at 135°F (57°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.</u>
	<i>(NOTE: Products held between 135°F (57°C) and 140°F (60°C) should be marked OUT in 8A. Record actual product and measured temperatures.)</i>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item may only be marked NA if there is no PHF hot holding in the establishment.
NO	This item should be marked NO only in rare instances, when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.
STATUS	19. Employee Health Policy
_____	<u>A. Facility has a written policy that is consistent with 2-201 of the Food Code for excluding and restricting employees on the basis of their health and activities as they relate to diseases that are transmissible through food. Written policy includes a statement regarding employee responsibility to notify management of symptoms and illnesses identified in the Food Code.</u>
IN / OUT	This item must be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance. <i>(NOTE: In order to mark this item IN the establishment must have a <u>WRITTEN</u> employee health policy.)</i>
STATUS	20. Treating Juice
_____	<u>A. When packaged in a food establishment, juice is treated under a HACCP Plan to reduce pathogens or be labeled as specified in the Food Code.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason it is marked OUT of compliance.
NA	This item is marked NA when juice is not packaged in the food establishment.

STATUS **21. Cooling – Raw Shell Eggs**

_____ **A. After receiving, raw shell eggs are immediately placed under refrigeration that maintains ambient air temperature of 45°F (7°C) or less.**

IN / OUT This item may be marked **IN** or **OUT** only if you are there to observe receipt of raw shell eggs and their disposition.

NA This item is marked **NA** when the establishment does not receive raw shell eggs.

NO This item is marked **NO** only when raw shell eggs are received but you are not there to observe their actual receipt and immediate disposition OR raw shell eggs are only a seasonal item,

STATUS **22. Cold Holding – Raw Shell Eggs**

_____ **A. After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45°F (7°C) or less.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason it is marked **OUT** of compliance.

NA This item is marked **NA** when the establishment does NOT receive raw shell eggs.

NO This item is marked **NO** when raw shell eggs are received but there were no raw shell eggs on the premises at this time and you were unable to determine compliance. Additionally **NO** is marked when raw shell eggs are a seasonal or a limited use item within the establishment and none are on the premises at the time of your inspection.

STATUS **23. Food & Food Preparation for Highly Susceptible Populations**

(NOTE: These items pertain specifically to those facilities that serve Highly Susceptible Populations as defined in the Food Code. Establishments would include such facility types as Hospitals, Nursing Homes and Elementary Schools.)

_____ **A. Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

NA This item is marked **NA** if no highly susceptible population is served or if the facility does not serve any juice.

NO This item is marked **NO** if juice is served to a highly susceptible population, but no juice or packages containing juice are present within the establishment to verify compliance.

_____ **B. Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures. (specified in Section 4.0 of this Baseline Form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls Salmonella Enteritidis.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

NA This item is marked **NA** if no highly susceptible population is served or if eggs are not served

NO This item is marked **NO** if eggs are used in the preparation of foods in an establishment that serves a highly susceptible population and the preparation of eggs is not observed and no eggs or pasteurized egg /pasteurized egg products are in the establishment

_____ **C. Raw or partially cooked animal food and raw seed sprouts not served.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

NA This item is marked **NA** if raw or partially cooked animal food or raw seed sprouts are not prepared for service within an establishment that services a highly susceptible population.

**BASELINE DATA COLLECTION
REFERENCE SHEET**

1997 FOOD CODE

<p align="center">CDC Risk Factor FOODS FROM UNSAFE SOURCES Food Source</p>	<p align="center">CDC Risk Factor INADEQUATE COOK Pathogen Destruction</p>
<p>1. Approved Source</p> <p align="center"><u>Data Item - 1A</u></p> <p>3-201.11* Compliance with Food Law 3-201.12* Food in A Hermetically Sealed Container. 3-201.13* Fluid Milk and Milk Products</p> <p align="center"><u>Data Item – 1B</u></p> <p>3-201.14* Fish 3-201.15* Molluscan Shellfish 3-202.18* Shellstock Identification</p> <p align="center"><u>Data Item – 1C</u></p> <p>3-201.16* Wild Mushrooms 3-201.17* Game Animals</p>	<p>4. Proper Cooking Temperature per PHF</p> <p align="center"><u>Data Item – 4A</u></p> <p>3-401.11(A)(1)(a)* Raw Animal Foods 3-401.11(A)(2)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4B</u></p> <p>3-401.11(A)(2)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4C</u></p> <p>3-401.11(B)(1)(2)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4D</u></p> <p>3-401.11(A)(3)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4E</u></p> <p>3-401.11(A)(3)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4F</u></p> <p>3-401.12* Microwave Cooking</p> <p align="center"><u>Data Item – 4G</u></p> <p>3-401.11(A)(2)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4H</u></p> <p>3-401.11(A)(1)(b)* Raw Animal Foods</p>
<p>2. Receiving/Sound Condition</p> <p align="center"><u>Data Item – 2A</u></p> <p>3-202.11* Temperature 3-202.15* Package Integrity 3-101.11* Safe, Unadulterated, and Honestly Presented</p>	
<p>3. Records</p> <p align="center"><u>Data Item – 3A</u></p> <p>3-202.18* Shellfish Identification 3-203.12* Shellfish Maintaining Identification</p> <p align="center"><u>Data Item – 3B</u></p> <p>3.402.11* Parasite Destruction 3.402.12* Records, Creation and Retention</p> <p align="center"><u>Data Item – 3C</u></p> <p>3-502.12* Reduced Oxygen Packaging, Criteria 8-103.12* Conformance with Approved Procedures</p>	<p>5. Rapid Reheating for Hot Holding</p> <p align="center"><u>Data Item 5A</u></p> <p>3-403.11(A)* Reheating for Hot Holding</p> <p align="center"><u>Data Item 5B</u></p> <p>3-403.11(B)* Reheating for Hot Holding - Microwave</p> <p align="center"><u>Data Item 5C</u></p> <p>3-403.11(C)* Reheating for Hot Holding – Commercially Processed RTE Food</p> <p align="center"><u>Data Item 5D</u></p> <p>3-403.11(E)* Reheating for Hot Holding – Remaining sliced portions roasts Of beef</p>

**Baseline Data Collection
 REFERENCE SHEET**

1997 FOOD CODE

CDC Risk Factor IMPROPER HOLD Limitation of Growth of Organisms of Public Health Concern	CDC Risk Factor IMPROPER HOLD Limitation of Growth of Organisms of Public Health Concern
<p>6. Proper Cooling Procedure</p> <p align="center"><u>Data Item 6A</u> 3-501.14(A)* Cooling – Cooked PHF</p> <p align="center"><u>Data Item 6B</u> 3-501.14(B)* Cooling – PHF prepared from ingredients at ambient temperature</p> <p align="center"><u>Data Item 6C</u> 3-501.14(C)* Cooling – PHF receipt of foods allowed at >41° F (5° C) during shipment</p>	<p>9. Time</p> <p align="center"><u>Data Item 9A</u> 3-501.17(A)(1)(2)* Ready-to-Eat, PHF, Date Marking – On-premises Preparation <i>(Food is to be date marked at the time of preparation with the “consume by” date. This consume by date should include the day if preparation and is: (1) ≤ 7 calendar days at 41° F (5° C) or less; or (2) ≤ 4 calendar days at 45° F (7° C))</i></p> <p align="center"><u>Data Item 9B</u> 3-501.18* Ready-to-Eat, PHF, Disposition <i>(Food shall be discarded if not consumed within ≤ 7 calendar days at 41° F (5° C) or less; or ≤ 4 calendar days at 45° F (7° C))</i></p> <p align="center"><u>Data Item 9C</u> 3-501.17(C)* Ready-to-Eat, PHF, Date Marking – commercially processed food <i>(Commercially processed food containers shall be clearly marked, at the time originally opened in a food establishment, with the consume by date which is, including the day the original container is opened: (1) ≤ 7 calendar days at 41° F (5° C) or less; or (2) ≤ 4 calendar days at 45° F (7° C))</i></p> <p align="center"><u>Data Item 9D</u> 3-501.19* Time as a Public Health Control</p>
<p>7. Cold Hold (41° F (5° C))</p> <p align="center"><u>Data Item 7A</u> 3-501.16(B)* PHF, Hot and Cold Holding <i>(For the purposes of this Baseline, 41° F (5° C) or below will be used as the criteria for assessing <u>all</u> PHF that are maintained/held cold.)</i></p>	
<p>8. Hot Hold (140° F (60° C))</p> <p align="center"><u>Data Item 8A</u> 3-501.16(A)* PHF, Hot and Cold Holding</p> <p align="center"><u>Data Item 8B</u> 3-501.16(A)* PHF, Hot and Cold Holding</p>	

**Baseline Data Collection
REFERENCE SHEET**

1997 FOOD CODE

<p align="center">CDC Risk Factor CONTAMINATED EQUIPMENT Protection from Contamination</p>	<p align="center">CDC Risk Factor POOR PERSONAL HYGIENE Personnel</p>
<p>10. Separation / Segregation /Protection</p> <p align="center"><u>Data Item 10A</u></p> <p>3-302.11(A)(1)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation <i>(Separate raw animal foods from raw RTE and cooked RTE foods)</i></p> <p align="center"><u>Data Item 10B</u></p> <p>3-302.11(A)(2)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation <i>(Separate raw animal foods by using separate equipment, special arrangement of food in equipment to avoid cross contamination of one type with another, or by preparing different types of food at different time or in separate areas)</i></p> <p align="center"><u>Data Item 10C</u></p> <p>3-302.11(A)(4-6)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation</p> <p>3-304.11(B)* Food Contact with Equipment and Utensils</p> <p align="center"><u>Data Item 10D</u></p> <p>3-306.14(A)(B)* Returned Food, Reservice or Sale</p>	<p>12. Proper, Adequate Handwashing</p> <p align="center"><u>Data Item 12A</u></p> <p>2-301.11* Clean Condition 2-301.12* Cleaning Procedure 2-301.14* When to Wash 2-301.15* Where to Wash</p> <hr/> <p>13. Good Hygiene Practices</p> <p align="center"><u>Data Item 13A</u></p> <p>2-401.11* Eating, Drinking, or Using Tobacco 2-401.12* Discharges from the Eyes, Nose and Mouth 2-403.11* Handling Prohibition – Animals 3-301.12* Preventing Contamination when Tasting</p> <hr/> <p>14. Prevention of Contamination from Hands</p> <p align="center"><u>Data Item 14A</u></p> <p>3-301.11* Preventing Contamination from Hands</p>
<p>11. Food Contact Surfaces</p> <p align="center"><u>Data Item 11A</u></p> <p>4-601.11(A) & (B)* Equipment, Food Contact Surfaces and Utensils 4-602.11* Equipment Food-Contact Surfaces and Utensils - Frequency 4-701.10* Sanitization of Equipment and Utensils – Food Contact Surfaces and Utensils 4-702.11* Sanitization of Equipment and Utensils – Before Use After Cleaning</p>	<p>15. Handwash Facilities</p> <p align="center"><u>Data Item 15A</u></p> <p>5-203.11* Handwashing Lavatory-Numbers and Capacity 5-204.11* Handwashing Lavatory-Location and Placement 5-205.11* Using a Handwashing Lavatory-Operation and Maintenance</p> <p align="center"><u>Data Item 15B</u></p> <p>6-301.11 Handwashing Cleanser, Availability 6-301.12 Hand Drying Provision</p>

**Baseline Data Collection
REFERENCE SHEET**

1997 FOOD CODE

<p align="center">CDC Risk Factor OTHER Foreign Substance</p>	<p align="center">CDC Risk Factor SUPPLEMENTAL ITEMS</p>
<p>16. Chemical</p> <p align="center"><u>Data Item 16A</u></p> <p>3-202.12* Additives 3-302.14* Protection from Unapproved Additives <i>(NOTE: Regarding SULFITES – Refers to any sulfites added in the food establishment, not to foods processed by a commercial processor or that come into the food establishment already on foods)</i></p> <p align="center"><u>Data Item 16B</u></p> <p>7-101.11* Identifying Information, Prominence-Original Containers 7-102.11* Common Name-Working Containers</p> <p><i>Operational Suppliers and Applications</i></p> <p>7-201.11* Separation-Storage 7-202.11* Restriction-Presence and Use 7-202.12* Conditions of Use 7-203.11* Poisonous or Toxic Material Containers – Prohibitions 7-204.11* Sanitizers, Criteria-Chemicals 7-204.12* Chemicals for Washing Fruits and Vegetables 7-204.13* Boiler Water Additives, Criteria 7-204.14* Drying Agents, Criteria 7-205.11* Incidental Food Contact, Criteria-Lubricants 7-206.11* Restricted Use Pesticides, Criteria 7-206.12* Rodent Bait Stations 7-206.13* Tracking Powders, Pest Control and Monitoring 7-207.11* Restriction and Storage-Medicines 7-207.12* Refrigerated Medicines, Storage 7-208.11* Storage-First Aid Supplies 7-209.11* Storage-Other Personal Care Items</p> <p align="center"><u>Data Item 16C</u></p> <p><i>Stock and Retail Sale of Poisonous or Toxic Material</i></p> <p>7.301.11* Separation-Storage and Display <i>(Separation is to be by spacing or partitioning)</i></p>	<p>17. Proper Cooking Temperature (supplement to 4G – 2001 Food Code)</p> <p align="center"><u>Data Item 17A</u></p> <p>3-401.11(A)(1)* Raw Animal Foods (pork)</p> <p align="center"><u>Data Item 17B</u></p> <p>3-401.11(A)(2)* Raw Animal Foods (ratites and injected meats)</p> <hr/> <p>18. Hot Hold (135° F) (supplement to 8A – 2005 Food Code(proposed))</p> <p align="center"><u>Data Item 18A</u></p> <p>3-501.16(A)(1)* PHF, Hot and Cold Hold</p> <hr/> <p>19. Employee Health Policy</p> <p align="center"><u>Data Item 19A</u></p> <p>2-201.11 Responsibility of Person in Charge 2-201.12* Exclusions and Restrictions 2-201.13 Removal of Exclusions and Restrictions 2.201.14* Responsibility of a Food Employee or an Applicant to Report to the Person in Charge 2-201.15* Reporting by the Person in Charge</p> <hr/> <p>20. Treating Juice – 2001 Food Code</p> <p align="center"><u>Data Item 20A</u></p> <p>3-202.110 Juice Treated 3-404.11 Treating Juice</p> <hr/> <p>21. Cooling Raw Shell Eggs – 2001 Food Code</p> <p align="center"><u>Data Item 21A</u></p> <p>3-501.14(D)* Cooling</p> <hr/> <p>22. Cold Holding – Raw Shell Eggs – 2001 Food Code</p> <p align="center"><u>Data Item 22A</u></p> <p>3-501.16(B) Hot and Cold Holding</p>

**Baseline Data Collection
 REFERENCE SHEET**

CDC Risk Factor Supplemental Items	
<p>23. Food & Food Preparation for Highly Susceptible Populations – 2001 Food Code</p> <p align="center"><u>Data Item 23A</u></p> <p>3-801.11(A)(2)* Prohibited Foods</p> <p align="center"><u>Data Item 23B</u></p> <p>3-801.11(B)* Prohibited Foods 3-801.11(E)* Prohibited Foods</p> <p align="center"><u>Data Item 23C</u></p> <p>3-801.11(D)* Prohibited Foods</p>	

LEGEND

C	= Celsius
F	= Fahrenheit
RTE	= Ready-to-Eat
PHF	= Potentially Hazardous Food
R.A.	= Regulatory Authority

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 056
Issue: 2010 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 - NVEAIS Committee

Issue you would like the Conference to consider:

The CFP National Voluntary Environmental Assessment Information System (NVEAIS) Committee seeks Council II's acknowledgement of its committee report and requests that the committee members be thanked for their services and completed work.

Public Health Significance:

The public health significance of a NVEAIS would be to identify factors that can be routinely monitored by food safety programs to prevent or reduce the risk of foodborne outbreaks associated with food service establishments through the systematic collection, analysis, interpretation and dissemination of environmental data from foodborne disease outbreak investigations. In addition to its summary report, the NVEAIS Committee will submit an issue for consideration at the 2010 meeting of the Conference for Food Protection. The issue recommends that the OUTCOME statement of Standard 5 be amended to encourage regulatory programs to participate in the CDC National Voluntary Environmental Assessment Information System (NVEAIS).

Recommended Solution: The Conference recommends...:

acknowledgement of the National Voluntary Environmental Assessment Information System (NVEAIS) Committee Report, thanking the Committee members for completed work, and dissolving the committee.

Submitter Information:

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Committee
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Attachments:

- "NVEAIS Committee Final Report"
- "NVEAIS Committee Roster"
- "NVEAIS Survey Results Charge 1"
- "CDC NVEAIS Background Paper"
- "NVEAIS and CFP Support_Charge2"

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: Report - National Voluntary Environmental Assessment Information System

Council II

DATE OF REPORT: December 2, 2009

SUBMITTED BY: Ric Mathis, Committee Chair

COMMITTEE CHARGE(s):

Charge 1: Review the concept of a National Voluntary Environmental Assessment Information System (NVEAIS) as proposed in the attached CDC NVEAIS Background Paper

Charge 2: Determine how a NVEAIS could be best supported by the Conference for Food Protection.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Charge 1) *Review the concept of a NVEAIS as proposed in the attached CDC NVEAIS Background Paper*

The committee reviewed the concept of NVEAIS via teleconference, a web-based live meeting, and a face to face meeting. The following is the results of these meeting:

(a) a brief description of a NVEAIS was developed as follows:

The NVEAIS is a detailed environmental assessment database that seeks to identify factors that can be routinely monitored by food safety programs to prevent or reduce the risk for foodborne outbreaks associated with food service establishments.

This system recognizes that although much has been done to focus inspection activities within a hazard surveillance framework, many food control authorities do not have the information necessary from foodborne outbreak investigations to understand the context of reported contributing factors or the food vehicles involved. This process elicits the critical thinking skills necessary to describe exposure events by focusing on the food flow and the performance of an environmental assessment, which integrates contributing factors (what happened) with environmental antecedents (why it happened). The NVEAIS will:

- provide a detailed characterization of food vehicles and monitor food vehicle trends;
- identify and monitor contributing factors and their environmental antecedents;
- establish the basis for hypothesis generation regarding factors that may support foodborne outbreak events; and
- guide the planning, implementation and evaluation of food safety programs.

Once fully developed, the data gathered into the system seeks to provide local jurisdictions with the ability to monitor the effectiveness of control and intervention measures and allow state regulatory jurisdictions the ability to demonstrate the need for food safety programs and resources and the allocation of those resources.

(b) a survey was developed to determine usefulness of a NVEAIS to food safety programs, the feasibility of reporting environmental assessment data to CDC by food safety programs, and the acceptability of a NVEAIS by food safety program managers. The results of the survey are contained in the Attachment 1 titled NVEAIS Survey Results Charge 1

The survey results, which are based on the responses of seven of the nine State EHS-Net Food Coordinators and other deliberations, allowed the NVEAIS committee to conclude that:

1. NVEAIS is useful to food safety programs.
2. NVEAIS is a feasible mechanism for reporting environmental assessment data to CDC.
3. NVEAIS is an acceptable tool for investigating foodborne disease outbreaks on the state level and has the potential to be a valuable resource in foodborne outbreak investigation training for local health departments.

Charge 2) determine how a NVEAIS could be best supported by the Conference for Food Protection

In addressing this charge, the committee explored:

(a) the appropriateness of an amendment to Standard 5, Foodborne Illness and Food security Preparedness and Response and,

(b) the development of a recommendation and/or issue for the 2010 CFP Biennial Meeting

The committee concluded that instead of incorporating into the Program Standards (FDA Voluntary Retail Food Regulatory Program Standards) criteria, an issue will be submitted that proposes adding the following additional language (indicated in underline format) be included in the Standard 5 OUTCOME Section:

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional, or deliberate food contamination.

Regulatory programs are encouraged to also participate in the CDC National Voluntary Environmental Assessment Information System (NVEAIS). NVEAIS is designed to provide a more comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention (The following link provides additional information regarding NVEAIS: <http://www.cdc.gov/nceh/ehs/>.

See Attachment 2 titled: **NVEAIS and CFP Support Charge 2**

REQUESTED ACTION: The NVEAIS committee will submit two (2) issues at the 2010 Conference based on the recommendations of the committee. The issues are:

1. Report - Acknowledgement of the National Voluntary Environmental Assessment Information System (NVEAIS) Committee
2. Amend OUTCOME Section of Program Standards #5

Attachment:

ATTACHMENT #1 NVEAIS Survey Results Charge 1
ATTACHMENT #2 NVEAIS and CFP Support Charge 2
CDC NVEAIS Background Paper
NVEAIS Committee Roster

National Voluntary Environmental Assessment Information System (NVEAIS) Committee Roster

Committee Name: NVEAIS

Last Name	First Name	Position (Chair/Mem)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
				Maricopa County						
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Coleman	Gary	Member	industry	Underwriters Laboratories	12 Laboratory Dr. Park	Research Triangle Park	NC	27709	919-549-1732	Gary.Coleman@us.ul.com
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Fuller	Steve	Member	state	Washington State Dept. of Health	P.O. Box 47825	Olympia	WA	98504	360-236-3339	steven.fuller@doh.wa.gov
Funk	Joshua	Member	industry	KFC Technical Centers	1900 Colonel Sanders	Louisville	KY	40213	502-874-8899	Joshua.Funk@yum.com
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Mack	James	Member	state	State of Wisconsin, Dept. of Hlth. Serv.	1 West Wilson Street, P.O. Box 2659	Madison	WI	53701	608-266-8351	james.mack@wisconsin.gov
Mathis	Alaric	Chair	state	FL Dept. of Health	4052 Bald Cypress Way, Bin A08	Tallahassee	FL	32399	850-245-1011 4277	ric_mathis@doh.state.fl.us
Nicholas	David	Member	state	NY Dept. Health	547 River Street	Troy	NY	12180	518-402-7600	dcn01@health.state.ny.us
Worzalla	Diann	Member	state	FL Division of Hotels and Restaurants	1940 N. Monroe St., Northwood Centre	Tallahassee	FL	32309	850-488-1133	Diann.Worzalla@dbpr.state.fl.us
Yamnik	Dale	Member	industry	Yum! Brands	542 Eaglestone Drive	Castle Rock	CO	80104	303-708-1536	dale.yamnik@yum.com

NVEAIS Survey Results Charge 1

As a result of the April 2009 Conference for Food Protection (CFP) National Voluntary Environmental Assessment Information System (NVEAIS) Committee meeting in Atlanta, GA, a subcommittee was formed to survey the EHS-Net Food Coordinators regarding their thoughts on the EHS-Net Outbreak Study tool. EHS-Net is a collaborative forum of environmental health specialists whose mission is to improve environmental health. These specialists collaborate with epidemiologists and laboratorians to identify and prevent environmental factors contributing to foodborne and waterborne illness and disease outbreaks. EHS-Net assists State Health Departments in their efforts to improve the practice of environmental health service programs. This is accomplished by identifying environmental antecedents (underlying factors) to illness and disease outbreaks, translating findings into improved prevention efforts using a systems-based approach, offering training opportunities to current and future environmental health specialists and by strengthening the relations among epidemiology, laboratory, and environmental health programs.

The NVEAIS is being proposed as a voluntary program to augment the EHS-Net Outbreak Study which is part of the current Foodborne Disease Outbreak Surveillance System maintained by the Centers for Disease Control and Prevention (CDC) to strengthen the role of food safety authorities in foodborne disease outbreak surveillance and in turn, CDC's ability to support their foodborne disease prevention and control efforts. The purpose of a NVEAIS would be to identify factors that can be routinely monitored by food safety programs to prevent or reduce the risk of foodborne outbreaks associated with foodservice establishments through the systematic collection, analysis, interpretation and dissemination of environmental data from foodborne disease outbreak investigations.

The purpose of the subcommittee was to determine the opinion of the EHS-Net Food Coordinators regarding their view of the Outbreak Study and if it is useful, feasible and acceptable. This very select group was chosen as our study experience for several reasons. EHS-Net Food Coordinators across nine States have been coordinating the collection of environmental data for foodborne outbreaks within their State for several years. They have multiple years of experience with collecting environmental data both prior to and during the existence of the Outbreak Study, and therefore would have the best opinion on whether or not the Outbreak Study is useful, feasible and acceptable. Other States were not solicited with this survey since they do not have experience using the Outbreak Study.

Seven of the nine EHS-Net Food Coordinators responded to our survey giving us a 78% response rate. Below each survey question is a summary of the responses received by the EHS-Net Food Coordinators.

Results:

1. Who conducts the EHS-Net Outbreak Study in your State?

EHS-Net Food Coordinator 6/7 = 86%

State Health Department Staff 4/7 = 57%

Local Health Department Staff 3/7 = 43%

2. Is the EHS-Net Outbreak Study accepted as an addition to foodborne outbreak investigations by your Food Safety Program Manager(s)?

Yes 4/7 = 57%
No 1/7 = 14%
I Don't Know 2/7 = 29%

For the States which replied 'No' and 'I don't know', one has very limited experience with the Outbreak Study and did not feel they could sufficiently answer the question. The other States felt the Outbreak Study adds an extra burden of work for the Local Health Department: and in one State, the State Food Program has no involvement with foodborne outbreak investigations. However, these concerns were not expressed by the majority of the States who responded. The majority found this study as an accepted addition to their Food Safety Program. Therefore, the NVEAIS committee would recommend this as acceptable to Food Safety Program Managers.

3. Is the EHS-Net Outbreak Study a useful or worthwhile undertaking?

Yes 6/7 = 86%
No 1/7 = 14%

One State replied 'No' and stated the EHS-Net data collected does not show anything. In their opinion, the data collected doesn't seem to add any more valuable information on top of what is collected by electronic Foodborne Outbreak Reporting System (eFORS)/National Outbreak Reporting System (NORS). The outbreak study tool would be more useful if tailored to specific suspected outbreak etiologies and it appears torn between functioning as a research data collection instrument and as a tool to be used during outbreak investigations, without doing either one very well. However, these concerns were not expressed by any of the other States which responded. 86% felt the Outbreak Study is a very useful and worthwhile undertaking. A review of the Outbreak Study and the NORS form by the NVEAIS committee identified many significant differences between the data collected for the Outbreak Study and the NORS form. Given these results, the NVEAIS committee would recommend this is a useful tool for food safety programs to identify and report other environmental antecedents to foodborne outbreaks which are not reported to CDC via NORS or other reporting systems. The majority of the States stated the Outbreak Study is worth the time it takes to conduct because the data collected illustrates the factors leading up to a foodborne disease outbreak.

4. Has your State experienced any significant roadblocks in conducting the EHS-Net Outbreak Study?

Yes 2/7 = 29%
No 5/7 = 71%

The two States which reported experiencing roadblocks both described miscommunication issues and needs for improving communication amongst Epidemiology and Environmental Health staff and between Local and State offices. These issues are seen throughout the Nation, whether or not the Outbreak Study is used, and are routine issues which are part of the nature of investigating outbreaks. The majority of the States interviewed (71%) did not experience any roadblocks; therefore the NVEAIS committee would recommend this as being both a feasible and useful tool.

5. Has your State experienced any significant roadblocks entering data or working with the EHS-Net Information System in reporting data to CDC?

Yes 0/7 = 0%
No 7/7 = 100%

No States reported any significant roadblocks in entering the data or working with the EHS-Net Information System in reporting data to CDC. Therefore, the NVEAIS committee would recommend that it is feasible for food safety programs to report environmental assessment data to CDC.

6. If EHS-Net Outbreak Studies are conducted by Local Health Department staff, is the Local Health Department compensated for conducting the studies?

Some sort of Compensation 3/3 = 100%
Monetary Compensation 2/3 = 67%
Provided with field supplies 2/3 = 67%

The three States which use Local Health Department staff to conduct EHS-Net outbreak studies provide the Local Health Departments with some sort of compensation. Further discussion with these three States emphasized that the compensation is minimal. Based on their responses, and overall that NVEAIS will be a voluntary system, the NVEAIS committee recommends this as being feasible as a reporting system.

7. If Local Health Departments are compensated for conducting EHS-Net Outbreak Studies in your State, do you think conducting the studies would be possible without compensation?

Yes 2/3 = 67%
No 1/3 = 33%

For the three States which do provide the Local Health Department's with some sort of compensation to conduct the EHS-Net Outbreak Study, two of them feel that the Local Health Department can conduct it without any additional compensation and one State felt this was not possible. Since the majority of the States who provide compensation feel this study can be conducted by Local Health Department offices without any additional compensation, the NVEAIS committee recommends that it is feasible for food safety programs to collect and report environmental assessment data to CDC without receiving any additional compensation.

8. Were there any hurdles you had to overcome initially before using the new form for Foodborne Outbreak Investigations?

No 6/7 = 86%
Required additional Environmental Health and Epidemiology Training 1/7 = 14%

Only one State reported a hurdle to overcome before using the Outbreak Study tool; however this hurdle was a benefit to their program. According this EHS-Net Food Safety Coordinator, the Outbreak Study allowed them to cross train both Epidemiology and Environmental Health staff to better investigate foodborne disease outbreaks. The majority of other States stated the Outbreak Study did not provide them with any hurdles to overcome, therefore the NVEAIS committee recommends this study is acceptable, feasible and useful for food safety programs to use as part of their routine foodborne disease outbreak investigations.

9. Do you think other States would be able to conduct the EHS-Net Outbreak Study without receiving any additional compensation?

Yes **4/7 = 57%**
No **1/7 = 14%**
Don't Know **2/7 = 29%**

The majority (57%) of respondents believe the EHS-Net Outbreak Study can be completed by other states without additional compensation. The majority of these respondents stated that the information collected for the EHS-Net Outbreak Study is virtually the same as what would be collected as part of the outbreak investigation itself, and so the only additional work is that of filling out the Study form which, in and of itself, should not require additional compensation. One 'yes' respondent also stated that the Outbreak Study improved outbreak investigation techniques, and is therefore providing a service to the states, rather than acting as a burden. The one respondent who answered 'No' stated that because many states are already lacking sufficient state and Local Health Department staff, it would be difficult to expect what personnel resources they currently have to take on the task of conducting the EHS-Net Outbreak Study. Of the two respondents who answered 'Don't Know,' one stated that without additional compensation, there wasn't much incentive to conduct the Study. The other 'Don't Know,' respondent stated that their state was fairly well-funded, so for them funding wasn't a big issue, but they were concerned that in a state lacking sufficient funding, the Outbreak Study might be too much of a burden to complete. Based on these responses, the NVEAIS committee recommends this study is acceptable, feasible and useful for food safety managers to incorporate into their programs without receiving any additional compensation.

10. Do you think other States would require additional training for personnel conducting the EHS-Net Outbreak Study?

Yes **7/7 = 100%**
No **0/7**
Don't Know **0/7**

Respondents overwhelmingly answered that they believe additional training is needed for personnel conducting the EHS-Net Outbreak Study. Specific areas of training that were suggested include:

- Basics of foodborne disease outbreak investigation
- Communication and cooperative work skills
- Intent of, purpose of, interpretation of, and data entry for the Outbreak Study itself
- Illustrations of the benefit of using the Outbreak Study instrument in an outbreak investigation, and for the long-term data findings
- Identification of contributing factors

Since this training will be made available by CDC to all State and Local Health Department Officials free of charge if they participate in NVEAIS, the NVEAIS committee recommends this study is acceptable, feasible and useful for food safety managers to incorporate into their programs.

11. Do you think additional personnel, other than the inspector of the facility, will be required to complete the EHS-Net Outbreak Study?

Yes **4/7 = 57%**
No **3/7 = 43%**
Don't Know **0**

This question was answered approximately 50/50, with a majority (57%) answering 'Yes,' and 43% answering 'No.' One of the respondents, who answered 'No,' stated that the data collection in the field could be completed without additional personnel, but that the data entry and analysis would require the help of additional personnel. Of those that answered 'Yes,' the tasks suggested for additional personnel to perform include limiting the personnel to Environmental Health personnel only to minimize inconsistency, as well as having additional personnel whose sole responsibility is data entry and analysis, leaving the data collection to a separate person/group of people. Additionally, one respondent who indicated additional personnel would be required stated that epidemiologists working together with environmental health specialists were the best way to conduct the EHS-Net Outbreak Study, as different components of the Study would be best filled out by the specialists in their respective fields. The NVEAIS committee sees the team approach between Epidemiology, Environmental Health and the Laboratory as the best approach to conduct foodborne disease outbreak investigations. Based on the responses, the NVEAIS committee recommends this study to be acceptable, feasible and useful.

12. Is it feasible for the inspector of the facility who conducts the EHS-Net Outbreak Study to also perform data entry for the Study?

Yes **5/7 = 72%**
No **1/7 = 14%**
Don't Know **1/7 = 14%**

The majority (72%) of respondents answered that it was feasible in their state for the inspector who conducts the EHS-Net Outbreak Study to also perform data entry for the Study. One person who answered 'Yes,' also added that while it is feasible, they did not believe the inspector was the best person to data enter as they believe the instrument collects information beyond the data collected in the establishment by the inspector. One respondent answered 'No,' to this question, stating that they believed the workload associated with inspecting an establishment after an outbreak, as well as collecting and reporting the data for the Outbreak Study is too much of a burden. One respondent answered 'Don't Know,' to this question, stating that their experience showed that the best person to conduct the EHS-Net Outbreak Study is someone who is part of EHS-Net, not necessarily the inspector of the facility. Since the goal of the NVEAIS committee is to expand the use of the Outbreak Study outside of EHS-Net and provide free training to the staff who will be using this tool, the NVEAIS committee recommends this study to be feasible for Local Health Departments to conduct and report the data to CDC in the best method which would be even more feasible for them.

Based on the responses of seven of the nine State EHS-Net Food Coordinators, the NVEAIS committee has concluded that:

1. NVEAIS is useful to food safety programs.
2. NVEAIS is a feasible mechanism for reporting environmental assessment data to CDC

3. NVEAIS is an acceptable tool for investigating foodborne disease outbreaks on the state level and has the potential to be a valuable resource in foodborne outbreak investigation training for Local Health Departments.

Draft National Voluntary Environmental Assessment Information System: Strengthening the Role of Food-Safety Programs in Foodborne Disease Surveillance

Abstract

This document proposes and describes a national information system of environmental factors to foodborne outbreaks for review and comment by technical experts. Many information systems used to support public health surveillance activities were developed for other purposes. Food-control authorities who manage retail foodservice regulatory programs are uniquely positioned to develop and use an information system of environmental factors to foodborne outbreaks that can identify environmental factors that can be monitored by food-control authorities to prevent or reduce the risk for foodborne illness outbreaks. Such a system can also support the existing foodborne disease outbreak surveillance system in the United States. If designed using the framework of public health surveillance systems as a model, such an information system could provide a more holistic view of foodborne disease outbreaks and provide a critical data source needed to begin to measure the impact of food-safety programs.

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Introduction

Background

With an estimated 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year, foodborne illness is a significant public health issue (Mead et al. 1999). In addition to the number of illnesses, hospitalizations, and deaths caused by foodborne disease, the annual cost for six foodborne bacterial pathogens has been estimated as \$6.7 billion (Buzby et al. 1996).

A review of foodborne outbreaks occurring in 1998 and 1999 in the seven states participating in active foodborne disease surveillance through the Foodborne Disease Active Surveillance Network (FoodNet) revealed that 66% (222 of 336 outbreaks) were associated with restaurants and an additional 9% (30 outbreaks) were associated with catered events (Jones et al. 2004a). A number of case control studies involving sporadic foodborne disease cases have found that people with foodborne illness were more likely to have eaten outside the home, specifically in restaurants or other commercial foodservice establishments, than were non-ill controls (Friedman et al. 2004;(Hennessy T 1998); Kassenborg et al. 1998, 2004; Kimura et al. 2004). Reviews of foodborne outbreaks reveal that factors identified as contributing to those outbreaks include factors found in commercial foodservice establishments (e.g., poor personal hygiene, time/temperature abuse of foods) (Bryan 1978, 1988).

According to the 2008 National Restaurant Association (NRA) industry overview, 945,000 restaurant locations will have more than 70 billion meal and snack occasions (National

Restaurant Association [NRA] 2007). In the United States, 44% of adults eat at a restaurant on a typical day (Jones et al. 2004). Although foodborne disease can be linked to many other points of final service—for example, the home—food handling policies and practices in restaurants and other commercial foodservice establishments provide the greatest opportunity to affect a larger number of people. Given the potential impact of poor policies or practices in commercial foodservice establishments and the findings from the studies described previously, commercial foodservice establishments play an important role in the epidemiology of foodborne disease.

Food-Safety Programs for Commercial Foodservice

Approximately 75 state and territorial agencies and approximately 3,000 local agencies assume the primary responsibility for preventing foodborne illness and licensing and inspecting retail foodservice establishments (Food and Drug Administration [FDA] 2005a). These establishments include restaurants, delicatessens, quick-service establishments, institutional food service (e.g., schools, daycare centers, hospitals), and temporary foodservice establishments (e.g., fairs, festivals). These food-safety programs collect data through their inspection programs; most aspects and uses of those data, such as frequency of collection, collection methods, and any regulatory action taken, are mandated by local or state statutes. These statutes or food codes are often based on a federal recommended model developed by the U.S. Food and Drug Administration (FDA) called Food Code (FC). The FC is developed using a collaborative process involving all stakeholders (local, state, tribal, territorial, federal, industry, consumer groups) through the Conference for Food Protection (CFP). Through the CFP, representatives from all stakeholder groups meet once every other year to consider and develop recommendations to the FDA with regard to FC content. Local, state, territorial, tribal, and federal agencies recognize the FC as the standard for regulatory requirements and although food-

safety programs may not adopt the FC in its entirety, much of it is adopted or incorporated into food-safety programs in one form or another across the United States.

FDA and CFP members use many sources to develop the FC. Various epidemiologic data sources including foodborne outbreak investigations provide the basis for recommendations found in the FC. For instance, because foodborne outbreak investigations have repeatedly identified five major factors related to employee behavior and preparation practices in retail establishments, FDA developed control measures for the FC to address each of these factors (Food and Drug Administration [FDA] 2005a):

- improper holding temperatures,
- inadequate or undercooking,
- contaminated equipment,
- food from unsafe sources,
- poor personal hygiene

In addition to these control measures, FDA developed five key public health interventions to protect consumer health (Food and Drug Administration [FDA] 2005a):

- demonstration of knowledge,
- employee health controls,
- controlling hands as a vehicle of contamination,
- time and temperature parameters for controlling pathogens, and
- consumer advisory (for hygiene).

Food-control authorities who focus inspections on implementation of these control measures and public health interventions refer to their inspections as Hazard Analysis Critical Control Point (HACCP) inspections. Using factors that contribute to foodborne outbreaks to develop control and intervention measures and then targeting inspection focus toward implementation of these measures is the basis for one type of foodborne disease surveillance called hazard surveillance (Guzewich et al. 1997). During 2001, more than 2.5 million inspections of food establishments were conducted by state food safety programs (Smoak 2005). These inspections are based, at least to some degree, on FC control measures and intervention strategies.

Food-control authorities have a regulatory and public health mandate to prevent diseases that can be transmitted through food. This task is enormous because more than 200 known diseases are transmitted through food—causes include viruses, bacteria, parasites, toxins, metals, and prions—and the health impacts range from a mild inconvenience to death (Mead et al. 1999). The 2007 FDA Food Protection Plan outlines the increasing complexities associated with the food supply; although the plan outlines FDA’s challenges in assuring the safety of the food supply, the same challenges are reflected at the local and state levels (Food and Drug Administration [FDA] 2007). Challenges for food-control authorities’ at all governmental levels include

- an aging population that is more susceptible to foodborne illness,
- increased production and consumption of convenience foods,
- a shift from eating locally grown foods to eating foods grown across the globe, and
- additions to an ever-increasing list of diseases known to be transmitted by food.

Like all environmental public health service programs, food-safety programs exist within a public health framework that is often referred to as fragmented. For food-safety programs, this fragmentation begins with the organizational structure for food safety in this country. Food-safety responsibilities do not reside with a single agency at any government level but are scattered across a variety of federal, state, and local regulatory agencies that are often criticized for not adequately assuring the safety of the nation's food supply. From the public health perspective, the most troubling challenge for food-control authorities is the fact that

“public health surveillance and outbreak investigation programs have evolved independently from food safety programs, and current human health statistics address the questions of communicable disease control officials better than the questions of food control authorities” (International Commission on Microbiological Specifications for Foods [ICMSF] 2006).

Surveillance is the critical first step in the cycle of public health prevention (Allos et al. 2004).

Foodborne Disease Surveillance

In a four-part series of articles on foodborne disease surveillance, Guzewich, Bryan, and Todd (Bryan et al. 1997a, 1997b; Guzewich et al. 1997; Todd et al. 1997)

- describe the purpose and types of surveillance systems and networks
- summarize and present descriptive data and epidemiologic patterns,
- summarize and present data on vehicles and contributory factors, and
- describe dissemination and uses of surveillance data.

Medical and scientific literature provides little information or guidance on developing foodborne disease surveillance systems, improving presentation of tabular data, or using the data to improve food-safety programs (Guzewich et al. 1997). This series of articles on surveillance helped fill that void with an emphasis on the data to collect, its review and inclusion in a surveillance dataset, its presentation, and how it can be used to improve food-safety programs.

In the first article of the series, Guzewich et al. (1997) describes at least four types of foodborne disease surveillance—reports of incidents (includes outbreaks), laboratory isolation of pathogens from human beings, sentinel community studies, and hazard surveillance—all of which are currently under way in the United States in some form (Figure 1).

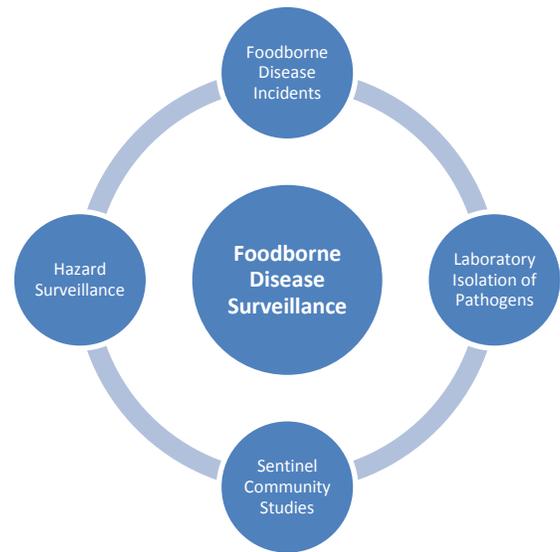


FIGURE 1

The Centers for Disease Control and Prevention (CDC) conducts surveillance of food-related diseases through 20 systems. Three of those systems are the key pillars of foodborne disease surveillance in the United States:

- Foodborne Disease Outbreak Surveillance System (FDOSS): Data from foodborne disease outbreaks (FBDOs; defined as the occurrence of two or more cases of a similar illness resulting from the ingestion of a food in common) are reported through FDOSS to CDC by state, local, and territorial health departments (Lynch et al. 2006).

- FoodNet: FoodNet conducts active surveillance for seven bacterial and two parasitic diseases to determine more precisely the frequency and severity of foodborne diseases in the United States, monitor trends in specific foodborne diseases, and determine the proportion of foodborne disease attributable to specific foods (Allos et al. 2004). FoodNet is a collaborative effort by CDC's Emerging Infections Program, U.S. Department of Agriculture's (USDA's) Food Safety Inspection Service, FDA, and nine state health departments.
- PulseNet: PulseNet is a network of laboratories that are able to identify and electronically share genetic DNA fingerprints of specific pathogens, enhancing the ability to detect, investigate, and control geographically distant yet related foodborne outbreaks (MMWR 1999). PulseNet supports the activities of both FoodNet and FDOSS.

Independently as well as collectively, these surveillance systems have provided guidance to food safety programs in their foodborne disease prevention efforts. For instance, these surveillance systems have played a role in identifying healthy food animals as reservoirs of foodborne pathogens, linking apparently unrelated illnesses with specific food vehicles, and identifying food vehicles previously unassociated with foodborne illness (MMWR 1999). These systems also represent three of the four types of foodborne disease surveillance systems as described by Guzewich et al (1997): reports of incidence (outbreaks), laboratory isolation of pathogens from human beings, and sentinel community studies.

The fourth type of foodborne disease surveillance, hazard surveillance, is the assessment of the occurrence of, distribution of, and secular trends in the prevalence of hazards (e.g., toxic

chemical agents, physical agents, biomechanical stressors, and biologic agents) responsible for disease and injury (Guzewich et al. 1997). Although the authors stated that hazard surveillance is not commonly practiced for foodborne disease concerns, they concluded that it is suited for that purpose. At about the same time the four-part series of articles was written in 1997 (Bryan et al. 1997a, 1997b; Guzewich et al. 1997; Todd et al. 1997), food-safety control authorities had been in the midst of a shift from inspections based on general sanitation (a focus on cleanliness of floors, walls, and ceilings) to a focus on factors that have been previously associated with foodborne outbreaks, such as time/temperature abuse of foods and employee health. These factors are referred to collectively as contributing factors.

Today, as a result of FDA's leadership through the CFP, the FC, the National Voluntary Retail Food Regulatory Program Standards, FDA's periodic reports on the occurrence of foodborne illness risk factors, and the individual independent initiative of food-control authorities, the inspection focus of many food-safety programs has moved from basic sanitation to contributing factor-based inspections of foodservice establishments. Although this shift to contributing factor-based inspections is not by any means uniform across all food-safety programs, it does represent a significant step toward laying the ground work for a national hazard surveillance system of factors linked to foodborne outbreaks. In fact, a CFP committee was formed to explore electronic data capture and sharing of data from state and local inspection programs. The committee's 2007 report to the CFP Executive Board revealed that approximately 74% of those responding to a survey of potential participants expressed some level of willingness to participate in sharing inspection data (Cannon and Lancaster 2007). If a data sharing arrangement evolves from this committee's work, it could be a precursor to a national hazard surveillance system that could be

used along with other epidemiologic data sources to measure the impact of food-safety programs on foodborne disease (International Commission on Microbiological Specifications for Foods [ICMSF] 2006).

Foodborne Disease Outbreak Surveillance

In 2006, the International Commission on Microbiological Specifications for Foods (ICMSF) published a position paper to describe epidemiologic data that are useful for evaluating the public health impact of food safety control programs and to identify how epidemiologic data can be used in the evaluative process (International Commission on Microbiological Specifications for Foods [ICMSF] 2006). The position paper states that the collection, synthesis, and analysis of data from a variety of sources are required to evaluate food-safety control programs. Foodborne outbreak investigations are one of those sources. One of the key elements of foodborne outbreak investigations is to identify the suspect food and factors that contribute to foodborne transmission of specific pathogens. According to the position paper, these data elements are infrequently determined by human disease surveillance systems, and they are critical for food-safety program evaluation.

Since 1973, CDC has maintained FDOSS for collection and periodic reporting of data on the occurrence and causes of FBDOs in the United States (Lynch et al. 2006). This surveillance system represents an important source for information on foodborne outbreak investigations in the United States and it includes information on identified food vehicles and contributing factors. Data from this public health surveillance system influenced FDA's development of control measures and intervention strategies for the FC. Until 1999, contributing factor data reported to CDC were reported in the five categories described earlier (improper holding temperatures,

inadequate or undercooking, contaminated equipment, food from unsafe sources, and poor personal hygiene; an 'other' category was also included). In October 1999, CDC revised the outbreak reporting form, expanding the range of food items, places, and contributing factors that could be reported (Lynch et al. 2006). There have been other efforts to improve FDOSS; for instance, beginning in 2001, foodborne outbreak reports could be submitted to CDC electronically (Lynch et al. 2006). The surveillance summary for 1998-2002 noted a substantial increase in the average annual number of outbreaks reported during that time period (Lynch et al. 2006). Although the majority (67%) of reports did not note an etiology, the proportion of outbreaks for which an etiology was determined increased during the reporting period from 28% in 1998 to 37% in 2002 (Lynch et al. 2006). Even with these improvements, in many of the FBDOs reported, the factors most important to food-safety programs, such as the implicated food vehicle or the factors that may have contributed to the outbreak, are missing or incomplete (Lynch et al. 2006).

Food-control officials are faced with a challenging mission, as are state and federal officials involved with foodborne outbreak surveillance. Two basic challenges for CDC are the fact that not all foodborne outbreaks are reported to CDC and balancing between the needs of FDOSS data users and the practical aspects of reporting.

The contributing factor category of data reported to FDOSS is a good example of the difficult balance among user needs, identification of data to include, willingness of officials to report, and accuracy of officials' reports. Before October 1999, contributing factor data was reported and summarized into five categories. Although the information was used by food-control authorities,

the broad categories did not fully meet their needs. The 1997 articles by Bryan et al., Guzewich et al., and Todd et al. (Bryan et al. 1997a, 1997b; Guzewich et al. 1997; Todd et al. 1997) framed foodborne disease surveillance systems in terms of the key end user—those charged with foodborne disease prevention. One article was devoted to data on vehicles and contributory factors and described the value and limitation of these data as well as how they can be summarized and presented (Bryan et al. 1997b). The article included a recommended list of specific contributing factors to be reported. CDC incorporated these contributing factors into the new FDOSS reporting form in October 1999. An additional factor, glove-handed contact by handler/worker/preparer, was added. Clearly this was an effort by FDOSS staff to try to meet the needs of data users.

With rare exception, communicable disease control officials or foodborne outbreak surveillance officials from state and local health departments report data into the FDOSS. They gather information on contributing factors in outbreaks from the environmental assessments conducted by food-control officials, from their own environmental assessments, or through some combination of the two. Although it may seem that the new contributing factors require little explanation, they are a sophisticated listing of factors based on the known microbiologic characteristics of and symptoms produced by specific pathogens, toxins, chemicals, etc., and historical associations between known pathogens, etc, and specific food vehicles. These factors, whether they are reported based on etiology identification or vehicle identification—or both—cannot be identified via a food-safety program inspection as conducted on a day-to-day basis by food-control authorities. The process of identifying contributing factors has to be driven by first describing what and how events likely unfolded, rather than by identifying regulation violations.

Failures to implement regulatory requirements will come to light over the course of this process. Unfortunately, many food-control authorities fail to adjust their day-to-day regulatory inspection process to adequately conduct an environmental assessment in the course of a foodborne outbreak investigation; therefore, contributing factors are not adequately assessed and reported.

Although CDC adjusted the FDOSS reporting form to address the needs of system users with regard to contributing factor data, the change is not without controversy among those who report and use this information. There are questions about whether food-control authorities have the expertise to accurately identify the most likely contributing factors from among the now complicated list of factors. Some believe the contributing factor list is too complex for a surveillance system and should be removed in its entirety or returned to the pre-1999 abbreviated list.

A brief review of the contributing factors reported in the 1998-2002 foodborne outbreak surveillance summary by Lynch et al. (2006) provides a glimpse of the concerns regarding contributing factor data. According to this summary, 657 norovirus outbreaks were identified and reported to CDC from 1998 to 2002. When contributing factors were reported, contamination factors were identified in 312 outbreaks, proliferation factors were reported in 28 outbreaks, and survival factors were reported in 319 outbreaks¹. People are the only known reservoir for Norwalk virus (norovirus) (Benenson 1995). Its mode of transmission is fecal-oral; the most likely factors contributing to norovirus outbreaks are infected persons touching ready-to-eat foods; shellfish harvested from sewage polluted waters; inadequate sewage disposal; and use of

¹ More than one contributing factor can be reported in any one outbreak. Contamination factors introduce or otherwise permit contamination. Proliferation factors allow proliferation of etiologic agents. Survival factors can allow survival of contaminants.

contaminated water (International Association for Food Protection [IAFP] 1999). Norovirus can be best prevented by using hygienic measures applicable to diseases transmitted via fecal-oral route and cooking foods that might be contaminated (e.g., raw shellfish harvested from contaminated water) (Benenson 1995). Contamination factors should be the most likely category of contributing factors to be noted in a norovirus outbreak; survival factors are possible contributing factors in some instances. Proliferation factors are not a contributing factor in a norovirus outbreak, yet proliferation factors were reported in 28 outbreaks. In addition, it is curious that more survival factors are reported than contamination factors for these norovirus outbreaks. This raises significant questions about the validity of the contributing factor data reported through FDOSS.

In addition to the challenge of balancing needs of users with reporting, FBDOs recognized and investigated by state and local food-control authorities are not all reflected in FDOSS. A 2002 survey conducted by the Association of Food and Drug Officials (AFDO) revealed that during 2001, state food-safety programs performed more than 3,000 foodborne illness investigations and investigated 46,000 consumer complaints (Smoak 2005). The AFDO report does not define foodborne illness investigations as foodborne outbreaks; however, only 1,243 foodborne outbreaks were reported to CDC for this time period (Lynch et al. 2006). A December 2006 report on food safety by the Center for Science in the Public Interest notes that 9% of outbreaks included in its report came from sources other than CDC (De Waal et al. 2006). Higgins reported that the state of Colorado did not report any cases of foodborne disease in 1986 and 1987, yet a review of records from six county health departments in Colorado revealed 52 possible foodborne outbreaks in 1986 and 67 in 1987 (Higgins 1994). Some of the local reports of these

possible outbreaks included information such as laboratory confirmation of pathogens and fairly complete epidemiologic information. Higgins found that local food-safety programs only reported possible foodborne outbreak events to state public health agencies when the events seemed 'significant.' Although this review took place in the early 1990s using data that is now 20 years old, it is not unlikely that the same scenario is playing out nationally in some form even today.

Hazard Surveillance

In addition to foodborne disease outbreak surveillance, hazard surveillance is considered part of the overall foodborne disease surveillance system. Current hazard surveillance activities conducted by food-control authorities in the form of HACCP inspections are often frustrating because violations and repeat violations frequently occur in the same establishments. For example, the 2004 FDA report (Food and Drug Administration [FDA] 2004) on the occurrence of foodborne illness risk factors identified poor personal hygiene in 31% of the agency's personal hygiene observations in fast food restaurants and almost 42% of its observations in full-service restaurants. Improper holding and time/temperature abuse was noted in almost 64% of observations of these events in full-service restaurants and almost 42% in fast food restaurants. In a review of 4,044 restaurant inspection records from 31 counties in Oklahoma, Phillips reported that repeat violations of the food-safety regulations accounted for about half of all violations recorded (Phillips et al. 2006).

The self-reported food-handling practices of foodservice workers also indicates that lapses in safe food handling practices are not infrequent events. In one study (Green et al. 2005), 60% of workers reported not wearing gloves when handling ready to eat foods. They also reported not

always washing their hands (23%), not always changing their gloves between handling raw meat and ready to eat food (33%), not using thermometers to check food temperatures (53%), and working while sick with vomiting or diarrhea (5%).

Although unsafe food-handling practices are frequent occurrences acknowledged by foodservice workers and food-control authorities identify and record them repeatedly, little if any context for these practices exists in inspection reports. Higgins states that food-safety violations or lapses exist within the very complex system a restaurant or other foodservice establishment represents. He suggests violations must be understood within the context of the system before sustainable changes in the implementation of basic prevention measures can be achieved (Higgins and Hartfield 2004).

In Buchholz's effort to identify restaurant characteristics that may be more likely to be associated with foodborne incident reporting in Los Angeles County, California, one study limitation included lack of information concerning the restaurant (e.g., number of meals served per day, menu complexity, preparation of meals for multiday use, egg-pooling practices, type of ownership, ethnicity of cuisine, and presence of a certified food handler on the shift) (Buchholz, Run et al. 2002). Thus, although inspection programs may focus on contributing factors, they must also record some context of their occurrence. The same is true of the environmental assessment conducted during foodborne outbreak investigations. Identification of one or two contributing factors, their occurrence lifted out of context, helps form a cycle of prevention activities that may or may not hit the foodborne disease prevention mark.

Problem

Foodborne disease surveillance is an essential component of a food safety program (Todd et al. 1997). Surveillance information is used to determine the need for food-safety actions, which involves planning and implementing programs and assessing the effectiveness of the actions taken (Todd et al. 1997). Hazard surveillance and foodborne outbreak investigations are two components of the foodborne disease surveillance system where food safety programs have a significant role. Although much has been done to focus their inspection activities within a hazard surveillance framework, food control authorities do not have the information necessary from foodborne outbreak investigations to understand the context of reported contributing factors or the food vehicles involved.

CDC's FDOSS is an excellent source of information on foodborne disease outbreaks, but it can only capture a small portion of the information on outbreaks that is required by food-control authorities to formulate food-safety actions. The entire burden of meeting the needs of food-control authorities for environmental data from foodborne outbreaks cannot rest on state and federal communicable disease control or foodborne outbreak investigation authorities alone. Food-control authorities responsible for food safety in foodservice establishments often do not take active roles in foodborne outbreak investigations; when they do, they focus on agent and vehicle identification over identification of contributing factors and their antecedents. Many think in terms of the five contributing factors to foodborne outbreaks and are not aware of the complex list of contributing factors now available for reporting purposes. Additionally, many have not received training on identifying contributing factors from outbreak environmental assessments. Even if they are trained and active in the environmental assessment of foodborne outbreak investigations, many food-control authorities have no way to capture information from

these investigations that will enable them to formulate food-safety action or measure food-safety program impact. If a system for capturing the data existed, most food-safety programs do not have the epidemiologic capacity to analyze, interpret, and present data collected and incorporate the information into the foodborne disease surveillance system that could support food-safety action or measurement of food-safety program impact.

According to a survey of CFP members, the number of food establishments a food safety program is responsible for ranges from 7 to 50,000, with a median of 600 (Cannon and Lancaster 2007). Foodborne outbreaks may not be recognized and investigated very often in any one food-safety program's jurisdiction. Even if food-control authorities were trained and active in environmental assessments of foodborne outbreak investigations and had the necessary epidemiologic capacity, foodborne outbreak events for most programs do not happen often. Thus, the quantity of data needed for meaningful analysis and use at the local level is inadequate.

Solution

To address the need for detailed environmental assessment data from foodborne disease outbreaks, a national voluntary environmental assessment information system (NVEAIS) is proposed to operate in conjunction with the existing CDC Foodborne Disease Surveillance System. Two articles will be used as models to justify the addition of this information system to the public health arena and to describe its proposed operation and attributes: one article describes a national public health surveillance system and its specifications (Meriwether 1995) and the other describes the evaluation of public health surveillance systems (MMWR 2001).

The purpose of an NVEAIS would be to identify factors that can be routinely monitored by food-safety programs to prevent or reduce the risk for foodborne outbreaks associated with foodservice establishments. Proposed objectives of the NVEAIS are to

- establish a detailed characterization of food vehicles and monitor food vehicle trends;
- identify and monitor contributing factors and their environmental antecedents;
- establish the basis for hypothesis generation regarding factors that may support foodborne outbreak events; and
- guide the planning, implementation, and evaluation of food-safety programs.

Stakeholders

Stakeholder involvement in the design and establishment of an NVEAIS must be broad. It must include food-safety program officials at all levels of government, officials responsible for communicable disease control and/or foodborne outbreak investigation, industry groups, and consumers. Stakeholder involvement can be facilitated through five avenues:

- Conference for Food Protection (CFP)
- Association of Food and Drug Officials (AFDO)
- Council to Improve Foodborne Outbreak Response (CIFOR)
- CDC's National Center for Environmental Health (NCEH)
- CDC's National Center for Zoonotic, Vector and Enteric Diseases (NCZVED).

Conference for Food Protection

CFP is a nonprofit organization established in 1971. The goal of the Conference is to identify problems, formulate recommendations and develop practices that promote food safety and consumer protection. It provides a unique opportunity for the balanced consideration of Issues in a deliberative forum. Issues may be submitted by anyone with a food safety or food protection

concern. Once issues are accepted they are assigned to one of three Councils for deliberation.

The resulting Council recommendations are then sent to the Assembly of State Delegates, the

official voting body of the Conference. Approved Conference recommendations may be

incorporated into the FDA FC and offered for adoption by regulatory agencies to help establish

nationwide uniformity. A Conference is convened every two years with work being carried on by

committees and the Executive Board between the biennial meetings. (CFP 2008)

In addition to developing recommendations to FDA regarding its FC, CFP plays an important

role in the development of recommendations to FDA regarding FDA's Draft Voluntary National

Retail Food Regulatory Program Standards (program standards). There are nine program

standards that range from regulatory foundation to program assessment. Standard 5, Foodborne

Illness and Food Security Preparedness and Response, applies to the surveillance, investigation,

response, and subsequent review of alleged food-related incidents and emergencies, either

unintentional or deliberate, which result in illness, injury, and outbreaks (Food and Drug

Administration [FDA] 2005b). This standard provides a natural framework within which

stakeholder involvement can be focused and decisions can be reached about the establishment

and operation of an NVEAIS.

As a deliberative forum for those concerned with food safety issues and its process for

consideration of issues, CFP provides the best avenue for stakeholder involvement in a

discussion of the establishment an NVEAIS.

Association of Food and Drug Officials

AFDO successfully fosters uniformity in the adoption and enforcement of science-based laws, rules, and regulations regarding food, drug, medical devices, cosmetics, and product safety (Smoak 2005). It has a 100-year history as a major voice for food and drug officials in the United States and Canada. Some food-control officials participating in AFDO often are involved in CFP as well, others are not; thus, AFDO is a key stakeholder group representing food-control authorities. An avenue of engagement with AFDO regarding the NVEAIS could be through its committee on food.

Council to Improve Foodborne Outbreak Response

CIFOR is a collaborative forum composed of epidemiologists, environmental health specialists, and laboratory scientists from local, state, and federal agencies. CIFOR is co-chaired by the Council of State and Territorial Epidemiologists (CSTE) and the National Association of County and City Health Officials (NACCHO). Members include representatives from CSTE, NACCHO, CDC, Association of State and Territorial Health Officials (ASTHO), National Environmental Health Association, Association of Public Health Laboratories (APHL), FDA, and USDA.

”CIFOR was created to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. The agenda includes improving the performance and coordination of relevant local, state, and federal public health agencies involved in epidemiology, environmental health, laboratory sciences, and regulatory affairs” (National Association of County and City Health Officials [NACCHO] 2007).

This group will provide an avenue of engagement with not only food safety program leaders but communicable disease control and foodborne outbreak investigation authorities as well.

Centers for Disease Control and Prevention

CDC's NCZVED and NCEH are also stakeholders. FDOSS is managed within NZVED and involvement and support by staff representatives of that surveillance system will be important in NVEAIS development and integration with FDOSS.

The prototype for NVEAIS emerged from the activities of the Environmental Health Specialists Network (EHS-Net) program in NCEH. EHS-Net was formed to conduct research on the environmental causes of foodborne illness and improve the practice of environmental health in relationship to foodborne illness prevention. EHS-Net is a network of environmental health specialists and epidemiologists at NCEH, FDA, USDA, and nine state health departments (California, Colorado [2000–2004], Connecticut, Georgia, Iowa, Minnesota, New York, Oregon, Rhode Island, and Tennessee). (<http://www.cdc.gov/nceh/ehs/EHSNet/default.htm>)

The genesis for NVEAIS was sparked by EHS-Net's Foodborne Illness Outbreak Study (unpublished). The study objective was to identify contributing factors to foodborne illness outbreaks in food-service facilities and to describe the characteristics, policies, and practices of those facilities. Much has been learned from this study that can be used in the development of NVEAIS. Because EHS-Net has played a significant role in the genesis of the proposal for an NVEAIS, it is expected to provide continued recommendations and guidance to CDC as the collaborative process with all stakeholders unfolds.

System Specifications

Justification

The systematic collection, analysis, interpretation, and dissemination of environmental data from foodborne disease outbreak investigations will support the overall foodborne disease surveillance system in the United States, strengthening the ability of food-control authorities at all levels of government to formulate food safety action and assess the effectiveness of those actions.

Potential justifications for an NVEIS include

- informing the need for regulatory or other appropriate actions to assure the safety of the food supply,
- better understanding food vehicles,
- developing, and/or modifying program policies and/or regulations,
- informing training programs for environmental health specialists regarding contributing factors to outbreaks, and
- measuring the impact of food safety programs.

Resources

A number of existing resources developed through EHS-Net can be used to support an NVEAIS, including the experience of this group in its focus on environmental assessment during foodborne outbreak investigations. For instance, EHS-Net has developed a systematic approach to the environmental assessment in an outbreak investigation, gained experience on what data should be collected, and gained experience determining what data can be collected with the least burden on food-control authorities and still be meaningful. Other experience and resources include the following.

- The Foodborne Illness Outbreak Study provides a model for a protocol and data collection instrument with specific data collection instructions.

- CDC is developing training materials for EHS-Net participants on how to conduct the environmental assessment during foodborne outbreak investigations and how to report data to CDC to support the outbreak study. This material could be a resource for those participating in an NVEAIS and serve as one means to ensure high-quality data.
- CDC has developed a Web-based application to support EHS-Net's data collection activities (<http://www.cdc.gov/nceh/ehs/EHSNet/ehsnis.htm>). This system has the capacity to support an NVEAIS.
- NCEH resources can support the analysis and dissemination of the data collected from environmental assessments and can support analytic studies triggered by the NVEAIS data.
- CDC staff will see that all federal requirements such as Office of Management and Budget requirements are met.

These are a few resources that are available through CDC to support an NVEAIS. State and local food-control agencies from California, Florida, New York, Washington and others with experience collecting and using the type of data to be captured through an NVEAIS represent a wealth of experience that could inform the development of an NVEAIS. A dialogue on NVEAIS could reveal other resources.

System Goals

With the size of the foodservice establishment inventory for any one food-safety program ranging from 7 to 50,000, it may be difficult to articulate a generic goal for an NVEAIS at the local level. Generally, the primary goal of NVEAIS at the local level would be to monitor the effectiveness of control and intervention measures. In addition to this goal for the local level, the

state level goals would be to demonstrate the need for food-safety programs and resources and to allocate resources. At the national level, NVEIAS' primary goals would be to judge the effectiveness of control and intervention measures from a national perspective and to develop hypotheses that can lead to analytic studies about environmental risk factors for foodborne outbreaks.

Case Definition

There is no case definition for NVAIS because it does not relate to ill people but rather foodservice establishments involved in outbreaks. The definition of a foodborne outbreak will be the same as that used by FDOSS: the occurrence of two or more cases of a similar illness resulting from the ingestion of a food in common (Lynch et al. 2006). Foodborne outbreaks can be identified in a number of ways via the federal, state, or local level, but generally the environmental assessment is conducted at the local level. Reporting will likely be dependent primarily on local food-control authorities. The data collected will be primarily from the environmental assessment of the foodborne outbreak investigation. Initially, NVEAIS would be considered a temporary system with an evaluation of the system planned after a 5-year period. Evaluation results could inform a decision as to whether it should become permanent.

System Operation

Foodborne outbreak events range from local events that are detected and investigated at the local level by a single agency to large multistate events involving local, state, and federal levels and a number of agencies (Figure 2). Food-control

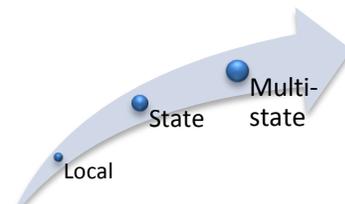


FIGURE 2

authorities involved may reside in an agriculture department or a public health agency or both.

An outbreak investigation does not occur in a linear fashion. Initially most of the energy of the investigation is focused on the epidemiologic aspects of establishing person, time, and place (Hedberg 2007). Place identification, efforts to identify the mode of

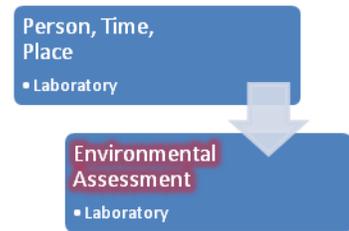


FIGURE 3

transmission and food vehicle initiates involvement of food-control authorities (Hedberg 2007). Determining contributing factors, conducting regulatory tracebacks, and implementing control measures are aspects of the environmental assessment and are led by food-control authorities (Hedberg 2007). Although data from clinical samples may help identify an outbreak event, once the investigation begins, information from laboratory analysis of clinical and environmental samples may support both the epidemiologic and environmental aspects of the investigation (Figure 3).

The steps in the environmental assessment information system begin with engagement of food-control authorities in a foodborne outbreak investigation, followed by the environmental assessment, the reporting of assessment data into NVEAIS, and, finally, feedback to stakeholders (Figure 4).

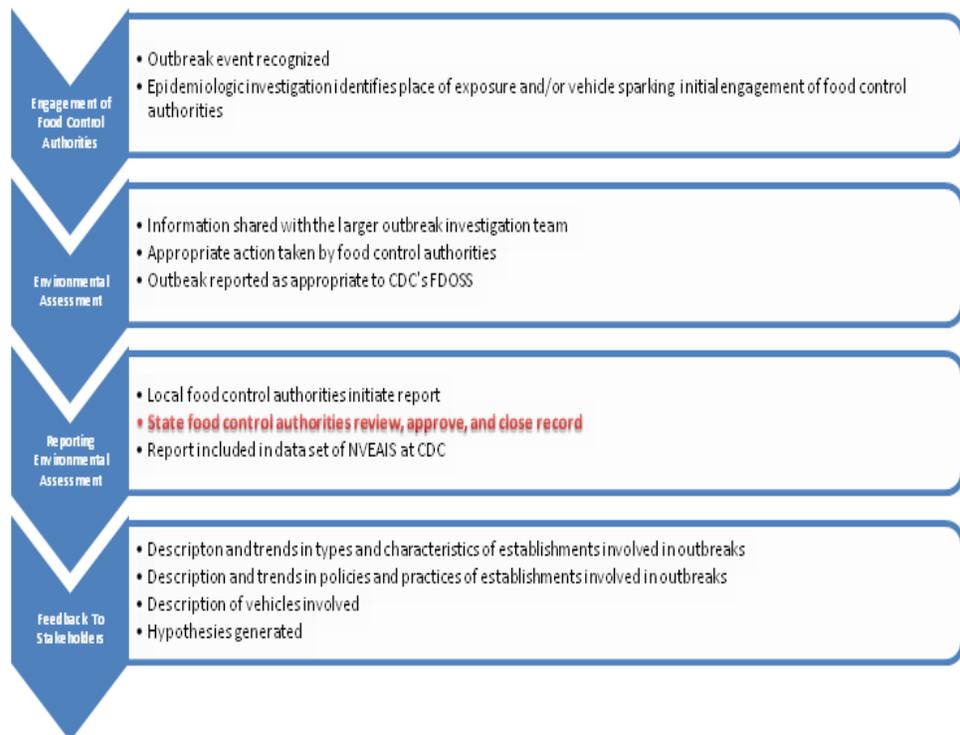


FIGURE 4

The process does not impact on the food control authorities' involvement on the larger foodborne outbreak investigation team or on the reporting of outbreaks to CDC's FDOSS by communicable disease control authorities. Generally, environmental assessments occur at the local level; thus, in the majority of events, local food-control authorities report environmental assessment data to the state food-control authorities. State food-control authorities review the assessments and work with local authorities where clarification is needed and communicate with disease control authorities as appropriate regarding epidemiologic data needed for the NVEAIS report. In the process, state food-control authorities assure that state communicable disease authorities are aware of outbreak events if the foodborne outbreak was locally contained, with the entire foodborne outbreak investigation conducted by local food-control authorities. At this point, the report will be included in the NVEAIS dataset where data can be analyzed, linked to CDC FDOSS as appropriate, and disseminated (Figure 5).

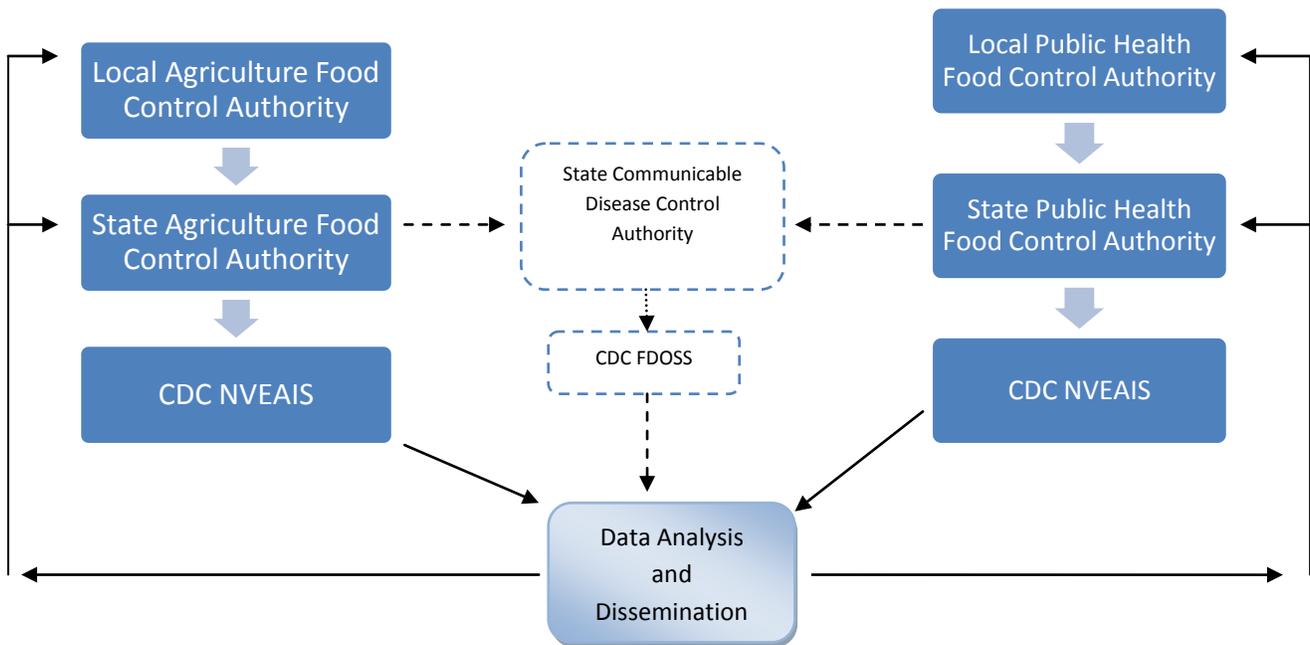


Figure 5

Data flow for the entire NVEAIS process occurs via the CDC Web application developed for EHS-Net data collection activities. The application complies with CDC and U.S. Department of Health and Human Services system security policies. No individual personal information is reported to NVEAIS. No information is reported regarding the identity of an outbreak establishment, but a code is assigned by the Web application to the environmental assessment record submitted by the state. CDC NVEAIS data are subject to the Freedom of Information Act and record codes are releasable. States may receive subsequent requests for outbreak establishment identity, but release of identifying establishment information regarding specific establishments involved in outbreaks is subject to the laws of the reporting state.

The Web application is maintained and administered by CDC NCEH staff (Figure 6). A standardized data collection instrument is posted on the Web. State food-control agencies apply to use the application. Approval is based on completion of an orientation on the Web application and training regarding environmental assessments and the data collection instrument. Once training is complete, the state food-control authority is given a group account with all administrative rights for that group. A group administrator can add and/or delete users and assign access rights as may be appropriate for the user.

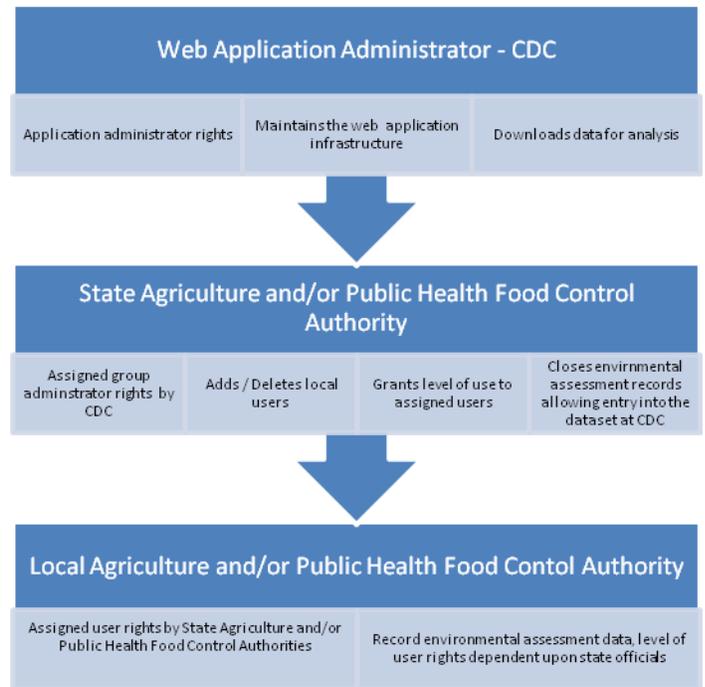


FIGURE 6

For example, read-only status may be appropriate for some users (e.g., the communicable disease control authority), whereas a read and write (data entry) status may be appropriate for other users (e.g., the local food control authority). Only the state food-control authority (group administrator) can close an environmental assessment record. As system administrator, CDC staff can only see that the group administrator has a record in process. Data from that record does not become a part of the dataset at CDC until the group administrator closes the record.

The state food control authority assigns user status and level of use for the local food and/or communicable disease control authorities. Input of environmental assessment data at the local level makes the entire reporting system a paperless process. With data entry taking place at the level where the actual environmental assessment was conducted, the clearest picture of circumstances for a specific assessment is more likely to be preserved. This arrangement may also reduce data entry errors. Ultimately, state food-control authorities are responsible for data quality of the environmental assessment records they close.

As group administrators, food-control authorities have full access to the data entered in the Web application by their assigned users. Data can be downloaded and analyzed by the group administrator to monitor and/or assess trends at the state level. In addition, the group administrator can monitor data quality provided by individual users, which may help identify general foodborne outbreak investigation training needs; specifically, training gaps in the environmental assessment of an outbreak investigation.

Although the Web application is designed with the group administrator level located at the state, it does not preclude local food-control authorities from applying for group administrator level rights for their jurisdictions. Some local food-control authorities oversee food-safety programs encompassing very large citizen and food establishment populations. An application to CDC for group administrator status for a local food-control authority must be made based on agreement by the state food-control authority.

System Attributes

NVEAIS is not a health surveillance system; however, it does represent the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action as described in CDC’s Updated Guidelines for Evaluating Public Health Surveillance Systems (MMWR 2001). Even though public health surveillance is characterized primarily in a clinical or disease context in these guidelines, a public health service program context, which is more relevant for food-safety programs, is not excluded.

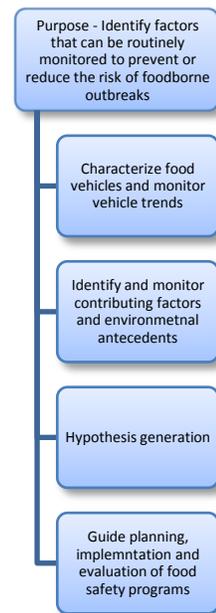


FIGURE 7

Public health surveillance systems are evaluated in part on usefulness and a number of potential system attributes such as simplicity, flexibility, data quality, acceptability, sensitivity, predictive value positive, representativeness, timeliness, and stability (MMWR 2001). Usefulness and system attributes are viewed in the context of the purpose and objectives of the surveillance system (Figure 7). Consideration of the evaluation process at the inception of an NVEAIS can guide its development and help assure accomplishment of purpose.

Usefulness

The CDC guidelines describe a system as useful ‘...if it contributes to the prevention and control of adverse health-events, including an improved understanding of the public health implications of such an event...’ Demonstrating a direct relationship between actions taken by food-safety programs based on information from NVEAIS and the actual prevention of foodborne disease is beyond the scope of this or any one aspect of the foodborne disease surveillance system. This might be possible if data sources such as hazard surveillance, foodborne outbreak surveillance including data from the NVEAIS, and sentinel foodborne disease surveillance such as that carried out by CDC’s FoodNet program are integrated along with other data sources and evaluated. Evaluation of NVEAIS usefulness must be framed in the context of the system objectives. The specific attributes of NVEAIS will play some role in overall system usefulness (Figure 8).

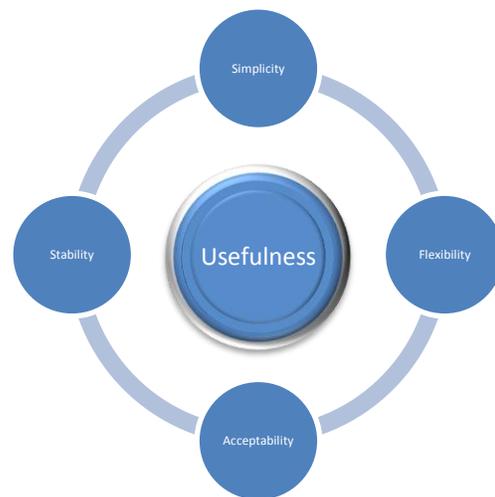


FIGURE 8

Questions an evaluator might ask to judge usefulness of the system include whether the system

- identified and characterized vehicles in enough detail to support monitoring of trends.
- identified contributing factors and environmental antecedents.
- generated information that led to improved environmental public health practice.
- stimulated research into new control or intervention measures.
- guided planning, implementation, and/or evaluation of food safety programs.

Simplicity

According to the CDC guidelines, public health surveillance systems that are simple, flexible, acceptable and stable will likely be more complete and useful for public health action. A number of features make NVEAIS simple:

- It is designed as an information system integrated into an existing disease surveillance program.
- The data collection method is integrated into the existing foodborne outbreak investigation process involving food-control authorities.
- System simplicity is reflected in the single Web application where data is entered once, accessed, and used at all levels of data management.
- The small amount of time anticipated for data entry and transfer will simplify system use.

Possible barriers to simplicity of the system may relate to staff training needs; the level of detail captured by the system; the amount of time required to review, approve, and close a record; and the time spent on integrating data between two systems, its analysis, and dissemination.

Flexibility

The CDC guidelines describe a flexible public health surveillance system as adaptable to changing information needs or operating conditions with little additional time, personnel, or allocated funds. NVEAIS uses a standard reporting format. It will allow the comparison of information across user groups and allow integration with FDOSS. Although the format can be changed, whether it is considered a flexible format probably will require a retrospective review. The Web application can support a state-specific form with additional questions; however, a standard reporting format may be a barrier to flexibility, at least to some extent.

Acceptability

Acceptability is described by the CDC guidelines as reflecting the willingness of persons and organizations to participate in the surveillance system. Food-safety programs, like all public health agencies, are challenged with substantial mandates and given limited resources to achieve those mandates. New program endeavors like an NVEAIS will be accepted by food-control authorities based in part on a combination of a general willingness and ability to try new programs. Acceptability must be judged in retrospect, but if the CFP survey of food-control authorities regarding inspection data sharing is an indicator, a significant number of officials may be willing to consider participation in an NVEAIS. Anticipated presentations on the type and uses of information gained from EHS-Net's Foodborne Illness Outbreak Study (unpublished) may demonstrate the value in reporting environmental assessment data and provide an incentive for food-control authorities to participate in an NVEAIS. Concern over the time involved, however, may represent a barrier to participation.

Stability

A stable surveillance system refers to the reliability (the ability to collect, manage, and provide data properly without failure) and availability (the ability to be operational when needed) of the system (MMWR 2001). Stability is largely a resource-dependent attribute and includes resources at the federal, state, and local level. For NVEAIS, the larger outlay of resources in terms of the Web application that will support the system has already been made and experience with its use by nine states provides a history that indicates a relative stable infrastructure from an operational aspect. CDC's NCEH is committed to maintaining this infrastructure in the near term and will base long-term decisions regarding its maintenance on NVEAIS use. Beyond the Web application infrastructure, considerable resources will be required to analyze data and

disseminate results. Of course, an investment of resources will be required by users as well.

Timeliness of data entry for environmental evaluations as well as record review and closure by group administrators will have a significant impact on the stability of the system; analysis of data cannot begin before records are closed.

Questions an evaluator might ask regarding the stability of the system might include the amount of time taken for records to be closed after data has been entered into the system, the amount of time taken to analyze and disseminate information from the system, and the number of unscheduled downtimes for the system.

Data Quality

Although data quality was not included in the attributes used to describe a complete and useful surveillance system for public health action, it is an attribute that must be mentioned specifically for NVEAIS (Figure 9). Data quality as a system attribute is described in the CDC guidelines as reflecting the completeness and validity of the data recorded in the surveillance system. There may be a number of perspectives regarding the questions to ask

and the data to collect; they must be balanced with the likelihood that the reporting form will be completed and the information reported actually reflecting the environmental factors of the outbreak. EHS-Net has gained a great deal of experience in the development of a standard environmental assessment report form for its Foodborne Illness Outbreak Study. Part of the difficulty in developing this reporting form involved completeness and validity issues. The

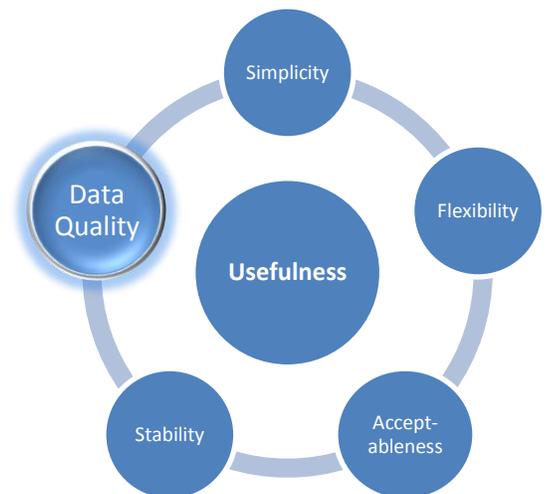


FIGURE 9

current form reflects the experience of actual collection of environmental assessment data in foodborne outbreaks and its subsequent analysis. Acceptance of NVEAIS will depend in large part on users' beliefs that the data are of high quality and the system accurately represents the environmental circumstances of foodborne outbreaks; thus, the EHS-Net Foodborne Illness Outbreak Study's data collection form will be recommended for the NVEAIS.

Integration with CDC's Foodborne Disease Outbreak Surveillance System

The basis for integration between NVEAIS and FDOSS began with previous EHS-Net studies, including the Foodborne Illness Outbreak Study. Integration between the two systems requires duplication of key data elements. The expectation is that environmental assessments from outbreaks will have a matching report in FDOSS, but this may not always be the case. Some epidemiologic data from foodborne outbreak investigations will be needed to characterize environmental assessments and allow the consistent reporting of information from NVEAIS. As experience is gained with NVEAIS and integration with FDOSS improves, duplication of data elements will be refined. A strengthening in communication between food-control authorities and communicable disease control authorities may eventually eliminate the need for duplication of any epidemiologic data elements.

Starting the Dialogue

The dialogue regarding the establishment of an NVEAIS begins with submission of an Issue to the CFP (Attachment A). If accepted, CFP's collaborative process will provide a variety of subject-matter experts, industry, academia, and consumer groups to provide recommendations and guidance in the establishment of an NVEAIS. CDC has planned other opportunities to

engage with stakeholders through other forums during 2008. The stage is set to begin the process of exploring the establishment of an NVEAIS.

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Attachment A

Conference for Food Protection

2008 Issue Pre-submission Form

Title: National Voluntary Environmental Assessment Information System (NVEAIS)

Issue you would like the Conference to consider:

BACKGROUND

In 2006 the International Commission on Microbiological Specifications for Foods (ICMSF) published a position paper to describe epidemiologic data that are useful for evaluating the public health impact of food safety control programs, and to identify how epidemiologic data can be used in the evaluative process. According to this report the collection, synthesis and analysis of data from a variety of sources is required to evaluate food safety control programs. Foodborne outbreak investigations are one of those sources. The report states that one of the key elements of foodborne outbreak investigations is identifying the suspect food and factors that contribute to foodborne transmission of specific pathogens. These data elements are infrequently determined by human disease surveillance systems, and they are critical for food safety program evaluation. (ICMSF) 2006)

Since 1973 the CDC has maintained a collaborative surveillance program for collection and periodic reporting of data on the occurrence and causes of foodborne-disease outbreaks (FBDOs) in the United States. Much has been done to improve reporting of FBDOs to CDC, yet all FBOs recognized and investigated by local and state food safety authorities are not reported to CDC (Higgins 1994) and in many of the outbreaks that are reported, the factors most important to food safety authorities, such as implicated food vehicles, or the factors that may have contributed to the outbreak, are missing or incomplete (Lynch, Painter et al. 2006)

According to the ICMSF position paper, public health surveillance and outbreak investigation programs have evolved independently from food safety programs, and current human health statistics address the questions of communicable disease control officials better than questions of food control authorities and this is noted as one challenge in evaluating food control programs ((ICMSF) 2006). Thus, food safety programs must become more engaged in FBDO investigations and take responsibility for the collection, analysis and interpretation of data relevant to the environmental factors that cause FBDOs. To assist food safety programs CDC is currently considering the establishment of a national voluntary environmental assessment information system (NVEAIS) based on experience from the Environmental Health Specialists Network (EHS-Net) program.

ISSUE

This issue relates to establishing a NVEAIS for foodborne outbreak investigations. This voluntary program will augment the current Foodborne Disease Outbreak Surveillance System maintained by the Centers for Disease Control and Prevention (CDC) to strengthen the role of food safety authorities in foodborne disease outbreak surveillance and in turn, CDC's ability to support their foodborne disease prevention and control efforts.

The purpose of a NVEAIS would be to identify factors that can be routinely monitored by food safety programs to prevent or reduce the risk of foodborne outbreaks associated with foodservice establishments. Proposed objectives of the NVEAIS are to:

- establish a detailed characterization of food vehicles and monitor food vehicle trends,
- identify and monitor contributing factors and their environmental antecedents,

- establish the basis for hypothesis generation regarding factors that may support foodborne outbreak events and,
- guide the planning, implementation and evaluation of food safety programs.

Public Health Significance:

Through the systematic collection, analysis, interpretation and dissemination of environmental data from foodborne disease outbreak investigations food safety authorities will have the information needed to take food safety action, assess its effectiveness, support program evaluation, develop and / or modify program policies and/or regulations based on sound epidemiologic data, train environmental health specialists regarding environmental factors related to foodborne outbreaks as well as how to conduct the environmental assessment in a foodborne outbreak investigation, and to justify program budgets.

Recommended Solution:

The Conference recommends the formation of a committee composed of interested stakeholders to consult with CDC regarding the establishment of a National Voluntary Environmental Assessment Information System (NVEAIS).

The recommended Committee charge:

- 1) review the concept of a NVEAIS as proposed in the attached background paper,
- 2) prepare a report on the NVEAIS concept for the fall 2009 Executive Board meeting to cover but not be limited to:
 - a brief description of a NVEAIS
 - a detailed description of the anticipated usefulness of a NVEAIS to food safety programs,
 - the feasibility of reporting environmental assessment data to CDC by food safety programs,
 - the acceptability of a NVEAIS by food safety program managers and the willingness to participate, and,
 - if appropriate, based on committee deliberations, a recommendation to continue the committee's work; if not appropriate based on committee deliberations, report the committee's work complete and recommend the committee be dissolved
- 3) determine how a NVEAIS could be best supported by the Conference for Food Protection
 - explore the appropriateness of an amendment to Standard 5, Foodborne Illness and Food Security Preparedness and Response, and,
 - as may be appropriate, develop a recommendation and/or issue for the 2010 Conference.

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ATTACHMENT 2 NVEAIS and CFP Support

Charge 3 from the 2008 CFP Biennial Meeting was to determine how NVEAIS could be best supported by the Conference for Food Protection by exploring the appropriateness of an amendment to Standard 5, Foodborne Illness and Food Security Preparedness and Response.

Findings:

Standard 5 of the “FDA Voluntary Retail Food Regulatory Program Standards” is designed to establish best practices related to FBI response and establishes criteria for the surveillance, investigation, response and review of food related incidents.

The CDC NVEAIS tool has a related but different focus. The CDC NVEAIS tool is designed to collect foodborne illness outbreak environmental assessment data and report that data to CDC. As a result, CDC can provide better information to programs on the causes of foodborne outbreaks. This information can be used to identify and monitor contributing factors and their environmental antecedents thus providing information needed to prevent or reduce the risk of foodborne outbreaks associated with food service.

Both the Program Standards and the NVEAIS reporting tool are important aspects for any regulatory program however we have determined that it would not be appropriate to attempt to incorporate use/participation in NVEAIS as a requirement of Program Standard # 5 for the following reasons:

- Difference in focus as stated above
- Lack of annual reports as required currently in Standard 5

Instead of incorporating NVEAIS into the Program Standards criteria, the committee is proposing that the following statement be included in the Standard 5 OUTCOME Section of the “FDA Voluntary Retail Food Regulatory Program Standards.” The current (existing) paragraph is as follows:

OUTCOME

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional, or deliberate food contamination.

New language to be added (indicated in underline):

Regulatory programs are encouraged to also participate in the CDC National Voluntary Environmental Assessment Information System (NVEAIS). NVEAIS is designed to provide a more comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention (The following link provides additional information regarding NVEAIS: <http://www.cdc.gov/nceh/ehs/>.

Currently the Program Standards do not contain any such endorsements to other documents; however we are hopeful that by avoiding changing the criteria of the Standard itself, and because of the recognition of the importance of the NVEAIS work, that this subtle change will be accepted.

- June 22, 2009 - Draft language submitted to NVEAIS Committee Members
- July 15, 2009 - Presented to FDA Clearinghouse Workgroup - **Accepted**
- July 23, 2009 - Presented to CFP Program Standards Committee - **Accepted**
- August 7, 2009- Presented to CFP NVEAIS Committee Members - **Accepted**

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 061
Issue: 2010 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:

Amend "Outcome" section of Program Standard No. 5

Issue you would like the Conference to consider:

One of the charges of the CFP National Voluntary Environmental Assessment Information System (NVEAIS) Committee was to *"Determine how a NVEAIS could be best supported by the Conference for Food Protection.* In addressing this, the committee explored the appropriateness of an amendment to Standard 5, FBI and Food Security Preparedness and Response. In this regard, the committee seeks the Conference's approval to incorporate the following statement in the "Outcome" section of Standard No. 5:

"Regulatory programs are encouraged to also participate in the CDC National Voluntary Environmental Assessment Information System (NVEAIS). NVEAIS is designed to provide a more comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention."

For full text of Standard 5 including recommended addition, see attachment titled:

Attachment: Voluntary National Retail Food Regulatory Program Standards, Standard 5 - April 2009

Public Health Significance:

In 1998 the Food and Drug Administration (FDA) developed the *Voluntary National Retail Food Regulatory Program Standards* (hereafter called the Standards), which consist of nine standards. Standard 5 is designed to establish best practices related to FBI response and establishes criteria for the surveillance, investigation, response and review of food related incidents. The CDC NVEAIS tool is designed to collect foodborne illness outbreak environmental assessment data and report that data to CDC. As a result, CDC can provide better information to programs on the causes of foodborne outbreaks. This information can be used to identify and monitor contributing factors and their environmental antecedents thus providing information needed to prevent or reduce the risk of foodborne outbreaks associated with food service. This amended language has also been endorsed by the CFP Program Standards Committee and the FDA Clearinghouse Work Group.

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 OUTCOME Section of FDA's *Voluntary National Retail Food Regulatory Program Standards, Standard 5 - April 2009*:

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional, or deliberate food contamination.

Regulatory programs are encouraged to also participate in the CDC National Voluntary Environmental Assessment Information System (NVEAIS). NVEAIS is designed to provide a more comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NVEAIS: <http://www.cdc.gov/nceh/ehs/>)

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Attachments:

- "Voluntary National Retail Food Regulatory Program Standards, Standard 5 - A"

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

STANDARD 5 FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in foodborne illness, food-related injury*, and outbreaks.

REQUIREMENT SUMMARY

The program has an established system to detect, collect, investigate and respond to complaints and emergencies that involve foodborne illness, food-related injury*, and intentional and unintentional food contamination.

DESCRIPTION OF REQUIREMENT

1. Investigative Procedures

- a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food-related injury*. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.
- b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.
- c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties and responsibilities of each party.
- d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.
- e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.
- f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or food-related injury* within 24 hours.
- g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.
- h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.
- i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

- a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.
- b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreak*s with CDC.-

3. Laboratory Support Documentation

- a. The program has a letter of understanding, written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.
- b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

- a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

- a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.
- b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.
- c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

- a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

Attachment: Voluntary National Retail Food Regulatory Program Standard 5 – April 2009

a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.

b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:

- 1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment;
- 2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type;
- 3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food;
- 4) Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food preparation processes;
- 5) Number of confirmed foodborne disease outbreaks*;
- 6) Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*;
- 7) Contributing factors most often identified;
- 8) Number of complaints involving real and alleged threats of intentional food contamination; and
- 9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection, and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak* investigations occur.

OUTCOME

A food regulatory program has a systematic approach for the detection, investigation, response, documentation, and analysis of alleged food-related incidents that involve illness, injury, unintentional, or deliberate food contamination.

“Regulatory programs are encouraged to also participate in the CDC National Voluntary Environmental Assessment Information System (NVEAIS). NVEAIS is designed to provide a more comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention (The following link provides additional information regarding NVEAIS: <http://www.cdc.gov/nceh/ehs/>.”

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 063
Issue: 2010 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:

Report - Food Contact and Utensil Barrier Usage Committee

Issue you would like the Conference to consider:

The Food Contact and Utensil Barrier Usage Committee seeks Council II's acknowledgement of the Committee Report which is made up of the Reference Document and PowerPoint presentation.

Public Health Significance:

The Committee recognizes the need for a Brand neutral guidance document illustrating the effective use of barriers and utensils when handling foods, including the use of disposable gloves, and the process of barrier use related to hand hygiene.

The purpose of the Reference document and PowerPoint presentation is to:

1. Reflect industry best practices regarding bare hand contact barriers
2. Provide a training and teaching tool that can be used by industry and regulatory agencies
3. Demonstrate alternatives to bare hand contact

Recommended Solution: The Conference recommends...:

acknowledgement of the work of the Food Contact and Utensil Barrier Usage Committee and thanks the Committee for their hard work and dedication to this issue.

The Conference further recommends that this Committee be disbanded as they have completed their charges.

Submitter Information:

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Attachments:

- "1. Food Contact and Utensil Barrier Usage Committee Final Report"

- "2. Barrier to Bare Hand Contact Reference Document - English"
- "3. Barrier to Bare Hand Contact Reference Document - Spanish"
- "4. Barrier to Bare Hand Contact Power Point Presentation - English"
- "5. Barrier to Bare Hand Contact Power Point Presentation - Spanish"
- "6. Food Contact and Utensil Barrier Usage 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: The Food Contact and Utensil Barrier Usage Committee

COUNCIL (I, II, or III): II

DATE OF REPORT: December 4, 2009

SUBMITTED BY: Stephen Posey

COMMITTEE CHARGE(s):

- Develop content for the fifth category (Forks, Chopsticks, and Toothpicks)
- Identify potential languages for translation
- Evaluate the cost associated with translating the document
- Provide additional pictures and/or illustrations representing utensil use and identify dissemination strategies
- A complete review and sign off by all committee members to gain full support of the document
- Post the document to a Conference approved Internet site
- Submit a final report to the 2010 Biennial Meeting of the Conference

COMMITTEE ACTIVITIES AND RECOMMENDATIONS (Outcomes):

1. The committee decided the best way to present the information in the user friendly manner is to provide a reference document along with a separate PowerPoint presentation. The following tools and utensils are now included in the document: gloves, scoops, spoons, ladles, spatulas, tongs, forks, deli papers, chopsticks, and toothpicks.
2. The committee identified the need to have the documents translated into Spanish.
3. The Spanish translation has been provided with the committee report. The translation was provided at no cost through volunteer work. The translation was completed by one volunteer and reviewed by another volunteer.
4. The reference document and PowerPoint presentation now sufficiently include pictures and illustrations representing all tools and utensils.
5. The entire committee has provided input and collectively agreed on the attached documents.

RECOMMENDATIONS:

The Committee is submitting two issues for Council II's consideration:

Issue #1: Report – Food Contact and Utensil Barrier Usage Committee

- The Conference recommends acknowledgement of the work of the Food Contact & Utensil Barrier Usage Committee and to thank the Committee for their hard work and dedication to this issue.
- The Conference recommends that the committee has completed all charges and secured consensus among all Committee members and recommends disbanding the Committee at this time.

See attachment titled: *Food Contact and Utensil Barrier Usage Committee Report*

Issue #2: Barriers to Bare Hand Contact Training Materials

- The Conference recommends that the training materials created by the Committee be approved and posted on the Conference web site, including:
 - Barrier to Bare Hand Contact Reference Document – English and Spanish

- Barrier to Bare Hand Contact PowerPoint Presentation – English and Spanish

See attachments titled:

Barrier to Bare Hand Contact Reference Document – English

Barrier to Bare Hand Contact Reference Document – Spanish

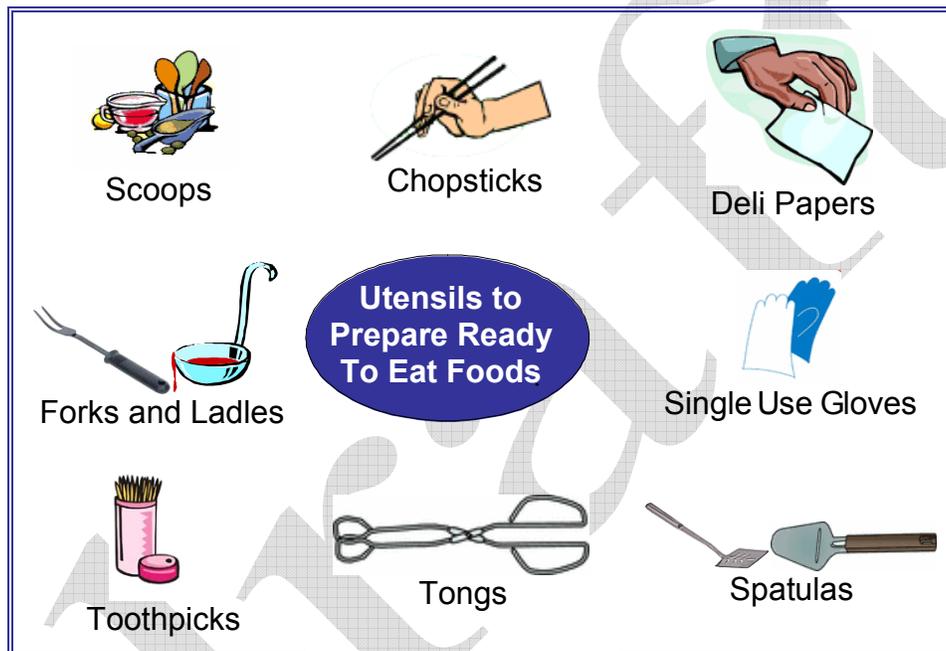
Barrier to Bare Hand Contact PowerPoint Presentation – English

Barrier to Bare Hand Contact PowerPoint Presentation - Spanish

COMMITTEE MEMBER ROSTER:

- See attached: Food Contact and Utensil Barrier Usage Committee Roster

BARRIERS TO BARE HAND CONTACT



Draft submitted for approval: April 2010

Thank you again for your efforts and focus on Food Safety and support of the Barriers to Bare Hand Contact.

Special thanks to the Conference for Food Protection Food Contact Utensil Barrier Usage Committee members:

2009-2010 Committee

Julie Albrecht, University of Nebraska-Lincoln

Anthony Carotenuto, Navy and Marine Corps Public Health Center

LeAnn Chuboff, SQFI

Sharon Ferguson, FDA

Andrew Harris, Division of Environmental Health, Summit County Health District

Stephen Posey, Brinker International

Jim Wagner, The Steritech Group, Inc.

Lisa Whitlock, FDA - Alternate

2007-2008 Committee

Michelle Motsinger

Janet Anderberg, Washington State Department of Health

Joseph Comello

Diane Benjamin, FDA

Jeannie Riess

Robert Joyce

Lacie Thrall, FoodHandler, Inc.

Doris Rittenmeyer, FoodHandler, Inc.

Jane Griffith, WaWa, Inc.

Frank Ferko, US Foodservice

Linda McClurg, Dunkin Brands, Inc.

Dr. Esah Yip, Malaysian Rubber Export Council

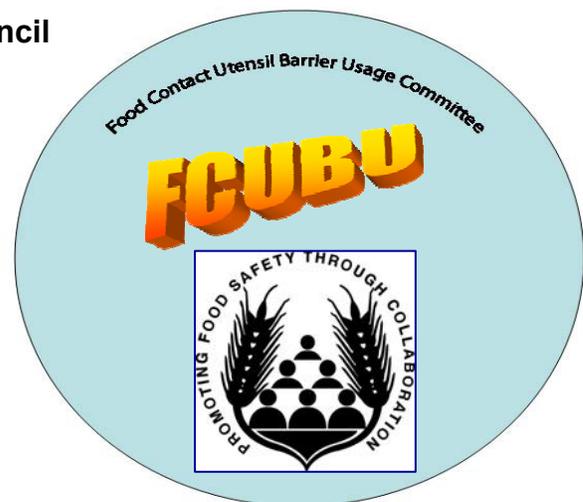


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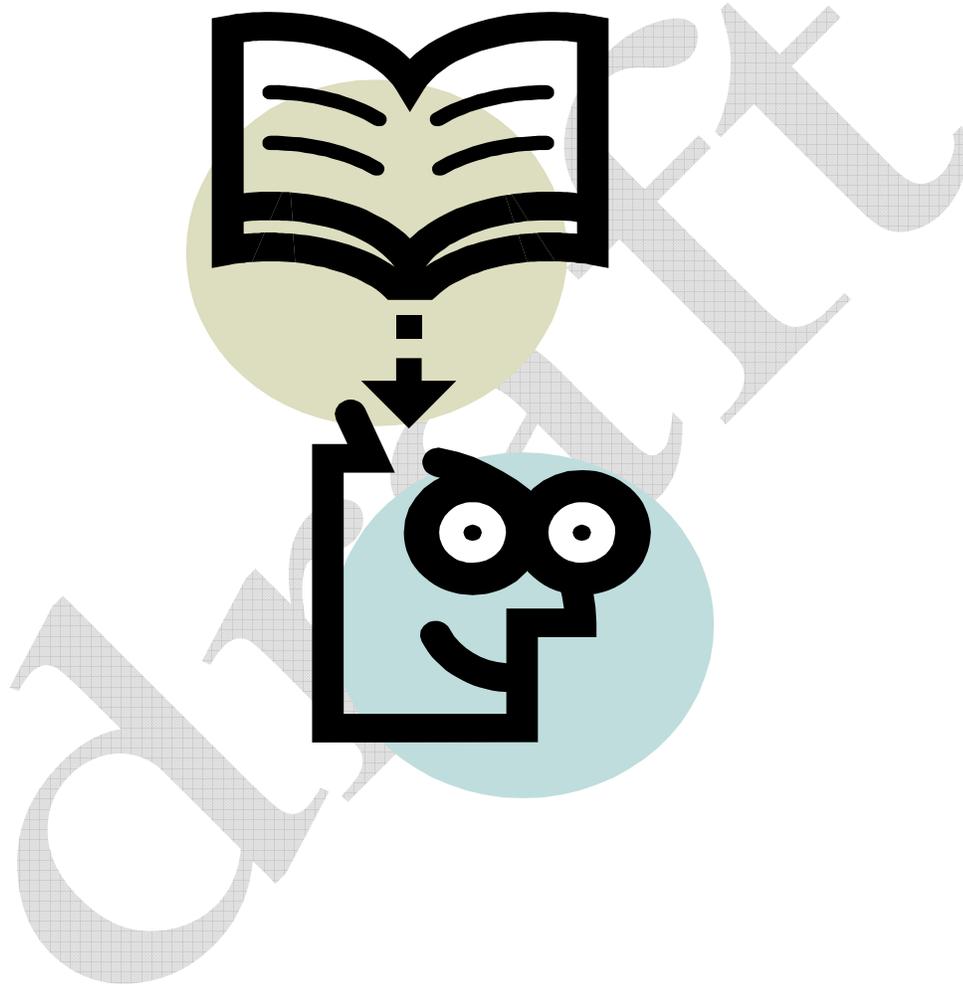
Introduction

The Barriers to Bare Hand Contact Training Manual has been developed to be used as a teaching and training tool for consumers, industry, and regulatory to demonstrate the industry's best practices regarding bare hand contact barriers and alternatives to bare hand contact.

A Power Point presentation is available at the end of this document.



Barriers to Bare Hand Contact Reference Material



SECTION 1 – SINGLE USE GLOVES



Section 1.1 – Glove Information

1. The correct use of glove barriers is important during food handling tasks. Single-use gloves can be an effective barrier against the transmission of microorganisms, such as bacteria & viruses, from fingertips or foods.
2. Handwashing is a primary barrier to cross contamination while barrier utensils & gloves are a secondary barrier.
3. Single-use gloves are defined as a “utensil” in the FDA Food Code.
4. Glove barriers work when handling any ready-to-eat (RTE) food while another utensil does not provide the hand dexterity for the task. (example: slicing carrots or celery). One glove may work on one hand with a utensil used by the other hand.

Section 1.2 – When Should a Food Employee Use Single Use Gloves?

1. If a food handler has a bandage, infection, cut, or sore on hands or arms, they must temporarily avoid direct bare hand contact during food handling duties.
2. When food employees wear artificial nails or fingernail polish, they must wear disposable gloves when handling food.
3. Glove use may be optional to handle raw meats, but can be used for preparation tasks such as breading/battering meats, poultry, seafood, or vegetables.

Section 1.3 – Glove Barriers Must be Task Specific

1. Use gloves for designated food tasks only. Disposable gloves are task-specific and should never be worn continuously.
2. Gloves designated for food use should not be used for non-food tasks, such as taking out the garbage, handling money, cleaning surfaces, etc.
3. Use vinyl, nitrile synthetic, or latex gloves when handling foods near a heat source cooking area, rather than poly (polyethylene) gloves, which are not resistant to heat.

Section 1.4 – Avoid Cross Contamination by Washing Hands and Changing Gloves

1. If someone handles raw meats, poultry, or seafood with gloves on, they must not touch RTE or cooked foods without washing hands and changing gloves.
2. Remove or change gloves when changing activity (for example from making sandwiches to making change) or whenever leaving the workstation. Hands must be washed before re-gloving.

3. Task-specific colored gloves are another option for cross contamination prevention.

Section 1.5 – Glove Change Frequency

1. Change gloves periodically and wash hands each time before changing gloves.
2. After handwashing, dry hands thoroughly before donning gloves to make them easier to slip on.
3. Base the frequency of glove changing on task changes.
4. Remove gloves if doing different tasks when not handling RTE foods.
5. Change gloves to handle a raw food or different raw species (for example raw chicken to raw beef).
6. Change gloves to handle another RTE food that might transfer a flavor or food allergen.
7. Wash hands and re-glove if a glove develops a hole or tear during usage.
8. Change gloves after sneezing, coughing, or touching hair or face.

Section 1.6 – Four Common Glove Materials

1. Polyethylene (Poly) Gloves
2. Latex Gloves
3. Vinyl Gloves
4. Nitrile Gloves

Section 1.7 – Glove Size

1. Glove size is important for safety and comfort.
2. Select the right size for hands— from small to extra large.
3. Poly, Vinyl, Latex, & Nitrile usually come in 4 or 5 sizes – Small, Medium, Large, X or XX-Large
4. Glove sizes are measured across the widest part of the palm as shown.



Section 1.8 – Avoid Cross Contamination with Cut Resistant Gloves

1. If wearing a cut-resistant glove to cut or handle raw or RTE food, wear a larger disposable glove over it to avoid cross-contamination of the reusable cut-resistant glove.
2. Wash, rinse & sanitize the cut-resistant glove between uses.

Section 1.9 – Glove Removal

1. To remove disposable gloves correctly, grasp at the cuff and peel them off inside-out.
2. DO NOT remove and re-use gloves OR re-wash single-use food contact gloves for multiple tasks.

Section 1.10 – Selecting the Right Glove for the Right Job

1. Consider specific tasks when determining the type of glove to be used.
2. Nitrile & Latex may be more durable for longer single tasks. Vinyl & Polyethylene may work better for shorter general food handling tasks. Be aware that some individuals may have allergen concerns with latex.
3. Polyethylene may work better for light duty tasks which involve high dexterity & durability.
4. Textured gloves may improve grip, tactile sensitivity or comfort.
5. Color-coding may help for cross-contamination prevention & visibility when handling foods.
6. Heat resistance may help around cooking equipment.
7. Cuff length extended (elbow length) can be considered depending on the tasks.
8. Dispensing stations should be located for easy quick access with close proximity to RTE food handling & handwashing.

Section 1.11 – Powdered or Powder Free Glove Barriers

1. Powder makes gloves easier to put on & absorbs perspiration, but some users prefer no powder.
2. Amount of powder (if used)
 - *Powdered gloves* do not exceed 120 mg trace powder per glove (vinyl, nitrile, latex)
 - Powder must be a Sterile Absorbable Dusting Powderd
 - Acts as a donning lubricant
 - Must be minimal
 - No talc or unsterilized powders
 - *Powder-free gloves* (vinyl, nitrile, latex)
 - Contain no more than 2 mg trace powder per glove
 - Some form-fit gloves are polyurethane coated or washed in chlorine to eliminate powder
 - Poly gloves contain no powder

Section 1.12 – Basic Poly or Cast Poly Gloves

1. “Basic seamed poly” glove – known as “blown polyethylene” & can be white, opaque, or colored. Usually a loose fit. Less dexterity than form-fit gloves. Seamed on the edges.
2. “Cast poly” has a better fit & softer feel than basic blown poly. Easier to slip on & sometimes textured for better grip.

3. A “Poly” glove is designed for light duty, short tasks. It is not designed for handling heat (approx. melt point 200°F(93°C)).
4. Elbow length gloves are for special light duty tasks requiring arm length reach or deep containers.

Section 1.13 – Rapid Dispensing or Short Task Poly Gloves

1. Loose fitting gloves are also designed in fingered glove or a mitt with unique dispensing systems to enable quick one-handed donning.
2. Applications may only use one glove for single tasks that require frequent glove changing in a fast-paced environment..
3. High Density Polyethylene (HDPE) which uses a different resin is more heat-resistant at 240°F(115°C) than Low Density Polyethylene at 200°F(93°C). However, it is not recommended for hot food tasks.

SECTION 2 - SCOOPS, SPOONS, AND LADLES



Section 2.1 – When Should a Food Employee Use Scoops, Spoons, and Ladles?

1. Spoons, scoops and ladles are used by foodhandlers, servers, and customers when preparing, portioning, or serving liquid or solid foods.
2. The construction and design of the food contact surface should follow FDA Food Code requirements in section 4-201.11 and be durable and able to retain its characteristic qualities under normal conditions.
3. All utensils should be washed, rinsed, sanitized and air dried between uses and at least every 4 hours when being used.
4. When not in use, utensils must be stored in a manner to prevent bacterial growth such as in the food, in a clean and protected environment, under running water, or in a container at a minimum temperature of 135°F(57°C).

5. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:
 - In food with their handles above the top of the food and the container.
 - On a clean portion of the food preparation table or cooking equipment that has been cleaned and sanitized.
 - In running water with a water velocity sufficient to flush particles to the drain for moist foods such as potatoes or ice cream.
 - In a washed and sanitized container of water, if the water is maintained at a temperature of at least 135°F (57°C).
 - In a clean protected location if utensils (such as ice scoops) are used for non-potentially hazardous foods (Time/Temperature Control for Safety Food).
6. In-use utensils may not be stored in chemical sanitizer or ice.

Section 2.2 – Using Scoops

1. Scoops are available in many different sizes and are an ideal utensil for portion control.
2. When using a scoop with a release trigger, the release trigger should be prevented from touching the food. This prevents pathogens from the hand transferring to the food.
3. Scoops can be used with or without the use of other barriers. Scoops are a practical alternative to handling food with bare hands in many situations.
Scoops may be used as a stand alone tool or in conjunction with another barrier such as gloves.

Section 2.3 – Using Spoons

1. Spoons typically have no predetermined serving size or shape.
2. Spoons used for tasting must be washed, rinsed, and sanitized between uses. Disposable or single serving utensils can work well for this task.
3. Improper use of tasting spoons can lead to foodborne illness.
4. Spoons can be used with or without the use of other barriers. Spoons are a practical alternative to handling food with bare hands in many situations.

Section 2.4 – Using Ladles

1. Ladles are available in many different sizes and are an ideal utensil for portion control.

2. Ladles can be used with or without the use of other barriers. Ladles are a practical alternative to handling food with bare hands in many situations.
3. Ladles may be used as a stand alone tool or in conjunction with another barrier such as gloves.

SECTION 3 – SPATULAS



Section 3.1 – When Should a Food Employee Use Spatulas?

1. Spatulas are used to stir, scoop, spread, or lift food by foodhandlers, servers and customers.
2. The construction and design of the food contact surface should follow FDA Food Code requirements in section 4-201.11 and be durable and able to retain its characteristic qualities under normal conditions.
3. All utensils should be washed, rinsed, sanitized and air dried between uses and at least every 4 hours when being used.
4. When not in use, utensils must be stored in a manner to prevent bacterial growth such as in the food, in a clean and protected environment, under running water, or in a container at a minimum temperature of 135°F.
5. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:
 - In food with their handles above the top of the food and the container.
 - On a clean portion of the food preparation table or cooking equipment that has been cleaned and sanitized.
 - In running water with a water velocity sufficient to flush particles to the drain for moist foods such as potatoes or ice cream.
 - In a washed and sanitized container of water, if the water is maintained at a temperature of at least 135°F (57°C).
 - In a clean protected location if utensils (such as ice scoops) are used for non-potentially hazardous foods (Time/Temperature Control for Safety Food).

6. In-use utensils may not be stored in chemical sanitizer or ice.

Section 3.2 – Using Spatulas

1. Spatulas are available in generalized and highly adapted designs widely available for specific tasks.
2. Spatulas should be dedicated to a specific task.
3. Spatulas can be used with or without the use of other barriers. Spatulas are a practical alternative to handling food with bare hands in many situations.



SECTION 4 – TONGS

Section 4.1 – When Should a Food Employee Use Tongs?

1. Tongs are used by foodhandlers and servers to grip or lift food, to move a food from one location to another, and to rotate food during cooking, especially during grilling.
2. The construction and design of the food contact surface should follow FDA Food Code requirements in section 4-201.11 and be durable and able to retain its characteristic qualities under normal conditions.
3. All utensils should be washed, rinsed, sanitized and air dried between uses and at least every 4 hours when being used.
4. When not in use, utensils must be stored in a manner to prevent bacterial growth such as in the food, in a clean and protected environment, under running water, or in a container at a minimum temperature of 135°F (57°C).
5. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:
 - In food with their handles above the top of the food and the container.
 - On a clean portion of the food preparation table or cooking equipment that has been cleaned and sanitized.
 - In running water with a water velocity sufficient to flush particles to the drain for moist foods such as potatoes or ice cream.
 - In a washed and sanitized container of water, if the water is maintained at a temperature of at least 135°F (57°C).

- In a clean protected location if utensils (such as ice scoops) are used for non-potentially hazardous foods (Time/Temperature Control for Safety Food).

6. In-use utensils may not be stored in chemical sanitizer or ice.

Section 4.2 - Using Tongs

1. Tongs are a practical alternative to handling food with bare hands in many situations.
2. Tongs are available in generalized and highly adapted designs widely available for specific tasks.
3. Specific tongs are designed for picking up items such as sugar cubes, asparagus, shredded cheese, ice, salad, spaghetti, hamburgers, fish bones, melon balls, bagels, cooked crabs, garnishes and tea bags.
4. Tongs should be dedicated to a specific task.
5. Tongs can be used with or without the use of other barriers. Tongs are a practical alternative to handling food with bare hands in many situations.

SECTION 5 – FORKS

Section 5.1 – When Should a Food Employee Use Forks?

1. Forks are used by foodhandlers and servers to grip or lift food, to move a food from one location to another, to rotate food during preparation, and to hold or grip a food while cutting or carving.
2. The construction and design of the food contact surface should follow FDA Food Code requirements in section 4-201.11 and be durable and able to retain its characteristic qualities under normal conditions.
3. All utensils should be washed, rinsed, sanitized and air dried between uses and at least every 4 hours when being used.
4. When not in use, utensils must be stored in a manner to prevent bacterial growth such as in the food, in a clean and protected environment, under running water, or in a container at a minimum temperature of 135°F(57°C).
5. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:



- In food with their handles above the top of the food and the container.
 - On a clean portion of the food preparation table or cooking equipment that has been cleaned and sanitized.
 - In running water with a water velocity sufficient to flush particles to the drain for moist foods such as potatoes or ice cream.
 - In a washed and sanitized container of water, if the water is maintained at a temperature of at least 135°F (57°C).
 - In a clean protected location if utensils such as ice scoops are used for non-potentially hazardous foods (Time/Temperature Control for Safety Food).
6. In-use utensils may not be stored in chemical sanitizer or ice.

Section 5.2 - Using Forks

1. Forks are a practical alternative to handling food with bare hands in many situations.
2. Forks should be dedicated to a specific task.
3. Forks which are designed and intended for single-use only must be discarded after each use.
4. Forks can be used with or without the use of other barriers. Forks are a practical alternative to handling food with bare hands in many situations.

SECTION 6 – DELI PAPERS

Section 6.1 – When Should a Food Employee Use Deli and Bakery Wrap?

1. Deli and Bakery Wrap are used by foodhandlers, servers/wait-staff, and customers to provide a sanitary barrier between the bare hand and food.

Section 6.2 – Selecting Bakery or Deli Wrap

1. Operators or purchasing agents must ensure all wrap components are in compliance with the FDA, Title 21, CFR 177.1520.
2. Deli wrap papers must be manufactured in accordance to Good Manufacturing Practices. Manufacturers of food contact wraps or sheets must demonstrate that all components are safe for use and do not leech components or toxic elements onto the food.



3. Deli wrap papers can be purchased in a variety of sheet sizes and packages from a foodservice supply vendor.
4. Wrap can be dry waxed or without wax. Dry wax will absorb some liquid and prevent the seeping of product liquid onto the hands. Wraps without wax are generally intended to be used for bakery products.
5. Dispensing packages must be well made to prevent contamination of the sheets from external debris and permit easy access to the sheet.
6. Food service operators should select wrap based on intended purpose.

Section 6.3 – Using Deli and Bakery Wrap

1. Sheets should be dispensed one at a time without tearing or contaminating the remaining sheets.
2. If sheets are used as the primary barrier, foodhandlers should discard used sheets immediately after use. Sheets should not be reused or remain with the food.
3. The dispensing container must be stored in a location to prevent cross contamination from other food or debris.

SECTION 7 – CHOPSTICKS



Section 7.1 – When Should a Food Employee Use Chopsticks?

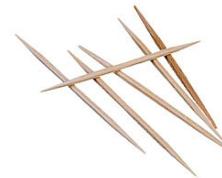
1. Chopsticks are usually used by consumers for eating but foodhandlers may use chopsticks to move food from one location to another during preparation or service.
2. The construction and design of the food contact surface should follow FDA Food Code requirements in section 4-201.11 and be durable and able to retain its characteristic qualities under normal conditions.

3. All utensils should be washed, rinsed, sanitized and air dried between uses and at least every 4 hours when being used.
4. When not in use, utensils must be stored in a manner to prevent bacterial growth such as in the food, in a clean and protected environment, under running water, or in a container at a minimum temperature of 135°F(57°C).
5. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:
 - In food with their handles above the top of the food and the container.
 - On a clean portion of the food preparation table or cooking equipment that has been cleaned and sanitized.
 - In running water with a water velocity sufficient to flush particles to the drain for moist foods such as potatoes or ice cream.
 - In a washed and sanitized container of water, if the water is maintained at a temperature of at least 135°F (57°C).
 - In a clean protected location if utensils such as ice scoops are used for non-potentially hazardous foods (Time/Temperature Control for Safety Food).
6. In-use utensils may not be stored in chemical sanitizer or ice.

Section 7.2 - Using Chopsticks

1. Chopsticks may be an alternative to handling food with bare hands.
2. Chopsticks should be used for a specific task.
3. Chopsticks constructed to be a multi-use item must be washed, rinsed, sanitized, and air dried between different tasks.
4. Chopsticks designed and intended for single-use only must be discarded after each use.
5. Chopsticks may be used as a stand alone tool or in conjunction with another barrier such as gloves.

SECTION 8 – TOOTHPICKS



Section 8.1 – When Should a Food Employee Use Toothpicks?

1. Toothpicks are typically used by foodhandlers to prevent bare hand contact with RTE foods such as hors d'oeuvres. However, toothpicks are also used to hold stacked/layered sandwiches or other items together and/or upright.

2. The construction and design of the food contact surface should follow FDA Food Code requirements in section 4-201.11 and be durable and able to retain its characteristic qualities under normal conditions.

Section 8.2 - Using Toothpicks

1. Toothpicks should be placed in food by staff prior to service, or presented and/or provided to consumer in a manner that will prevent possible contamination of the food contact portion of the toothpick, such as, upright in a small/slender glass or container.
2. Toothpicks are usually designed to be a single-use item and must be discarded after use.
3. If designed to be multi-use, toothpicks must be washed, rinsed, sanitized, air dried between tasks.

Frequently Asked Questions



Frequently Asked Questions:

1. What is the purpose of this document?

The Barriers to Bare Hand Contact Training Manual has been developed to be used as a teaching and training tool for consumers, industry, and regulators to demonstrate the industry's best practices regarding bare hand contact barriers and alternatives to bare hand contact.

2. How should I use this document?

This document can be used to educate and inform consumers, industry, and regulators of best practices and options for use of bare hand contact barriers.

3. Is this manual approved by health departments?

This document has been developed in conjunction with the combined efforts of the Conference for Food Protection and input from federal, state, and local regulators, industry, academia, and consumers.

4. Can I use information from this document in my presentations?

This information can be used for educational purposes.

5. Who should I contact if I have additional questions?

Please contact your local health department or the Conference for Food Protection if you have additional questions.

6. What if I have a question about a utensil that is not mentioned?

This document is not meant to take the place of local regulatory requirements. Please consult your local health department for final requirements.

7. Do utensils have to be certified?

Please consult your local health department to determine utensil certification requirements.

Appendix / Tools



References

2005 Model Food Code sections applicable to Barriers to Bare Hand Contact.

1-2 DEFINITIONS

1-201 – Applicability and Terms Defined
Ready-to-Eat Food
Utensil

2-3 PERSONAL CLEANLINESS

2-301 Hands and Arms
2-301.11 Clean Condition Fingernails (refers to glove use)
2-301.12 Cleaning Procedure
2-301.14 When to Wash (refers to glove use)
2-301.15 Where to Wash

3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING

Preventing Contamination by Employees
3-301.11 Preventing Contamination from Hands (refers to deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment)
3-301.11(B) Preventing contamination from hands

PREVENTING CONTAMINATION FROM EQUIPMENT, UTENSILS, AND LINENS

3-304.11 – Food Contact with Equipment and Utensil
3-304.12 In-use utensils, between-use storage
3-304.15 – Gloves, Use Limitation
3-304.16 Using clean tableware for second portions and refills
3-502.12 Reduce oxygen packaging, criteria
3-502.12(B) (5) (a) (prohibits bare hand contact)
3-801.11 Pasteurized Foods, prohibited re-service and prohibited food
3-801.11(F) (3) (b) (prohibits bare hand contact)

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Single-Service and Single Use
4-101.17 Wood, use limitations
4-102.11 Characteristics (single-service and single use)
4-102.11 Characteristics
4-2 Design and Constructions
4-201.11 Equipment and utensils
4-205.10 Food Equipment, certification and classification
4-302.11 Utensils, consumer self-service
4-502.11 Single-service and single-use, required
4-502.13 Single-service and single-use, use limitations
4-6 Cleaning of Equipment and utensils
4-7 Sanitization of equipment and utensils

4-9 Protection of clean items

4-9 PROTECTION OF CLEAN ITEMS

Storing

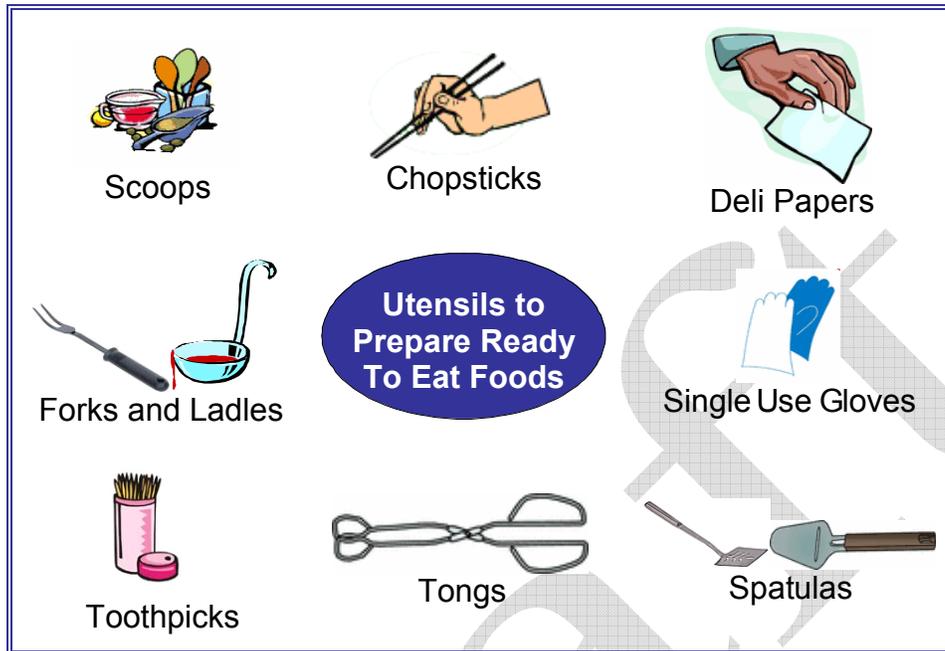
4-903.11 – Equipment, Utensils, Linens, and Single Service and Single Use Articles

Annex 3: Public Health Reasons/Administrative Guidelines:

Each Code Section will have back ground information or guidance in this Section of the Food Code.

Draft

Presentation



A separate presentation is available to support this reference document

BARRERAS AL CONTACTO CON LAS MANOS DESCUBIERTAS



Borrador sometido a aprobación: Abril de 2010

Quisiéramos agradecer nuevamente sus esfuerzos y enfoque en la Seguridad Alimentaria y su apoyo al Comité de Barreras al Contacto Con Manos Descubiertas (FCUBU).

Nuestro especial agradecimiento a los miembros del Comité del Uso de Utensilios de Barrera para el Contacto con Alimentos de la Conference for Food Protection:

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Presentación.....	27

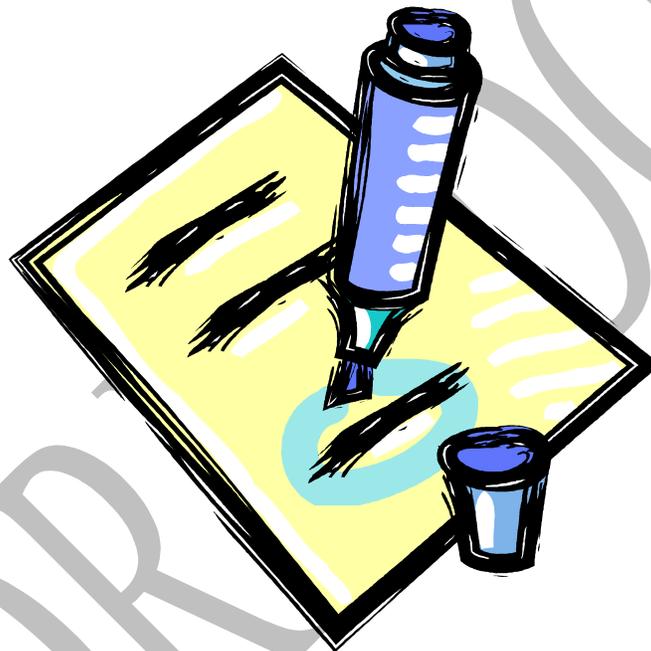
BORRADOR

Introducción

El Manual de Entrenamiento para el Contacto Con Manos Descubiertas ha sido desarrollado para su utilización como una

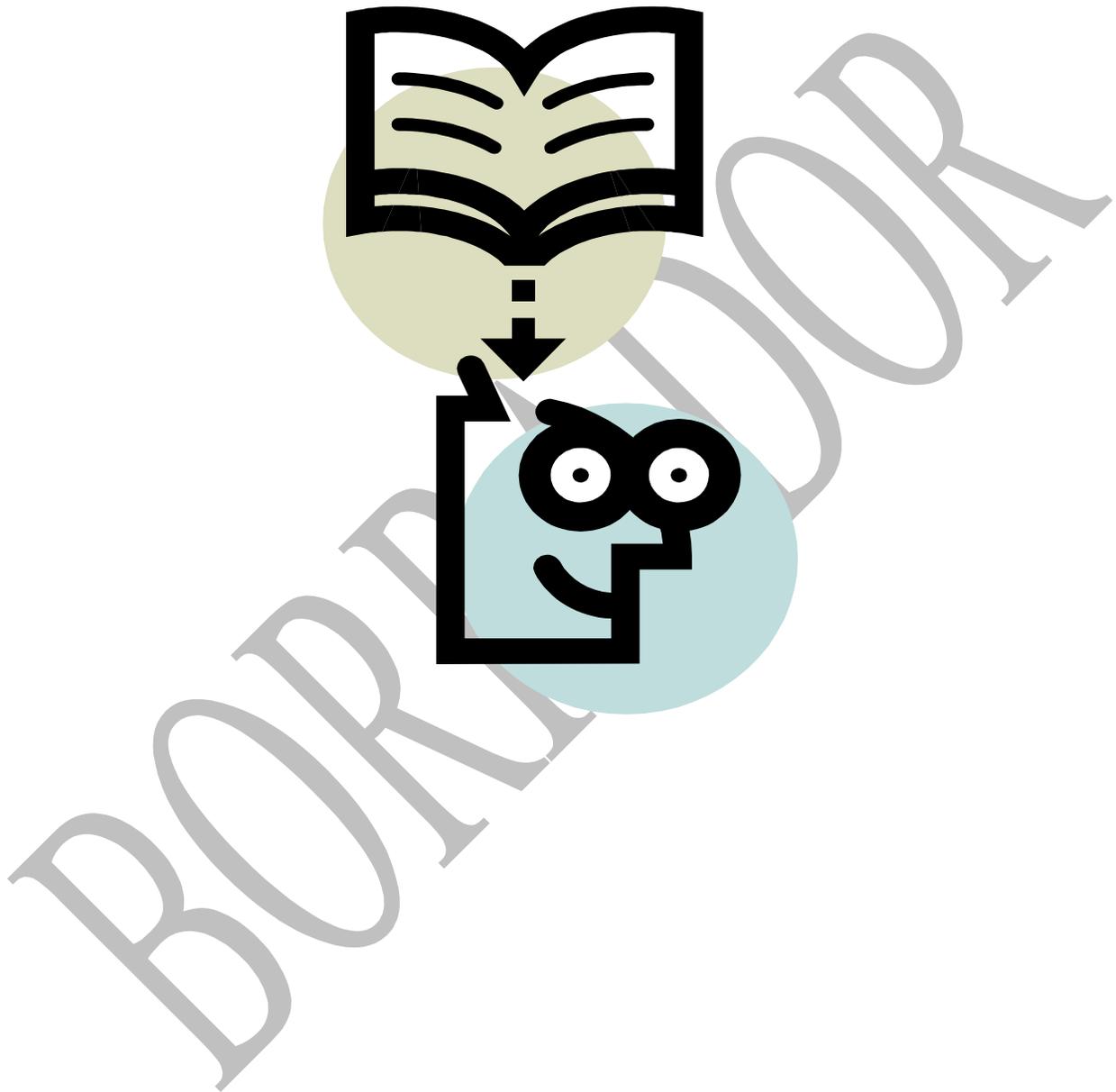
herramienta de enseñanza y entrenamiento para consumidores, la industria y las autoridades regulatorias para demostrar las mejores prácticas en la industria del servicio de alimentos en lo referente a las barreras al contacto con las manos descubiertas y las alternativas al contacto con las manos descubiertas.

Usted encontrará una presentación en Power Point al final de este documento.



Barreras al Contacto con Manos Descubiertas

Material de Referencia



SECCIÓN 1 – USO DE GANTES DESECHABLES



Sección 1.1 – Información referente a los guates

1. El uso correcto de guantes como barrera es muy importante durante las distintas tareas de manipulación de los alimentos. El uso de guantes desechables puede establecer una barrera efectiva contra las transmisión de microorganismos como bacterias y/o virus que se pudieran alojar en las puntas de los dedos o los alimentos. El lavado de manos es la primera barrera para prevenir la contaminación cruzada mientras
2. el uso de utensilios de barrera o guantes constituye una barrera secundaria.
3. los guantes desechables han sido clasificados como “utensilios” en el Código Alimentario de la FDA.
4. las barreras de guante son efectivas para la manipulación de alimentos listos para comer (RTE) cuando ningún otro utensilio puede proveer la destreza manual requerida para la tarea en cuestión (por ejemplo, rebanar zanahorias o apio). Se puede utilizar un guante en una mano mientras se sostiene algún otro utensilio con la otra mano.

Sección 1.2 – ¿Cuándo debe usar Guantes Desechables un empleado que manipula alimentos?

1. En caso de que alguien tenga una curita, infección o herida en las manos o brazos se deberá suspender cualquier actividad que involucre el contacto de los alimentos con las manos descubiertas.
2. En caso de que los empleados que manipulan alimentos usen uñas postizas o esmalte para las uñas se deberá utilizar guantes desechables al manipular alimentos.
3. El uso de guantes es opcional para la manipulación de carnes crudas pero pueden ser utilizados para desempeñar actividades de preparación como empanizar/capear carnes, aves, mariscos o vegetales

Sección 1.3 – Las Barreras de Guante deben ser específicas para cada tarea

1. Use sólo los guantes designados para las labores específicas. Los guantes desechables son específicos para cada tarea y no deben ser usados de manera indefinida.
2. Los guantes asignados para manipular alimentos no deben ser utilizados para ninguna otra tarea como sacar la basura, manipular dinero, limpiar superficies, etc.

3. Use guantes de vinilo, nitrilo sintético o látex cuando vaya a preparar (cocinar) alimentos cerca de fuentes de calor en vez de guantes de polietileno ya que éstos no son resistentes al calor.

Sección 1.4 – Evite la contaminación cruzada mediante el lavado de manos y cambio de guantes

1. En caso de que alguien esté manipulando carne, aves o mariscos con guantes, no podrá tocar alimentos RTE sin haber lavado sus manos y cambiado los guantes previamente.
2. Se deberán remover o cambiar los guantes cada vez que se cambie de actividad (por ejemplo, de la preparación de sandwiches a alguna otra actividad) o bien cuando se abandone la estación de trabajo. Antes de volver a colocarse los guantes debe haber un lavado de manos previo.
3. Los guantes de colores para tareas específicas son otra opción para la prevención de la contaminación cruzada.

Sección 1.5 – Frecuencia de Cambio de Guantes

1. Cambie los guantes periódicamente y lave sus manos cada vez que realice cambio de guantes.
2. Seque bien sus manos después de lavarlas para facilitar la colocación del nuevo par de guantes.
3. Establezca una base de frecuencia para el cambio de guantes durante el cambio de tareas.
4. Retire los guantes si realiza actividades distintas de la manipulación de alimentos listos para comer (RTE).
5. Cambie los guantes para manipular alimentos crudos o la carne cruda de distintas especies (pollo crudo a carne de res cruda).
6. Cambie los guantes para manipular cualquier alimento listo para comer que pudiera transferir sabor o algún alérgeno alimentario.
7. Lave sus manos y cambie los guantes en caso de que los guantes que esté usando se rompan o rasguen.
8. Cambie los guantes después de estornudar, toser o tocarse la cara o el cabello.

Sección 1.6 – Los cuatro materiales de guantes más comunes

1. Guantes de Polietileno
2. Guantes de Látex
3. Guantes de Vinilo
4. Guantes de Nitrilo

Sección 1.7 – La Talla de los Guantes

1. La talla de los guantes es importante para trabajar con seguridad y comodidad.
2. Elija la talla correcta para sus manos — de chico (s) a extra grande (xl).
3. A los guantes de Polietileno, Vinilo, Látex, y Nitrilo se les puede encontrar en 4 o 5 tallas – Chico (S), Mediano (M), Grande (L), Extra o Extra Grande (XL o XXL).
4. La talla de los guantes se mide a través de la parte más ancha de la palma de la mano como se muestra en la ilustración.



Sección 1.8 – Evite la contaminación cruzada mediante el uso de guantes resistentes a las cortaduras

1. En caso de que utilice un guante resistente a las cortaduras para cortar o manipular alimentos RTE, coloque un guante desechable más grande para evitar la contaminación cruzada del guante resistente a las cortaduras reutilizable.
2. Lave, enjuague y desinfecte el guante resistente a las cortaduras entre las distintas tareas que realice.

Sección 1.9 – Para retirar los Guantes

1. Para retirar los guantes desechables de un modo apropiado, sostenga el borde de la muñeca y jale desde adentro hacia afuera.
2. POR NINGÚN MOTIVO retire y reutilice los guantes O los lave con el propósito de emplearlos en múltiples tareas.

Sección 1.10 – Eligiendo el guante correcto para la tarea apropiada

1. Tome en cuenta las tareas específicas para las que destinará el tipo de guante a utilizar.
2. Los guantes de Nitrilo y Látex son más durables para tareas individuales prolongadas. Los guantes de Vinilo y Polietileno podrían ser los más adecuados para períodos breves de manipulación de alimentos. Tome en cuenta que algunas personas podrían tener alergias relacionadas con el uso de Látex.
3. Los guantes de Polietileno podrían ser los más apropiados para trabajos sencillos que requieran destreza y durabilidad.
4. Los guantes texturizados podrían mejorar la adherencia entre superficies, la sensibilidad táctil o comodidad.
5. El utilizar guantes bajo un esquema de código de colores podría ayudar a prevenir la contaminación cruzada durante la manipulación de los alimentos.

6. La resistencia al calor de algunos materiales podría facilitar el trabajo en áreas cercanas a los equipos de cocción.
7. Se podría considerar el uso de guantes largos (hasta el codo) dependiendo de las tareas a desempeñar.
8. Los despachadores de guantes deberán estar localizados en sitios cercanos a las áreas de preparación y manipulación de alimentos listos para comer y de lavado de manos para facilitar su utilización.

Sección 1.11 – Barreras de guante con o sin Polvo Lubricante

1. El polvo lubricante facilita la colocación de los guantes y absorbe la transpiración, sin embargo algunas personas prefieren guantes sin polvo lubricante.
2. Cantidad de polvo lubricante añadido (en caso de que se utilice este tipo de guantes)
 - *Guantes con Polvo Lubricante*. El contenido de polvo en los guantes no excede los 120 mg por guante (vinilo, nitrilo, látex)
 - Debe usarse únicamente como lubricante para la colocación del guante
 - Debe aplicarse la menor cantidad posible
 - No puede utilizarse talco o cualquier otro polvo no estéril
 - *Guantes Libres de Polvo Lubricante* (vinilo, nitrilo, látex)
 - Deberán contener trazas de polvo lubricante no superiores a 2 mg por guante
 - Algunos guantes ajustables tienen recubrimiento de poliuretano o son lavados en Cloro para eliminar el polvo lubricante
 - Los guantes de polietileno no contienen polvo lubricante

Sección 1.12 – Guantes de Polietileno Puro o de Mezclas de Polímeros

1. El guante “Básico de Polietileno con costura” consiste en una película extruída de polietileno conocida como “Polietileno Soplado” y puede ser blanca, opaca o de colores. Generalmente son de ajuste holgado. En el caso contrario de los guantes ajustables, este guante es útil para tareas que requieren un bajo nivel de destreza. Este guante tiene costuras en los bordes.
2. Los guantes elaborados con “mezclas de polímeros” tienen un mejor ajuste y son más suaves que los guantes de polietileno básico soplado. Estos guantes se

pueden colocar con mayor facilidad y en algunos casos están texturizados para dar un mejor agarre.

3. Estos guantes son útiles para tareas sencillas y breves y no son los más adecuados para áreas de cocción de productos (su punto de fusión aproximado es de 200° F).
4. Los guantes con manga hasta el codo están diseñados para el desempeño de tareas simples específicas que requieren un alcance del largo del brazo o recipientes profundos.

Sección 1.13 –Guantes de Polietileno de fácil acceso o tareas breves

1. Los guantes de ajuste holgado pueden tener dedos o ser de tipo “mitón” y ser despachados mediante dispositivos de fácil acceso para facilitar la colocación rápida con una sola mano.
2. Útiles para tareas únicas que requieren un cambio rápido de guantes en operaciones de alta demanda.
3. El Polietileno de Alta Densidad es más resistente al calor (distinta resina) que el Polietileno de Baja Densidad (LDPE, 200°F vs. 240°F para el HDPE), pero no es el apropiado para *tareas que involucren alimentos calientes*.

SECCIÓN 2 – PALAS, CUCCHARAS Y CUCCHARONES



Sección 2.1 – ¿Cuándo debe usar palas, cucharas o cucharones un empleado que manipula alimentos?

1. Las cucharas, palas y cucharones son empleadas por manipuladores de alimentos, personal de servicio y clientes al momento de preparar, porcionar o servir alimentos líquidos o sólidos.
2. El material de construcción y diseño de las superficies de contacto con alimentos debe cumplir con los requerimientos del Código Alimentario de la FDA mencionados en la sección 4-201.11 y debe ser durable y mantener sus cualidades características bajo condiciones de uso normal.
3. Todos los utensilios deben ser lavados, enjuagados, desinfectados y secados al aire entre cada uso y por lo menos cada cuatro horas mientras se les esté usando.
4. Cuando no se les esté utilizando, los utensilios deben ser almacenados de tal modo que se prevenga el desarrollo de bacterias, adentro del mismo alimento, en un medio ambiente limpio y protegido, dentro de un recipiente con agua corriente o bien en un recipiente con agua a una temperatura mínima de 135° F.
5. Durante pausas en la preparación o servicio de alimentos, los utensilios de preparación y servicio de alimentos deberán ser almacenados:
 - Dentro del mismo alimento con el mango encima del alimento y fuera del recipiente.
 - En una porción limpia de la mesa de preparación o de la superficie de cocción que esté limpia y desinfectada.

- En agua corriente cuya velocidad sea la suficiente para separar las partículas de alimentos húmedos como helado o puré de papa y ser drenada al exterior del recipiente.
 - En un recipiente de agua limpio y desinfectado, siempre y cuando el agua se mantenga a una temperatura mínima de 135°F.
 - En un sitio limpio y protegido en caso de que los utensilios como palas para hielo se utilicen para manipular alimentos que no sean potencialmente peligrosos (que no requieran control de tiempo/temperatura para mantenerlos seguros).
6. Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.

Sección 2.2 – El uso de las Palas

1. A las palas se les encuentra en varias medidas y son el utensilio ideal para el control de porciones.
 2. Cuando se utilice una pala con dispensador, es necesario que se evite el contacto del mecanismo del dispensador con el alimento. De este modo se podrá prevenir la transferencia de patógenos de las manos al alimento.
 3. Las palas se pueden utilizar con o sin el uso de otras barreras. Las palas son una alternativa práctica al amnejo de alimentos con las manos descubiertas en muchas situaciones.
- Las palas pueden ser empleadas como único utensilio o bien en conjunto con algún otro utensilio de barrera como los guantes.

Sección 2.3 – El uso de las Cucharas

1. Generalmente, las cucharas no tienen un tamaño de porción o forma predeterminados.
2. Las cucharas usadas para probar alimentos deben ser lavadas, enjuagadas y sanitizadas entre cada uso. Las cucharas desechables o utensilios de un sólo uso podrán ser una buena opción para este tipo de tareas.
3. El uso inapropiado de cucharas de prueba podría provocar enfermedades alimentarias.
4. Las cucharas pueden ser utilizadas con o sin la ayuda de otros utensilios de barrera. Las cucharas son una alternativa práctica para la manipulación de alimentos con las manos descubiertas en muchas situaciones.

Sección 2.4 – El uso de Cucharones

1. Los cucharones están disponibles en varios tamaños y son un utensilio ideal para el control de porciones.
2. Los cucharones pueden ser utilizados con o sin la ayuda de otros utensilios de barrera. Los cucharones son una alternativa práctica para la manipulación de alimentos con las manos descubiertas en muchas situaciones.
3. Los cucharones se pueden utilizar solos o con la ayuda de otros utensilios de barrera como los guantes.

SECCIÓN 3 – ESPÁTULAS



Sección 3.1 – ¿Cuándo debe usar espátulas el empleado que manipula alimentos?

1. Los manipuladores de alimentos, el personal de servicio o los consumidores emplean las espátulas se usan para revolver, porcionar, untar o levantar los alimentos.
2. Los materiales de construcción y el diseño de las superficies en contacto con alimentos deben cumplir con los requerimientos establecidos por la sección 4-201.11 del Código Alimentario de la FDA y deben ser durables y conservar sus cualidades características bajo condiciones normales de uso.
3. Todos los utensilios deben ser lavados, enjuagados, desinfectados y secados al aire entre cada uso o al menos cada cuatro horas durante su uso continuo.
4. Cuando no se les esté utilizando, los utensilios deben ser almacenados de tal manera que se prevenga el desarrollo de microorganismos, dentro del mismo alimento, en un sitio limpio y protegido, en un recipiente con agua corriente o en un recipiente con agua caliente a una temperatura mínima de 135° F.

5. Durante pausas en la preparación o servicio de alimentos, los utensilios para preparar o server alimentos deberán ser almacenados:
 - Dentro del mismo alimento con el mango encima del alimento y fuera del recipiente.
 - En una porción limpia de la mesa de preparación o de la superficie de cocción que esté limpia y desinfectada.
 - En agua corriente cuya velocidad sea la suficiente para separar las partículas de alimentos húmedos como helado o puré de papa y ser drenada al exterior del recipiente.
 - En un recipiente de agua limpio y desinfectado, siempre y cuando el agua se mantenga a una temperatura mínima de 135°F (57°C).
 - En un sitio limpio y protegido en caso de que los utensilios como palas para hielo se utilicen para manipular alimentos que no sean potencialmente peligrosos (que no requieran control de tiempo/temperatura para mantenerlos seguros).
 - Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.
6. Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.

Sección 3.2 – El uso de Espátulas

1. A las espátulas se les encuentra disponibles tanto en diseños genéricos como sumamente adaptados para tareas específicas.
2. Sólo use la espátula indicada para cada tarea específica.
3. A las espátulas se les puede utilizar con o sin la ayuda de otros utensilios de barrera. Las espátulas son una alternativa práctica para la manipulación de alimentos con las manos descubiertas en muchas situaciones.

SECCIÓN 4 – PINZAS



Sección 4.1 – ¿Cuándo debe usar Pinzas un empleado que manipula alimentos?

1. Los empleados que manipulan y/o sirven alimentos emplean las pinzas para sostener o levantar alimentos, para mover alimentos de un sitio a otro y para voltear los alimentos mientras se cocinan, especialmente durante el asado.
2. Los materiales de construcción y el diseño de las superficies en contacto con alimentos deben cumplir con los requerimientos establecidos por la sección 4-201.11 del Código Alimentario de la FDA y deben ser durables y conservar sus cualidades características bajo condiciones normales de uso.
3. Todos los utensilios deben ser lavados, enjuagados, desinfectados y secados al aire entre cada uso o al menos cada cuatro horas durante su uso continuo.
4. Cuando no se les esté utilizando, los utensilios deben ser almacenados de tal manera que se prevenga el desarrollo de microorganismos, dentro del mismo alimento, en un sitio limpio y protegido, en un recipiente con agua corriente o en un recipiente con agua caliente a una temperatura mínima de 135° F.
5. Durante pausas en la preparación o servicio de alimentos, los utensilios para preparar o server alimentos deberán ser almacenados:
 - Dentro del mismo alimento con el mango encima del alimento y fuera del recipiente.
 - Dentro del alimento que no sea potencialmente peligrosos (que requiera control de tiempo/temperatura para mantenerlo seguro) con el mango encima del alimento dentro del mismo recipiente o equipos en recipientes y recipientes que puedan ser cerrados (como en el caso de azúcar o harina).
 - En una porción limpia de la mesa de preparación o de la superficie de cocción que esté limpia y desinfectada.
 - En agua corriente cuya velocidad sea la suficiente para separar las partículas de alimentos húmedos como helado o puré de papa y ser drenada al exterior del recipiente.
 - En un recipiente de agua limpio y desinfectado, siempre y cuando el agua se mantenga a una temperatura mínima de 135°F (57°C).
 - En un sitio limpio y protegido en caso de que los utensilios como palas para hielo se utilicen para manipular alimentos que no sean potencialmente peligrosos (que no requieran control de tiempo/temperatura para mantenerlos seguros).
 - Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.
6. Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.

Sección 4.2 - El uso de Pinzas

1. Las pinzas son una alternativa práctica para la manipulación de alimentos con las manos descubiertas en muchas situaciones.
2. A las pinzas se les encuentra disponibles tanto en diseños genéricos como altamente adaptados para tareas específicas.
3. Hay pinzas específicamente diseñadas para levantar artículos como cubos de azúcar, espárragos, queso rayado, hielo, ensalada, spaghetti, hamburguesas, espinas de pescado, perlas de melón, bagels, cangrejo cocido, garnituras y bolsas de té.
4. A cada pinza debe dársele el uso específico para el cual fue diseñada.
5. A las pinzas se les puede utilizar con o sin la ayuda de otros utensilios de barrera.

SECCIÓN 5 – TENEDORES

Sección 5.1 – ¿Cuándo un empleado que manipula alimentos debe usar los Tenedores?

1. Los empleados que manipulan y/o sirven alimentos utilizan los tenedores para sostener o levantar alimentos, para moverlos de un sitio a otro, para voltear los alimentos durante su preparación y para sostener los alimentos al cortarlos o tallarlos.
2. Los materiales de construcción y el diseño de las superficies en contacto con alimentos deben cumplir con los requerimientos establecidos por la sección 4-201.11 del Código Alimentario de la FDA y deben ser durables y conservar sus cualidades características bajo condiciones normales de uso.
3. Todos los utensilios deben ser lavados, enjuagados, desinfectados y secados al aire entre cada uso o al menos cada cuatro horas durante su uso continuo.
4. Cuando no se les esté utilizando, los utensilios deben ser almacenados de tal manera que se prevenga el desarrollo de microorganismos, dentro del mismo alimento, en un sitio limpio y protegido, en un recipiente con agua corriente o en un recipiente con agua caliente a una temperatura mínima de 135° F.



5. Durante pausas en la preparación o servicio de alimentos, los utensilios para preparar o server alimentos deberán ser almacenados:
 - Dentro del mismo alimento con el mango encima del alimento y fuera del recipiente.
 - En una porción limpia de la mesa de preparación o de la superficie de cocción que esté limpia y desinfectada.
 - En agua corriente cuya velocidad sea la suficiente para separar las partículas de alimentos húmedos como helado o puré de papa y ser drenada al exterior del recipiente.
 - En un recipiente de agua limpio y desinfectado, siempre y cuando el agua se mantenga a una temperatura mínima de 135°F (57°C).
 - En un sitio limpio y protegido en caso de que los utensilios como palas para hielo se utilicen para manipular alimentos que no sean potencialmente peligrosos (que no requieran control de tiempo/temperatura para mantenerlos seguros).
 - Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.
6. Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.

Sección 5.2 - El uso de Tenedores

1. Los tenedores son una alternativa práctica para la manipulación de alimentos con las manos descubiertas en muchas situaciones.
2. Los tenedores deberán utilizarse para tareas específicas.
3. Los tenedores que han sido diseñados para usarse sólo una vez deberán ser desechados después de haber sido usados.
4. Los tenedores pueden ser utilizados con o sin la ayuda de otros utensilios de barrera.

SECCIÓN 6 – PAPEL DE ENVOLTURA

Sección 6.1 – ¿Cuándo debe usar Papel Delicatessen o Envoltura de Panadería un empleado que manipula alimentos?



1. Los empleados que manipulan alimentos, el equipo de servicio/atención a clientes y los clientes emplean las envolturas de panadería o delicatessen para mantener una barrera sanitaria entre los alimentos y las manos descubiertas.

Sección 6.2 – La selección de la Envoltura de Panadería o Delicatessen

1. Los operadores de servicios de alimentos o representantes de compras deben asegurarse de que todos los componentes de las envolturas cumplen con los requerimientos de la sección 21, CFR 177.1520 de la FDA.
2. Las envolturas deben ser fabricadas mediante la aplicación de Buena Prácticas de Manufactura. Los fabricantes de envolturas para alimentos deben demostrar que todos los componentes utilizados son seguros y que no habrá migración de los componentes o de elementos tóxicos a los alimentos.
3. A las envolturas para alimentos se les encuentra disponibles en una gran variedad de tamaños y empaques en los almacenes de artículos para servicios de alimentos.
4. Las envolturas pueden ser enceradas o sin encerar. La envoltura encerada puede absorber un poco de líquido evitando que se ensucien las manos. La envoltura sin cera se usa generalmente para manipular productos de panadería.
5. Los paquetes o empaques dispensadores deben ser bien contruidos, de modo tal que las envolturas no se contaminen con impurezas externas y que se permita tomar las hojas con facilidad.
6. Los operadores de servicios de alimentos debe seleccionar la envoltura apropiada tomando en consideración el uso que les dará.

Sección 6.3 – El uso de Envolturas de Panadería y Delicatessen

1. Las hojas de envoltura deben retirarse una a la vez sin que se rompan o se contamine el resto de las hojas.
2. Si se va a usar papel de envoltura como barrera primaria, los empleados que manipulan alimentos deben desechar inmediatamente las hojas usadas. Las hojas de envoltura no pueden ser reutilizadas ni los alimentos almacenarse en ellas.
3. El despachador de hojas debe ser almacenado en un sitio adecuado en el que se evite la contaminación cruzada con otros alimentos o impurezas externas.

SECCIÓN 7 – PALILLOS



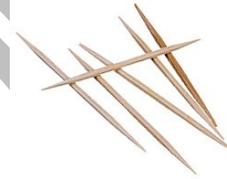
Sección 7.1 – ¿Cuándo deben usar Palillos los empleados que manipulan alimentos?

1. Generalmente los consumidores usan los palillos para comer pero los empleados que manipulan alimentos los pueden usar para mover los alimentos de un sitio a otro durante la preparación o servicio de los mismos.
2. Los materiales de construcción y el diseño de las superficies en contacto con alimentos deben cumplir con los requerimientos establecidos por la sección 4-201.11 del Código Alimentario de la FDA y deben ser durables y conservar sus cualidades características bajo condiciones normales de uso.
3. Todos los utensilios deben ser lavados, enjuagados, desinfectados y secados al aire entre cada uso o al menos cada cuatro horas durante su uso continuo.
4. Durante pausas en la preparación o servicio de alimentos, los utensilios para preparar o server alimentos deberán ser almacenados:
 - Dentro del mismo alimento con el mango encima del alimento y fuera del recipiente.
 - En una porción limpia de la mesa de preparación o de la superficie de cocción que esté limpia y desinfectada.
 - En agua corriente cuya velocidad sea la suficiente para separar las partículas de alimentos húmedos como helado o puré de papa y ser drenada al exterior del recipiente.
 - En un recipiente de agua limpio y desinfectado, siempre y cuando el agua se mantenga a una temperatura mínima de 135°F (57°C).
 - En un sitio limpio y protegido en caso de que los utensilios como palas para hielo se utilicen para manipular alimentos que no sean potencialmente peligrosos (que no requieran control de tiempo/temperatura para mantenerlos seguros).
 - Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.

5. Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo.

Sección 7.2 - El uso de los Palillos

1. Los palillos pueden ser una alternativa para la manipulación de alimentos con las manos descubiertas.
2. Los palillos deben ser utilizados sólo para tareas específicas.
3. Los palillos fabricados con materiales reutilizables deben ser lavados, enjuagados, desinfectados y secados al aire entre cada uso.
4. Los palillos diseñados y fabricados para usarse sólo una vez deben ser desechados después de haber sido utilizados.
5. Los palillos pueden usarse con o sin la ayuda de otros utensilios de barrera como los guantes.



SECCIÓN 8 – PALILLOS PARA DIENTES

Sección 8.1 – ¿Cuándo debe usar Palillos para Dientes un empleado que manipula alimentos?

1. Los palillos para dientes se usan típicamente para evitar el contacto de las manos descubiertas con alimentos RTE como los entremeses. A los palillos para dientes también se les utiliza para sostener o mantener acomodados alimentos apilados o en capas como los sandwiches u otras preparaciones.
2. Los materiales de construcción y el diseño de las superficies en contacto con alimentos deben cumplir con los requerimientos establecidos por la sección 4-201.11 del Código Alimentario de la FDA y deben ser durables y conservar sus cualidades características bajo condiciones normales de uso.

Sección 8.2 - El uso de Palillos para Dientes

1. Los palillos para dientes deben ser colocados por el personal antes del servicio de los alimentos o bien presentados a los consumidores de tal manera que se evite una posible contaminación de la porción que estará en contacto con el alimento, de modo vertical en un recipiente angosto de plástico o vidrio.
2. Los palillos para dientes están típicamente diseñados para ser de un sólo uso y deben ser desechados una vez se les haya utilizado.

3. En el caso específico de que los palillos de dientes hayan sido diseñados para reutilizarse, éstos deberán ser lavados, enjuagados, desinfectados y secados al aire entre cada uso.

BORRADOR

Preguntas Más Frecuentes



Preguntas más Frecuentes:

1. ¿Cuál es el propósito de este documento?

El Manual de Entrenamiento para el Contacto Con Manos Descubiertas ha sido desarrollado para su utilización como una herramienta de enseñanza y entrenamiento para consumidores, la industria y las autoridades regulatorias para demostrar las mejores prácticas en la industria del servicio de alimentos en lo referente a las barreras al contacto con las manos descubiertas y las alternativas al contacto con las manos descubiertas.

2. ¿Cómo debo usar este documento?

Este documento puede ser utilizado para instruir e informar a los consumidores, miembros de la industria del servicio de alimentos y las autoridades regulatorias acerca de las mejores prácticas en el uso de barreras a las manos descubiertas para la manipulación de alimentos.

3. ¿Los Departamentos de Salud aprueban este manual?

Este documento se desarrolló con los esfuerzos conjuntos y la aportación de las instancias reguladoras federales, estatales y locales, la industria, académicos y los consumidores.

4. ¿Puedo utilizar la información de este documento para mis presentaciones?

Esta información puede ser utilizada con propósitos educativos.

5. ¿Con quién me debo poner en contacto en caso de tener más preguntas?

Si tiene preguntas adicionales por favor consulte con su Departamento de Salud local o con la Conferencia para la Protección de los Alimentos (Conference for Food Protection).

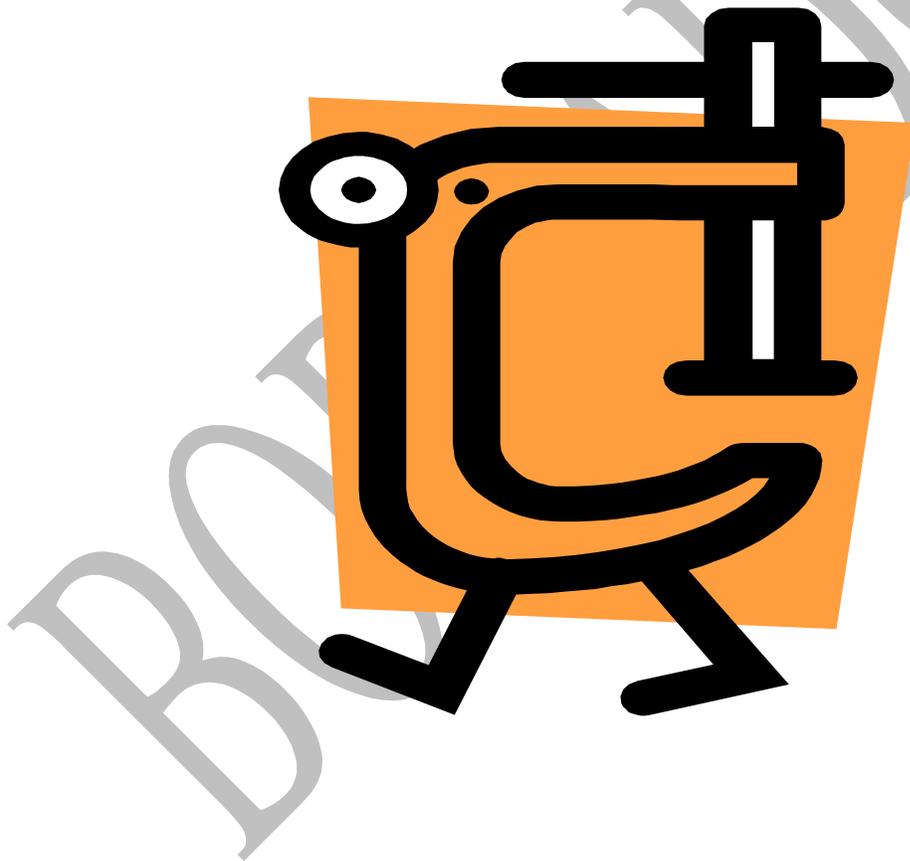
6. ¿Qué debo hacer si tengo una pregunta referente a un utensilio que no está incluido en este documento?

Este documento no pretende reemplazar los requerimientos de la regulación local. Por favor consulte con su Departamento de Salud local acerca de los requerimientos definitivos.

7. ¿Los utensilios deben contar con alguna certificación?

Por favor consulte con el Departamento de Salud de su localidad acerca de los requerimientos de certificación de utensilios.

Apéndice / Herramientas



Referencias

2005 Model Food Code sections applicable to Barriers to Bare Hand Contact.

Nota: La traducción de las referencias se encuentra en *cursivas* entre paréntesis facilitar la búsqueda debido a que el documento fuente (Código Alimentario) no tiene traducción al Español.

1-2 DEFINITIONS (DEFINICIONES)

1-201 – Applicability and Terms Defined (*Aplicabilidad y Definición de Términos*)
Ready-to-Eat Food (*Alimento Listo para Comer*)
Utensil (*Utensilio*)

2-3 PERSONAL CLEANLINESS (LIMPIEZA DEL PERSONAL)

2-301 Hands and Arms (*Manos y Brazos*)
2-301.11 Clean Condition Fingernails (refers to glove use) (*Uñas limpias*) (*refiriéndose a uso de guantes*)
2-301.12 Cleaning Procedure (*Procedimiento de limpieza*)
2-301.14 When to Wash (refers to glove use) (*Cuándo lavar*) (*refiriéndose a uso de guantes*)
2-301.15 Where to Wash (*En dónde lavar*)

3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING (PROTECCIÓN DE LA CONTAMINACIÓN DESPUÉS DE RECIBIR)

Preventing Contamination by Employees (*previniendo la contaminación por parte de los empleados*)
3-301.11 Preventing Contamination from Hands (refers to deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment) (*Previniendo la contaminación de las manos*) (*refiriéndose a papel de envoltura, espátulas, pinzas, guantes desechables o equipo de servicio*)
3-301.11(B) Preventing contamination from hands (*previniendo la contaminación a través de las manos*)

PREVENTING CONTAMINATION FROM EQUIPMENT, UTENSILS, AND LINENS (PREVINIENDO LA CONTAMINACIÓN PROVENIENTE DE EQUIPO, UTENSILIOS Y TEXTILES)

3-304.11 – Food Contact with Equipment and Utensil (*Contacto de los alimentos con equipos y utensilios*)
3-304.12 In-use utensils, between-use storage (*Utensilios en uso, almacenamiento entre usos*)
3-304.15 – Gloves, Use Limitation (*Guantes, limitaciones de uso*)
3-304.16 Using clean tableware for second portions and refills (*Utilizando cubiertos limpios para segundas porciones y rellenos*)

- 3-502.12 Reduce oxygen packaging, criteria (*Empacado con reducción de Oxígeno, criterios*)
3-502.12(B) (5) (a) (prohibits bare hand contact) (*prohibición de contacto con manos descubiertas*)
3-801.11 Pasteurized Foods, prohibited re-service and prohibited food (*Alimentos pasteurizados, prohibida la reutilización, alimento prohibido*)
3-801.11(F) (3) (b) (prohibits bare hand contact) (*prohibición de contacto con las manos descubiertas*)

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR (MATERIALES DE FABRICACIÓN Y REPARACIÓN)

Single-Service and Single Use (*Un sólo servicio y un sólo uso*)

- 4-101.17 Wood, use limitations (*Madera, limitaciones de uso*)
4-102.11 Characteristics (single-service and single use) (*Características*) (*un solo servicio y un solo uso*)
4-102.11 Characteristics (*Características*)
4-2 Design and Constructions (*Diseño y fabricación*)
4-201.11 Equipment and utensils (*Equipos y utensilios*)
4-205.10 Food Equipment, certification and classification (*Equipo para uso con alimentos, certificación y clasificación*)
4-302.11 Utensils, consumer self-service (*Utensilios, auto servicio para consumidores*)
4-502.11 Single-service and single-use, required (*Un sólo servicio y un sólo uso, requerido*)
4-502.13 Single-service and single-use, use limitations (*Un sólo servicio y un sólo uso, limitaciones de uso*)
4-6 Cleaning of Equipment and utensils (*Limpieza de equipos y utensilios*)
4-7 Sanitization of equipment and utensils (*Desinfección de equipos y utensilios*)
4-9 Protection of clean items (*Protección de artículos limpios*)

4-9 PROTECTION OF CLEAN ITEMS (PROTECCIÓN DE ARTÍCULOS LIMPIOS)

Storing (*Almacenamiento*)

- 4-903.11 – Equipment, Utensils, Linens, and Single Service and Single Use Articles (*Equipo, Utensilios, Textiles, artículos de un sólo servicio y artículos de un sólo uso*)

Anexo 3: Motivos de Salud Pública / Lineamientos Administrativos:

Cada sección del Código tendrá información acerca de sus antecedentes o guías en esta Sección del Código Alimentario.

Presentación



A separate presentation is available

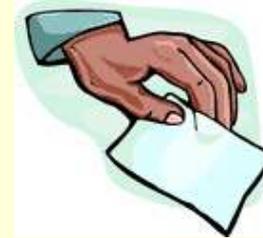
Barriers to Bare Hand Contact



Scoops



Chopsticks



Deli Papers



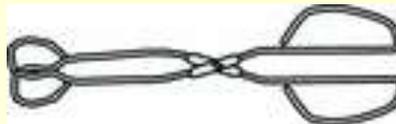
Forks and Ladles



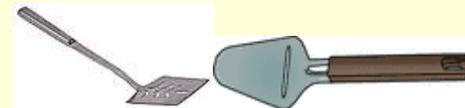
Single Use Gloves



Toothpicks



Tongs



Spatulas

There is a Tool for Every Job!



Presentation prepared by the Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection Revised December 2009

MISSION



Provide alternative best practices and tools to avoid bare hand contact

Purpose: identify alternative ways to handling food with bare hand contact and address right and wrong ways in handling utensils

Audience: developed for use by industry and regulatory as a training and teaching tool

Document: reflects industry's best practices regarding bare hand contact barriers and will demonstrates alternatives to bare hand contact

When Should a Food Worker Choose a Glove Barrier?

- The correct use of glove barriers is important during food handling tasks. Single-use gloves can be an effective barrier against the transmission of microorganisms, such as bacteria & viruses, from fingertips or foods
- Hand washing is a primary barrier to cross contamination; barrier utensils & gloves are a secondary barrier
- Single-use gloves are defined as a “utensil” in the FDA Food Code
- Glove barriers work when handling any ready-to-eat food and another utensil does not provide the hand dexterity for the task (example: slicing carrots or celery). One glove may work on one hand with a utensil used by the other hand



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When Should a Food Worker Choose a Glove Barrier?

Gloves must be worn:

- If you have a bandage, infection, cut, or sore on hands or arms
- When food workers wear artificial nails or fingernail polish they must wear disposable gloves when handling food
- Glove use is optional to handle raw meats, but can be used for preparation tasks such as breading/battering meats, poultry, seafood, or vegetables



Glove Barriers Must Be Task-Specific

- Use gloves for designated food task only. Disposable gloves are task-specific and should never be worn continuously
- Gloves designated for food use should not be used for non-food tasks, such as taking out the garbage, handling money, cleaning surfaces, etc.
- Use vinyl, nitrile synthetic, or latex gloves when handling foods near a heat source cooking area, rather than poly (polyethylene) gloves, which are not resistant to heat

4 Most Common Materials Used for Food Contact Gloves

Poly gloves



Latex gloves



Vinyl gloves



Nitrile gloves



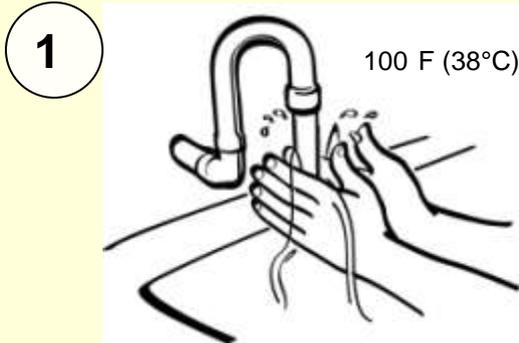
Avoid Cross-contamination by Washing Hands & Changing Gloves

- If you handle raw meats, poultry, or seafood with gloves on, do not touch ready-to-eat or cooked foods without washing hands and changing gloves
- Remove or change gloves when you change activity (for example: making sandwiches or handling money) or whenever you leave your workstation; wash hands before putting on gloves
- Consider using task-specific colored gloves for cross contamination prevention

Hand washing

Always wash your hands before putting on a new pair of gloves.

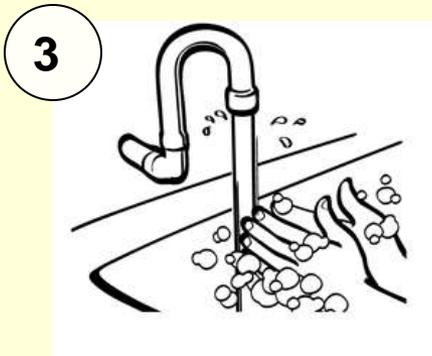
Follow these five steps to wash your hands properly:



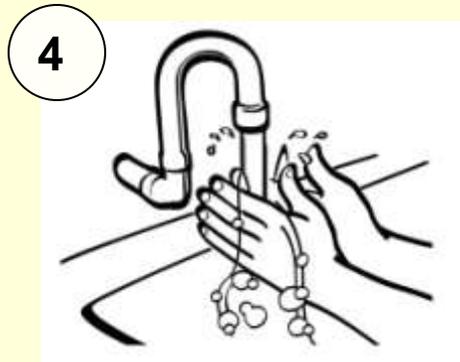
Wet your hands with running water as hot as you can comfortably stand (at least 100 F (38°C))



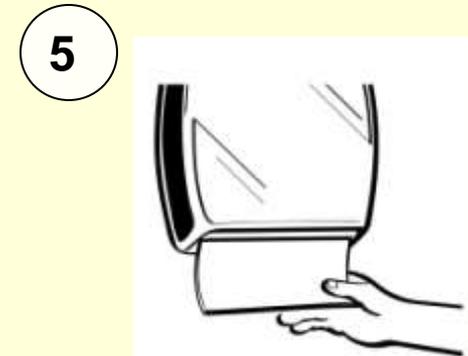
Apply Soap



Vigorously scrub hands and arms for 10 to 15 seconds. Clean under fingernails and between fingers.



Rinse thoroughly under running water



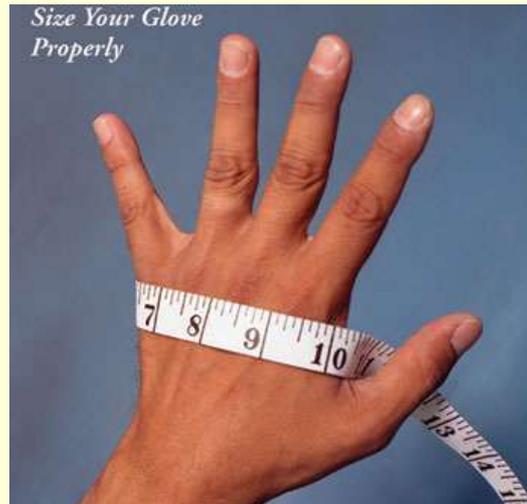
Dry hands and arms with a single-use paper towel or warm-air hand dryer or a hand drying device that uses high velocity pressurized air

Glove Change Frequency

- Change gloves periodically and wash hands each time before & after gloving
- After hand washing, dry hands properly and thoroughly before donning gloves to make them easier to slip on
- Base the **frequency of glove changing** on TASK changes
 - remove gloves if doing different task not handling ready-to-eat foods;
 - change gloves to handle a raw food or different raw species (for example: raw chicken or raw beef);
 - change gloves to handle another ready-to-eat food that might transfer a flavor or food allergen
- Wash hands and re-glove if a glove develops a hole or tear during usage
- Change gloves after sneezing, coughing, or touching your hair or face

Get the Correct Glove Fit

- Glove size is important for safety and comfort
- Select the right size for your hand— from small to extra large
- Poly, Vinyl, Latex, & Nitrile usually come in 4 or 5 sizes – Small, Medium, Large, X or XX-Large
- Glove sizes are measured across the widest part of the palm as shown



Avoid Cross-contamination with Cut-resistant Gloves

- If wearing a cut-resistant glove to cut or handle raw or ready-to-eat food, wear a larger disposable glove over top to avoid cross-contamination of the reusable cut-resistant glove
- Wash, rinse & sanitize the cut-resistant glove between uses

Cut-resistant Safety Glove Needed	+	Disposable Glove Needed	=	Disposable Glove Over Top
				

Removing Gloves Correctly

- To remove disposable gloves correctly, grasp at the cuff and peel them off inside-out



★ **DO NOT** remove and re-use gloves OR re-wash single-use food contact gloves for multiple tasks

Utensils

(scoops, spoons, ladles, spatulas, tongs, forks, chopsticks, toothpicks)

- The construction and design of the food contact surface should follow FDA Food Code requirements in section 4-201.11 and be durable and able to retain its characteristic qualities under normal conditions
- All utensils should be washed, rinsed, sanitized and air dried between uses and at least every 4 hours when being used.
- All in-use utensils shall be changed at least every **4 hours** during continual use

Utensils

(scoops, spoons, ladles, spatulas, tongs, forks, chopsticks, toothpicks)

- When not in use, utensils must be stored in a manner to prevent bacterial growth such as in the food, in a clean and protected environment, under running water, or in a container at a minimum temperature of 135°F (57°C)
- In-use utensils may not be stored in chemical sanitizer or ice



Scoops

- Scoops are used by food preparers, servers and customers when preparing, portioning or serving liquid or solid food
- Scoops can be used with or without the use of other barriers
- When using a scoop with a release trigger, prevent the release trigger from touching the food. This prevents pathogens from the hand transferring to the food



Spoons



- Spoons typically have no predetermined serving size or shape
- Spoons are used by food preparers, servers and customers when preparing, portioning or serving liquid or solid food
- When using spoons for tasting, the spoon used for tasting must only be used once. Disposable or single serving utensils can be used for this task
- Improper use of tasting spoons can lead to foodborne illness

Ladles



- Ladles are available in many different sizes and are an ideal utensil for portion control
- Ladles are used by food preparers, servers and customers when preparing, portioning or serving liquid or solid food
- Ladles can be used with or without the use of other barriers



Spatulas



Spatulas



- Find a spatula that works best for the task. There are generalized and highly adapted designs widely available
- Spatulas are used to stir, scoop, spread or lift food
- Spatulas are a practical alternative to handling food with bare hands in many situations

Using Spatulas

- Spatulas are used by food preparers and servers when preparing or serving food
- Spatulas should be dedicated to a specific task
- Wash, rinse, sanitize and air dry spatulas between different tasks
- Spatulas may be used as a stand alone tool or in conjunction with another barrier, such as gloves





A wide variety of tongs



Keeping hands off food



**Color coded,
different sizes,
multi-use tongs**

Tongs

Bread or pastry



Tongs



- Tongs are a practical alternative to handling food with bare hands in many situations
- Tongs are a group of kitchen tools that are used to grip or lift food
- They are typically used to move a food from one location to another during preparation or service
- They can also be used to rotate food during cooking, especially during grilling

Tongs for the Task

- Find a tong that works for the task. There are generalized and highly adapted designs widely available. Tongs are a practical alternative to handling food with bare hands in many situations
- There are specific designs that are intended to pick up and maneuver sugar cubes, asparagus, shredded cheese, ice, salad, spaghetti, hamburgers, fish bones, melon balls, bagels, cooked crabs, garnishes and tea bags



Using Tongs

- Tongs should be dedicated to a specific task.
- Wash, rinse, sanitize, and air dry all tongs between different tasks
- Use the right tong for the job. Tongs can be used as a stand alone tool or in conjunction with another barrier such as gloves





Multi-
purpose
tongs

Sushi tongs

Garnish tongs



**Asparagus
tongs**

**Bagel or toast
tongs**



**Tender touch
pastry tongs**



**High Heat
nylon tongs**



Fine tip tongs



**Pastry or meat
tongs**



Cake tongs



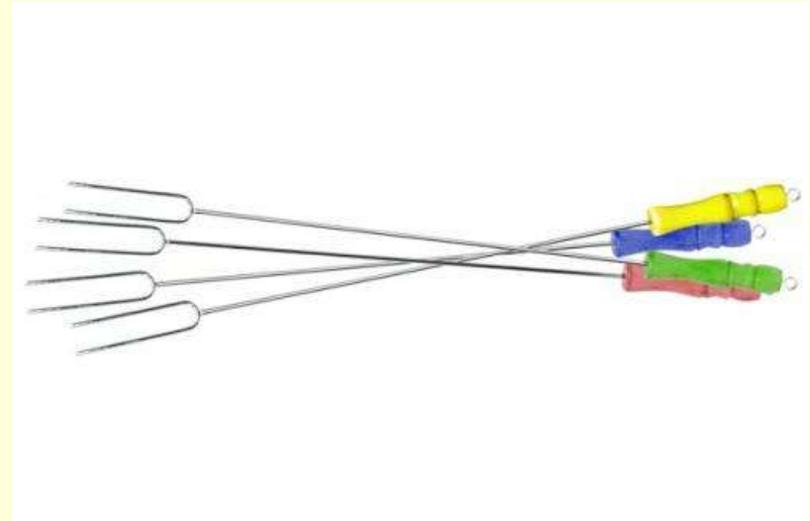
Spaghetti tongs



Pickle tongs



**Buffet
tongs**



Forks



Presentation prepared by the Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection Revised December 2009

Forks

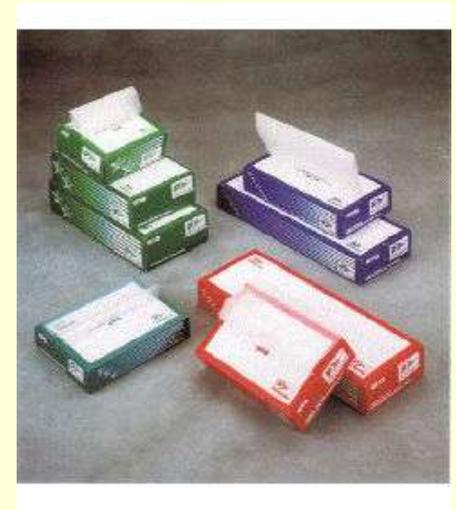


- Forks are a practical alternative to handling food with bare hands in many situations
- Forks are used to grip or lift food
- They are typically used to move food from one location to another or rotate food (while grilling for instance) during preparation
- They may also be used during service, such as, to hold or grip a roast on a meat carving station

Using Forks

- Forks should be dedicated to a specific task
- Wash, rinse, sanitize and air dry forks between different tasks
- Forks designed and intended for single-use only must be discarded after each use
- Forks may be used as a stand alone tool or in conjunction with another barrier, such as gloves





DELI PAPER



Presentation prepared by the Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection Revised December 2009

Deli and Bakery Wrap

- Deli and Bakery Wrap can be used as a barrier to bare-hand contact
- Sheets are single-use and can be used in the foodservice area, by wait-staff, and customers
- Sheets can be purchased in a variety of sheet sizes and packages from any restaurant or foodservice supply vendor



Selecting Bakery or Deli Wrap

- The main purpose of the wrap is to act as a sanitary barrier between the bare hand and food. Food service operators should select wrap based on intended purpose
- Wrap can be dry waxed or without wax. Dry wax will absorb some liquid and prevent the seeping of product liquid onto the hands
- Wraps without wax are generally intended to be used for bakery products. Food service operators should select wrap based on intended purpose



Selecting Bakery or Deli Wrap

- Operators or purchasing agents must ensure all wrap components are in compliance with the FDA, Title 21, CFR 177.1520
- Sheets are manufactured in accordance to Good Manufacturing Practices
- Manufacturers of food contact wraps or sheets must demonstrate that all components are safe for use and do not leach components or toxic elements onto the food
- Dispensing packages should be well made to prevent contamination of the sheets from external debris and permit easy access to the sheet



Deli and Bakery Wrap Benefits

- Dispensing container protects the sheets from contamination before use
- Easy to use for foodservice employees and customers
- Helps keep food fresh
- Absorbs grease and oil while acting as a barrier for food

Using Deli and Bakery Wrap

- Sheets should be dispensed one at a time without tearing or contaminating the remaining sheets
- If sheets are used as the primary barrier, food preparers should discard used sheets immediately after use. Sheets should not be reused or remain with the food
- Store the dispensing container in a location so as to prevent cross contamination from other food or debris





Chopsticks



Presentation prepared by the Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection Revised December 2009

Chopsticks



- Chopsticks may be an alternative to handling food with bare hands
- They are typically or most commonly used for eating but may be used to move food from one location to another during preparation or service



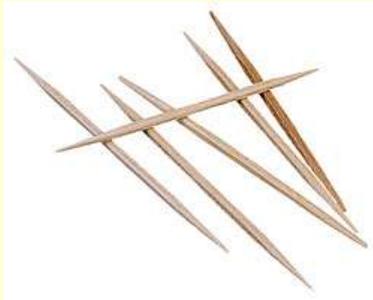
Using Chopsticks



- Chopsticks should be task specific
- Chopsticks may be constructed of a variety of woods, plastics or metals
- Chopsticks constructed to be a multi-use item must be washed, rinsed, sanitized, and air dried between different tasks
- Chopsticks designed and intended for single-use only must be discarded after each use
- Chopsticks are generally used as a stand alone tool/barrier, but may be used in conjunction with another barrier



Toothpicks



Presentation prepared by the Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection Revised December 2009

Toothpicks

- Toothpicks are typically used to prevent bare hand contact with ready-to-eat foods such as hors d'oeuvres, but are also used to hold stacked/layered sandwiches or other items together and/or upright
- Toothpicks should be placed in food, by staff, prior to service or presented/provided to consumer in a manner that will prevent possible contamination of the food contact portion of the toothpick, such as, upright in a small/slender glass or container
- Toothpicks may be constructed of a variety of woods, plastics or metals. In almost all cases, toothpicks are designed to be single-use items only, discarded after use
- If designed to be multi-use, toothpicks must be washed, rinsed, sanitized, and air dried between tasks



QUESTIONS



Presentation prepared by the Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection Revised December 2009

Barreras al Contacto con las Manos Descubiertas



Palas



Palillos



Papel de Envoltura



Tenedores y Cucharones

Utensilios para
Alimentos Listos
para Comer



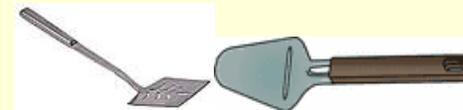
Guantes
Desechables



Palillos para dientes



Pinzas



Espátulas

¡Hay una Herramienta Para cada Tarea o Uso!



Presentación preparada por el Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection - Revisada en Diciembre 2009

Puede usar objetivo en vez de MISIÓN

- *Proporcionar la mejore orientacion y utensilios para evitar contacto con las Manos descubiertas*

Propósito: identificar maneras alternativas a la manipulación de alimentos con las manos descubiertas e indicar los modos correctos e incorrectos de manejar los utensilios

Audiencia: desarrollado para su uso por parte de la industria del servicio de alimentos y autoridades regulatorias como herramienta de entrenamiento y enseñanza

Documento: refleja Las mejores prácticas en la industria en cuanto a las barreras al contacto con las manos descubiertas y demuestra las alternativas al contacto con las manos descubiertas



¿Cuándo debe elegir una barrera de guante un empleado que manipula alimentos?

- El uso correcto de los guantes desechables es muy importante durante el desempeño de tareas de manipulación de alimentos. Los guantes desechables pueden ser una barrera efectiva para prevenir la transmisión
- de microorganismos como las bacterias y virus que se alojan en las
- puntas de los dedos o en los alimentos
- El lavado de manos es la primera barrera contra la contaminación
- cruzada; los utensilios de barrera y guantes constituyen una barrera secundaria
- El uso de utensilios y guantes como barrera constituyen una barrera secundaria
- A los guantes desechables se les ha definido como “utensilios” por el Código Alimentario de la FDA
- Las barreras de guante son efectivas para la manipulación de alimentos listos para comer cuando ningún otro utensilio puede proveer la destreza manual requerida para la tarea en cuestión (por ejemplo, rebanar zanahorias o apio). Se puede utilizar un guante en una mano mientras se sostiene algún otro utensilio con la otra mano



¿Cuándo debe elegir una barrera de guante un empleado que manipula alimentos?

Los guantes de vinil:

- En caso de que alguien tenga una curita, infección o herida en las manos o brazos deberá suspender cualquier actividad que involucre el contacto de los alimentos con las manos descubiertas
- En caso de que los empleados que manipulan alimentos usen uñas postizas o esmalte para las uñas se deberá utilizar guantes desechables al manipular alimentos
- El uso de guantes es opcional para la manipulación de carnes crudas pero pueden ser utilizados para desempeñar actividades de preparación como empanizar/capear carnes, aves, mariscos o vegetales,



Las Barreras de Guante deben ser específicas para cada Tarea

- Use sólo los guantes designados para las labores específicas. Los guantes desechables son específicos para cada tarea y no deben ser usados de manera indefinida
- Los guantes asignados para manipular alimentos no deben ser utilizados para ninguna otra tarea como sacar la basura, manipular dinero, limpiar superficies, etc.
- Use guantes de vinilo, nitrilo sintético o látex cuando vaya a preparar (cocinar) alimentos cerca de fuentes de calor en vez de guantes de polietileno ya que éstos no son resistentes al calor

Los cuatro materiales de guantes más comunes

Guantes de Polietileno



Guantes de Látex



Guantes de Vinilo



Guantes de Nitrilo



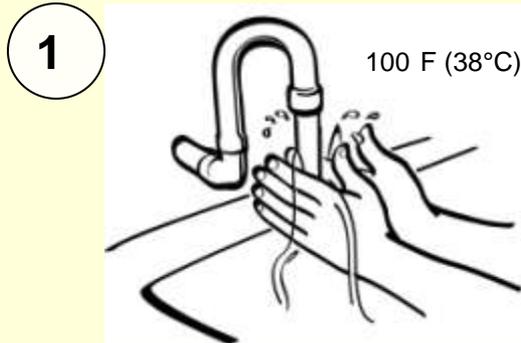
Evite la contaminación cruzada mediante el lavado de manos y cambio de guantes

- En caso de que esté manipulando carne, aves o mariscos con guantes, no podrá tocar alimentos RTE sin haber lavado sus manos y cambiado los guantes previamente
- Deberá remover o cambiar los guantes cada vez que se cambie de actividad o bien cuando se abandone la estación de trabajo. Antes de volver a colocarse los guantes debe haber un lavado de manos previo
- Los guantes de colores para tareas específicas son otra opción para la prevención de la contaminación cruzada

Lavado de Manos

Siempre lave sus manos antes de colocarse un nuevo par de guantes.

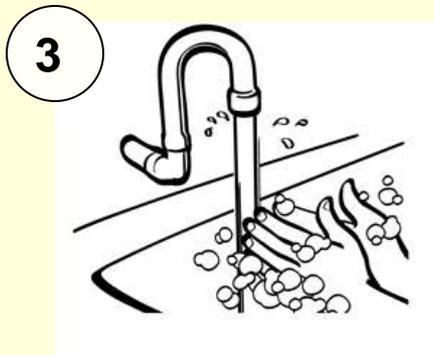
Siga estos cinco pasos para lograr un lavado de manos apropiado:



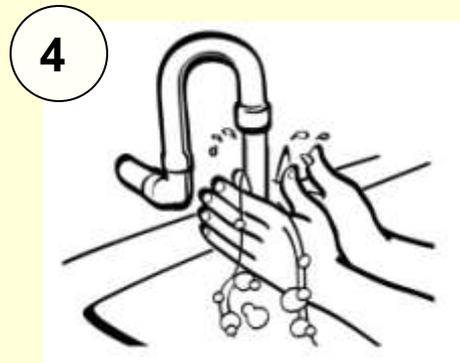
Remoje sus manos con agua a una temperatura que soporte cómodamente (al menos 100 F (38° C))



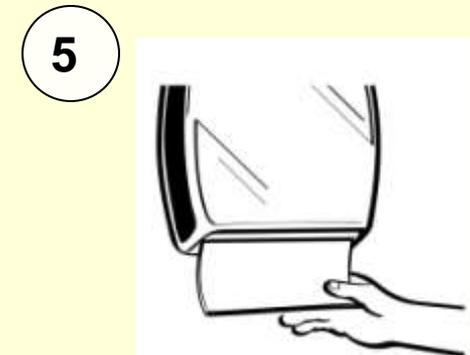
Aplique Jabón



frote vigorosamente sus manos y antebrazos durante 10 a 15 segundos. Lave bajo sus uñas y entre los dedos.



Enjuague sus manos vigorosamente bajo el chorro de agua



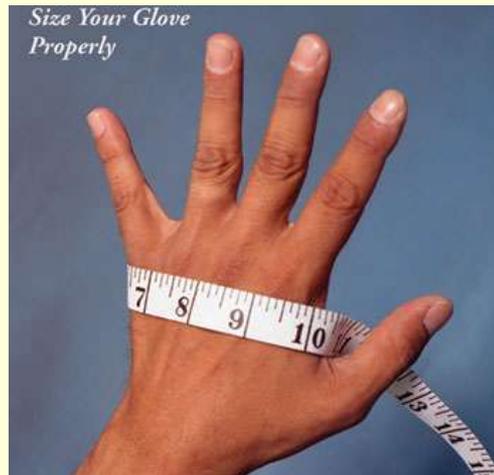
Seque sus manos y antebrazos con toalla de papel desechable o con secador de aire

Frecuencia de Cambio de Guantes

- Cambie los guantes periódicamente y lave sus manos antes y después de que realice cambio de guantes
- Seque bien sus manos después de lavarlas para facilitar la colocación del nuevo par de guantes
- Establezca una frecuencia en vez de Establezca una base de frecuencia durante el cambio de tareas
 - retire los guantes si realiza actividades distintas de la manipulación de alimentos RTE
 - cambie los guantes para manipular alimentos crudos o la carne cruda de distintas especies (pollo crudo a carne de res cruda)
 - cambie los guantes para manipular cualquier alimento listo para comer que pudiera transferir sabor o algún alérgeno alimentario
- Lave sus manos y cambie los guantes en caso de que los guantes que esté usando se rompan o rasguen
- Cambie los guantes después de estornudar, toser o tocarse la cara o el cabello

Elija la Talla de Guantes Correcta

- La talla de los guantes es importante para trabajar con seguridad y comodidad
- Elija la talla correcta para sus manos — de chico (s) a extra grande (xl)
- A los guantes de Polietileno, Vinilo, Látex, y Nitrilo se les puede encontrar en 4 o 5 tallas – Chico (S), Mediano (M), Grande (L), Extra o Extra Extra Grande (XL o XXL)
- La talla de los guantes se mide a través de la parte más ancha de la palma de la mano como se muestra en la ilustración



Presentación preparada por el Food
Contact and Utensil Barrier Usage
Committee for the Conference for the
Food Protection - Revisada en
Diciembre 2009

Evite la contaminación cruzada mediante el uso de guantes resistentes a las cortaduras

- En caso de que utilice un guante resistente a las cortaduras para cortar o manipular alimentos listos para comer, coloque un guante desechable más grande para evitar la contaminación cruzada del guante resistente a las cortaduras reutilizable
- Lave, enjuague y desinfecte el guante resistente a las cortaduras entre las distintas tareas que realice

<p>Si se requiere Guante de Seguridad Resistente a las Cortaduras</p>	<p>+</p>	<p>También se requiere Guante Desechable</p>	<p>=</p>	<p>Guante Desechable Arriba</p>
				

Para Retirar los Guantes Apropriadamente

- Para retirar los guantes desechables de un modo apropiado, sostenga el borde de la muñeca y jale desde adentro hacia afuera



★ **POR NINGÚN MOTIVO retire y reutilice los guantes O los lave con el propósito de emplearlos en múltiples tareas**

Utensilios

(palas, cucharas, cucharones, espátulas, pinzas, tenedores, palillos, palillos de dientes)

- El material de construcción y diseño de las superficies de contacto con alimentos debe cumplir con los requerimientos del Código Alimentario de la FDA mencionados en la sección 4-201.11 y debe ser durable y mantener sus cualidades características bajo condiciones de uso normal
- Todos los utensilios deben ser lavados, enjuagados, desinfectados y secados al aire entre cada uso
- Todos los utensilios en uso continuo deben ser cambiados al menos cada **cuatro horas**

Utensilios

(palas, cucharas, cucharones, espátulas, pinzas, tenedores, palillos, palillos de dientes)

- Cuando no se les esté utilizando, los utensilios deben ser almacenados de tal modo que se prevenga el desarrollo de bacterias, adentro del mismo alimento, en un medio ambiente limpio y protegido, dentro de un recipiente con agua corriente o bien en un recipiente con agua a una temperatura mínima de 135° F
- Los utensilios en uso no podrán ser colocados en solución sanitizante o hielo



Palas

- Las palas son utilizadas por el personal que prepara o sirve alimentos o por clientes para preparar, porcionar o servir alimentos sólidos o líquidos
- La palas se pueden utilizar con o sin el uso de otros utensilios de barrera
- Cuando se utilice una pala con dispensador, es necesario que se evite el contacto del mecanismo del dispensador con el alimento. De este modo se podrá prevenir la transferencia de patógenos de las manos al alimento



Cucharas



- Generalmente, las cucharas no tienen un tamaño de porción o forma predeterminados
- Las cucharas son utilizadas por el personal que prepara o sirve alimentos o por clientes para preparar, porcionar o servir alimentos sólidos o líquidos
- Las cucharas usadas para probar alimentos deben ser lavadas, enjuagadas y desinfectadas entre cada uso. Las cucharas desechables o utensilios de un sólo uso podrían ser una buena opción para este tipo de tareas
- El uso inapropiado de cucharas de prueba podría provocar enfermedades alimentarias

Cucharones



- Los cucharones están disponibles en varios tamaños y son un utensilio ideal para el control de porciones
- Los cucharones son utilizados por el personal que prepara o sirve alimentos o por clientes para preparar, porcionar o servir alimentos sólidos o líquidos
- Los cucharones se pueden utilizar solos o con la ayuda de otros utensilios de barrera



Espátulas



Espátulas



- Elija la espátula que mejor se adapte a la tarea a realizar. A las espátulas se les encuentra disponibles tanto en diseños genéricos como sumamente adaptados para tareas específicas
- Las espátulas se usan para revolver, dividir en porciones, untar o levantar los alimentos
- Las espátulas son una alternativa práctica para la manipulación de alimentos con las manos descubiertas en muchas situaciones

El Uso de Espátulas

- Los manipuladores de alimentos, el personal de servicio o los consumidores emplean las espátulas para revolver, dividir en porciones, untar o levantar los alimentos.
- Sólo use la espátula indicada para cada tarea específica
- Lave, enjuague, desinfecte y seque al aire las espátulas entre cada uso
- A las espátulas se les puede utilizar con o sin la ayuda de otros utensilios de barrera, como los guantes





Hay gran variedad de pinzas



Manteniendo las manos fuera de los alimentos



Con código de colores, distintos tamaños, pinzas para usos múltiples

Pinzas

Pan o galletas



Pinzas



- Las pinzas son una alternativa práctica para la manipulación de alimentos con las manos descubiertas en muchas situaciones
- Las pinzas son un grupo de utensilios de cocina que se usan para sostener o servir alimentos
- Típicamente se les usa para mover los alimentos de un sitio a otro durante su preparación o servicio
- También se les puede usar para voltear los alimentos durante su cocción, especialmente durante el asado

Una pinza para cada uso

- Elija la pinza apropiada para la tarea que va a realizar. A las pinzas se les encuentra disponibles tanto en diseños genéricos como altamente adaptadas para tareas específicas. Las pinzas son una alternativa práctica a la manipulación de alimentos con las manos descubiertas en muchas situaciones
- Hay pinzas específicamente diseñadas para levantar artículos como cubos de azúcar, espárragos, queso rayado, hielo, ensalada, spaghetti, hamburguesas, espinas de pescado, perlas de melón, bagels, cangrejo cocido, garnituras y bolsas de té



El Uso de Pinzas

- A cada pinza debe dársele el uso específico para el cual fue diseñada.
- Lave, enjuague, desinfecte y seque al aire las pinzas entre cada tarea
- Use la pinza apropiada para cada tarea. A las pinzas se les puede utilizar con o sin la ayuda de otros utensilios como son los guantes





Multi-
purpose
tongs

Pinzas para Sushi

**Pinzas para
Bagels o pan
tostado**



**Pinzas para
adornos**



**Pinzas para
espárragos**



**Pinzas para
piezas
delicadas**



Pinzas de Nylon para altas temperaturas



Pinzas de punta delgada



Pinzas para productos horneados o carne



Pinzas para pastel



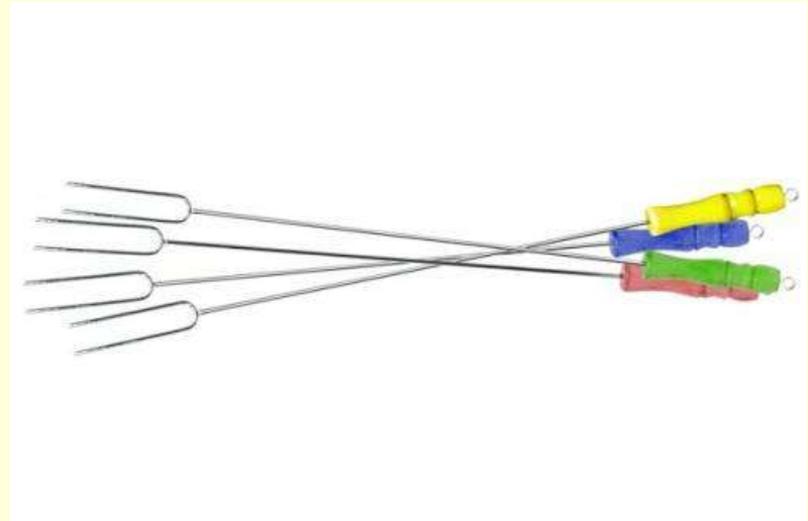
Pinzas para Spaghetti



Pinzas para encurtidos



Pinzas de Buffet



Tenedores



Presentación preparada por el Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection - Revisada en Diciembre 2009

Tenedores

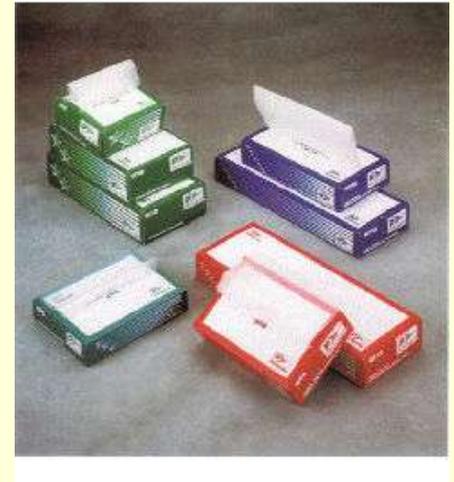


- Los tenedores son una alternativa práctica para la manipulación de alimentos con las manos descubiertas en muchas situaciones
- Los tenedores se usan para sostener o levantar alimentos
- Se les usa típicamente para sostener o levantar alimentos, para moverlos de un sitio a otro o para voltear los alimentos durante su preparación para sostener los alimentos al cortarlos o tallarlos
- También se les puede usar durante el servicio para sostener los alimentos al cortarlos o tallarlos

El uso de los Tenedores

- Se debe utilizar el tenedor apropiado para cada tarea
- Lave, enjuague, sanitice y seque al aire los tenedores entre cada tarea
- Los tenedores que han sido diseñados para usarse sólo una vez deberán ser desechados después de haber sido usados
- Los tenedores pueden ser utilizados con o sin la ayuda de otros utensilios como son guantes





PAPEL DE ENVOLTURA



Presentación preparada por el Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection - Revisada en Diciembre 2009

Papeles de Envoltura

- Los papeles de envoltura de panadería o delicatessen se usan para mantener una barrera sanitaria entre los alimentos y las manos descubiertas
- Los pliegos individuales son de un sólo uso y pueden ser utilizados en el área de servicio de alimentos, por meseros o clientes
- A las envolturas para alimentos se les encuentra disponibles en una gran variedad de tamaños y empaques en los almacenes de artículos para servicios de alimentos



Eligiendo el Papel de Envoltura Adecuado

- Los papeles de envoltura de panadería o delicatessen se usan para mantener una barrera sanitaria entre los alimentos y las manos descubiertas. Los operadores de servicios de alimentos debe seleccionar la envoltura apropiada tomando en consideración el uso que les dará
- Las envolturas pueden ser enceradas o sin encerar. La envoltura encerada puede absorber un poco de líquido evitando que se ensucien las manos.
- Las envolturas sin encerar generalmente se usan para manipular productos de panadería.



Eligiendo el Papel de Envoltura Adecuado

- Los operadores de servicios de alimentos o representantes de compras deben asegurarse de que todos los componentes de las envolturas cumplen con los requerimientos de la sección 21, CFR 177.1520 de la FDA.
- Las envolturas deben ser fabricadas mediante la aplicación de Buena Prácticas de Manufactura.
- Los fabricantes de envolturas para alimentos deben demostrar que todos los componentes utilizados son seguros y que no habrá migración de componentes o de elementos tóxicos a los alimentos.
- Los paquetes o empaques dispensadores deben ser bien contruidos, de modo tal que las envolturas no se contaminen con impurezas externas y que se permita tomar las hojas con facilidad.



Beneficios del uso de Papel de Envoltura

- Los distribidores automaticos protegen las hojas de la contaminación previa a su uso
- Son fáciles de usar por parte de operadores de servicios de alimentos y clientes
- Ayudan a mantener los alimentos frescos
- Absorben grasa y aceite mientras actúan como barreras para proteger los alimentos

Uso de los Papeles de Envoltura

- Las hojas de envoltura deben retirarse una a la vez sin que se rompan o se contamine el resto de las hojas.
- Si se va a usar papel de envoltura como barrera primaria, los empleados que manipulan alimentos deben desechar inmediatamente las hojas usadas. Las hojas de envoltura no pueden ser reutilizadas ni los alimentos almacenarse en ellas.
- El distribuidor automático de hojas debe ser almacenado en un sitio adecuado en el que se evite la contaminación cruzada con otros alimentos o impurezas externas.





Palillos



Presentación preparada por el Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection - Revisada en Diciembre 2009

Palillos



- Los palillos pueden usarse con sin la ayuda de otros utensilios como son los guantes
- Generalmente los consumidores usan los palillos para comer pero los empleados que manipulan alimentos los pueden usar para mover los alimentos de un sitio a otro durante la preparación o servicio de los mismos



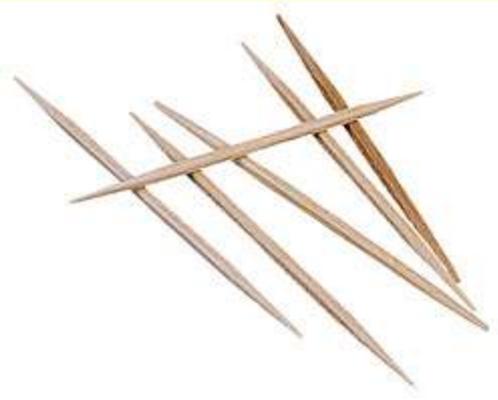
El uso de los Palillos



- Los palillos deben ser utilizados sólo para tareas específicas
- Los palillos pueden ser fabricados con varios materiales derivados de maderas, plásticos o metales
- Los palillos fabricados con materiales reutilizables deben ser lavados, enjuagados, desinfectados y secados al aire entre cada uso
- Los palillos diseñados y fabricados para usarse sólo una vez deben ser desechados después de haber sido utilizados
- Los palillos pueden usarse con o sin la ayuda de otros utensilios de barrera como los guantes



Palillos para Dientes



Presentación preparada por el Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection - Revisada en Diciembre 2009

Palillos para Dientes

- Los palillos para dientes se usan típicamente para evitar el contacto de las manos descubiertas con alimentos listos para comer como los entremeses. A los palillos para dientes también se les utiliza para sostener o mantener acomodados alimentos apilados o en capas como los sandwiches u otras preparaciones
- Los palillos para dientes deben ser colocados por el personal antes del servicio de los alimentos o bien presentados a los consumidores de tal manera que se evite una posible contaminación de la porción que estará en contacto con el alimento, de modo vertical en un recipiente angosto de plástico o vidrio
- Los Palillos para Dientes pueden ser fabricados con una variedad de materiales derivados de maderas, plásticos o metales. Los palillos para dientes están típicamente diseñados para ser de un sólo uso y deben ser desechados una vez se les haya utilizado
- En el caso específico de que los palillos de dientes hayan sido diseñados para reutilizarse, éstos deberán ser lavados, enjuagados, desinfectados y secados al aire entre cada uso



PREGUNTAS



Presentación preparada por el Food Contact and Utensil Barrier Usage Committee for the Conference for the Food Protection - Revisada en Diciembre 2009

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 062
Issue: 2010 II-021**

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

All information above the line is for conference use only.

Title:

Food Protection Manager Certification

Issue you would like the Conference to consider:

Modify the Food Code to require that at least one Person in Charge in each food establishment be certified according to a CFP recognized program. Low risk establishments (e.g. all prepackaged foods, just coffee, etc) would be exempt from the new certified food protection manager requirement.

In addition, if Food Code Priority Item violations are found during inspections and the Person in Charge is not able to answer questions concerning Food Code requirements to prevent foodborne illness specific to the establishment's operations, the Regulatory Authority could require that any non certified Person in Charge become a certified food protection manager through a CFP recognized program.

Public Health Significance:

In a 2006 letter from Dr. Howard Frumkin from the Centers for Disease Control and Prevention (CDC) to the CFP Chair, Dr. Frumkin stated "Results of a recent EHS-Net cross-sectional study strongly suggest that the presence of a certified food safety manager significantly reduces the risk for outbreaks of foodborne illness in restaurants. In fact, the presence of a certified food safety manager was the major distinguishing factor between restaurants in which foodborne illness outbreaks occurred and restaurants in which foodborne illness outbreaks did not occur... Certified food safety kitchen managers were also associated with the absence of bare-hand contact with food as a contributing factor for foodborne illness outbreaks and with fewer Norovirus and Clostridium perfringens outbreaks" (see attached Managercertificationreferences).

Cates et al. (2009) found in an analysis of 8,338 inspections in Iowa that restaurants with a Certified Kitchen Manager present during inspection were less likely to have a critical violation for personnel ($P < 0.01$), food source or handling ($P < 0.01$), facility or equipment requirements ($P < 0.05$), and hot holding ($P < 0.05$).

A 2004 FDA baseline survey evaluated the correlation between certified food protection managers and compliance with the Food Code. FDA reported "It appears that the presence of a Certified Food Protection Manager has a positive effect on the overall percent IN Compliance within some facility types." "Fast Food and Full Service Restaurant facility types with a Certified Food Protection Manager had overall IN Compliance percentages

that were significantly higher than establishments without a Certified Food Protection Manager." Significantly better overall IN Compliance rates were also found in meat and poultry departments and in produce departments with certified managers.

In 2009, a CDC EHS-Net funded food protection manager certification survey was distributed by the Rhode Island Department of Health and the University of Rhode Island to 2008 CFP delegates and/or state health department representatives from all 50 states, Washington D.C., Guam and Puerto Rico. There were 52 respondents representing 44 states, Washington DC, Guam and Puerto Rico. The results indicated that 22 states, Washington DC, Guam, and Puerto Rico all had state/jurisdiction wide mandatory certification programs. Twenty-five percent of respondents indicated their agency rules require a certified food protection manager be present at all hours of operation. Respondents from 4 states without requirements expressed explicitly that attempts are currently being made to implement mandatory statewide certification.

In summary, the science indicates that the lack of a certified food protection manager is associated with outbreaks and the presence of risk factors associated with outbreaks. The lack of uniformity and reciprocity in food manager certification requirements also creates needless costs for the food industry in retraining and/or retesting personnel who move from one regulatory jurisdiction to another. A national uniform standard for food protection manager certification is needed in the Food Code for at least one certified food protection manager per food establishment (exempting low risk establishments) to reduce foodborne illness, obtain active managerial control of foodborne illness risk factors, obtain uniformity, and reduce costs for the food industry.

In 2009, the National Association of County and City Health Officials (NACCHO) found that 51% of local health departments were impacted by layoffs, attrition, reduced hours and/or furloughs. With the reduction of regulatory personnel, it is all the more critical for the food industry to assure Active Managerial Control through certified food protection managers in order to prevent foodborne illness.

This issue is supported by CDC and the nine Environmental Health Specialist Network (EHS-Net) states.

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.

In addition to the above basic requirement, if Priority Item violations are found during inspections and the Person in Charge is not able to answer questions concerning food protection requirements specific to the food operation, the Regulatory Authority should be able to require that a non certified Person in Charge become a certified food protection manager through a CFP recognized program.

The suggested new wording and placement in the Food Code is as follows:

Existing 2009 Food Code Language

"2-102.20 Food Protection Manager Certification.

A PERSON IN CHARGE who demonstrates knowledge by being a FOOD protection manager that is certified by a FOOD protection manager certification program that is

evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs is deemed to comply with ¶ 2-102.11(B)."

Proposed Addition to Food Code

2-102.21 Certified Food Protection Manager.

(A) Except as specified in (B) of this section, each FOOD ESTABLISHMENT must have at least one PERSON IN CHARGE who is a FOOD protection manager certified in accordance with the provisions detailed in 2-102.20; has supervisory, training, and management responsibilities; and is responsible for food preparation and service with the authority to direct and control such activities.

(B) Establishments that serve or sell only pre-packaged foods; establishments that prepare only nonpotentially hazardous foods (nonTCS foods); and establishments that heat only commercially processed, potentially hazardous foods (TCS foods) for hot holding for less than four hours are exempt from the requirements of paragraph (A).

(C) Should there be failure to demonstrate knowledge of foodborne disease prevention during inspections in any food establishment through violations of PRIORITY ITEMS and should there be a failure to correctly respond to the inspector's food protection questions as they relate to the specific FOOD operation, the REGULATORY AUTHORITY may require that the PERSON IN CHARGE who is not certified become a certified FOOD protection manager in accordance with the provisions detailed in 2-102.20.

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Attachments:

- "Managercertificationreferences"

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.

Manager Certification References

Issue submitted by: Ernest Julian, Ph.D._

Cates, S.C., M.K. Muth, S.A. Karns, M.A. Penne, C.N. Stone, J.E. Harrison, V.J. Radke. 2009. Certified kitchen managers: Do they improve restaurant inspection outcomes? J. Food Prot. 72:384-391.

Frumkin, H. MD. April 5, 2006. CDC letter to the Conference of Food Protection. Available at: http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf.

Hedberg, C.W., S. J. Smith, E. Kirkland, V. Radke, T.F. Jones, C. A. Selman, and the EHS-Net Working Group. 2006. Systematic environmental evaluations to identify food safety differences between outbreak and nonoutbreak restaurants. J. Food Prot. 69:2697-2702.

National Association of City and County health Officials. 2009. LHD Budget Cuts and Job Losses. Available at: <http://www.naccho.org/advocacy/upload/fact-sheet-V2.pdf>

U.S. Food and Drug Administration. 2004. FDA report on the occurrence of foodborne illness risk factors in selected institutional food service, restaurant, and retail food store facility types. Available at: <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm089696.htm>

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 064
Issue: 2010 II-015**

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

All information above the line is for conference use only.

Title:

FPMTTC Committee - Amend training language in Standards

Issue you would like the Conference to consider:

The Food Protection Manager Training, Testing and Certification (FPMTTC) Committee was charged by the 2008 Biennial Meeting to evaluate Annex B Section B3 of the *Standards for Accreditation of Food Protection Manager Certification Programs* and to consider incorporating the training recommendations suggested by the committee as shown below:

"Annex B Section B3: Qualifications for Certification. In order to become a Certified Food Protection Manager an individual must pass a food safety certification examination from an accredited certifying program recognized by the CFP. To prepare for certification, it is recommended that the individual obtain training based on the content of the areas of knowledge prescribed in Paragraph 2-102.11 (C) of the FDA Food Code and content outlined based on job task analyses developed by accredited certification organizations." The FPMTTC Committee discussed the suggested language and has recommended the following ALTERNATIVE wording for Section B3, which meets the intent of the charge: *(note: italicized words are defined within the Standards)*

B3. Qualifications for **Certification**. To become a *Certified Food Protection Manager*, an individual must pass a *food safety certification examination* from an accredited certifying program 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.

Public Health Significance:

Assisting with the certification of food protection managers will promote continued reduction in critical risk factors at food establishments. Providing content guidance for training programs that prepare candidates for certification will further promote the success of food protection manager certification programs.

See also the CDC endorsement letter to the Conference dated April 5, 2006, and referenced on the Conference Website at http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf.

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
B3. Qualifications for **Certification**. ~~To In order to become a Certified Food Protection Manager, an individual must pass a food safety certification examination from an accredited certifying program 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. To prepare for certification, it is recommended that the individual obtain training. Based on the content of the areas of knowledge prescribed in Paragraph 2-102.11 (C) of the FDA Food Code.~~

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 065
Issue: 2010 II-033**

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

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Title:

Barriers to Bare Hand Contact Training Materials

Issue you would like the Conference to consider:

The Food Contact and Utensil Barrier Usage Committee seeks Council II's approval of the following training materials:

1. Barrier to Bare Hand Contact Reference Document - English and Spanish
2. Barrier to Bare Hand Contact PowerPoint Presentation - English and Spanish

See attachments to Issue titled: Report - Food Contact and Utensil Barrier Usage Committee

Public Health Significance:

The Committee recognizes the need for a Brand neutral guidance document illustrating the effective use of barriers and utensils when handling foods, including the use of disposable gloves, and the process of barrier use related to hand hygiene.

1. The committee decided the best way to present the information in a user friendly manner is to provide a reference document along with a separate PowerPoint presentation. The following tools and utensils are now included in the document: gloves, scoops, spoons, ladles, spatulas, tongs, forks, deli papers, chopsticks, and toothpicks.
2. The committee identified the need to have the documents translated into Spanish.
3. The Spanish translation has been provided with the committee report.
4. The reference document and PowerPoint presentation now sufficiently include pictures and illustrations representing the appropriate tools and utensils.
5. The entire committee has provided input and collectively agreed on the attached documents.

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.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 066
Issue: 2010 II-016**

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

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Title:

FPMTTC Committee - Amend Section 5 of the Standards for Accreditation

Issue you would like the Conference to consider:

The Food Protection Manager Training, Testing and Certification (FPMTTC) Committee propose revisions to Section 5 of the *Standards for Accreditation of Food Protection Manager Certification Programs* as noted below:

- clarify that an instructor, trainer, or educator can no longer serve as test administrator, or proctor;
- define the role and responsibilities for test administrators, proctors, and certification personnel;
- establish competency requirements for test administrators and proctors;
- establish item and examination exposure controls;
- require formal agreements with test administrators/proctors, to include a code of conduct, conflict of interest statement, and a statement of consequences for breach of the agreement;
- reorganize and renumber relevant subsections; and
- insert changes into the Table of Contents as needed.

Public Health Significance:

Food establishments have fewer critical risk factors when there are employees who have a Food Protection Manager Certification in accordance with the Conference for Food Protection's *Standards*, according to the CDC as stated in the endorsement letter to the Conference dated April 5, 2006, and referenced on the Conference Website. (http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf)

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:

note: language to insert is indicated with underline; language to delete is with strike through

5.3 Proctoring Food Safety Certification Examinations ~~Instructor/Educator/Trainer as Test Administrator/Proctors~~. ~~An~~ When an instructor/educator/trainer of food safety training shall not be a test administrator or proctor administers, proctors or monitors a food safety certification examination, from an accredited certification program, the accredited Instructor/educator/trainer and test administrator/proctor may exist in the same legal entity but shall be structurally and functionally separated to insure the confidentiality and security of the examination. The 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.~~

5.4 ~~8~~ Test Administrator and Monitors/Proctor Qualifications, Training and Duties.

Certification ~~Certifying organizations~~ must specify the responsibilities of *test administrators* and of *monitors/proctors*, set minimum criteria for approval of *test administrators* and for *monitors/proctors*, and provide suitable programs of training to enable persons to meet those criteria. Responsibilities, duties, qualifications and training of *test administrators* and *monitors/proctors* must 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 monitors/proctor* fails to meet job responsibilities must be implemented and documented. ~~Where instructors/educators/trainers are used as test administrators/proctors, the certifying organization shall enter into a formal contractual relationship with the test administrators/proctors to ensure they follow all administrative procedures.~~

5.5 The certification organization shall define and provide descriptions for the roles of test administrators, proctors, and certification personnel that will clearly delineate the responsibilities of each role. The certification organization shall demonstrate how it ensures that all certification personnel, including test administrators and proctors, understand and practice the procedures identified for their roles.

5.6 The certification organization shall ensure that all test administrators and proctors meet the competency requirements established by the certification organization, comply with all requirements of the certification organization, and are not instructors, educators, or trainers participating in training for Certified Food Protection Managers.

5.7 The certification organization shall enter into a formal agreement with the test administrators/proctors and shall assess and monitor the performance of test administrators and proctors in accordance with all documented procedures and agreements. The formal agreement shall include, at a minimum, provisions that relate to code of conduct, conflict of interest and a statement of consequences for breach of the agreement.

5.8 Item & 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.

5.13-9 *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 *monitors/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.~~

The Conference further recommends that non-substantial revisions to the *Standards* such as renumbering and changes to the Table of Contents be approved as documented in the FPMTTC Final Report attachment, *Standards for Accreditation of Food Protection Manager Certification*.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 069
Issue: 2010 II-017**

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

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Title:

FPMTTC Committee - Remove "monitor" from Standards for Accreditation

Issue you would like the Conference to consider:

The Food Protection Manager Training, Testing and Certification (FPMTTC) Committee recommends removing the definition and use of the term "monitor" from the *Standards for Accreditation of Food Protection Manager Certification Programs*. The term "monitor" is no longer used by certification organizations and in the Standards is always used synonymously with the term "proctor."

Proposed revisions are noted in the FPMTTC Committee report attachment titled: *Standards for Accreditation of Food Protection Manager Certification*.

Public Health Significance:

Food establishments have fewer critical risk factors when there are employees who have a Food Protection Manager Certification in accordance with the Conference for Food Protection's *Standards*, according to the CDC as stated in the endorsement letter to the Conference dated April 5, 2006, and referenced on the Conference Website. (http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf)

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:

(note: underlined sections are due to proposed Standards revisions in other FPMTTC Committee submitted Issues)

- 1.29 (definition)
- 1.36 c.
- 4.17.a.
- 5.3.
- 5.4
- 5.13
- 5.14
- 5.15
- Annex A

As these are non-substantial revisions to the *Standards*, exact language changes can be found in the FPMTTC Committee Final Report attachment, *Standards for Accreditation of Food Protection Manager Certification*.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 072
Issue: 2010 II-018**

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

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Title:

FPMTTC Committee - Name Change

Issue you would like the Conference to consider:

Changing the standing committee name from "Food Protection Manager Training, Testing and Certification Committee" to "Food Protection Manager Certification Committee" with the acronym FPMCC. The proposed committee name better reflects the actual food protection manager certification program as written by the standards.

Public Health Significance:

Food establishments have fewer critical risk factors when there are employees who have a Food Protection Manager Certification in accordance with the Conference for Food Protection's *Standards*, according to the CDC as stated in the endorsement letter to the Conference dated April 5, 2006, and referenced on the Conference Website.

(http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf)

Recommended Solution: The Conference recommends...:

1) 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.

2) 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.

Submitter Information:

Name: Joyce Jensen, REHS, CP-FS, Chair
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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 074
Issue: 2010 II-019**

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

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Title:

FPMTTC Committee - Revise Bylaws

Issue you would like the Conference to consider:

The proposed revision to *the Food Protection Manager Training, Testing, Certification Committee Bylaws* includes:

- adding training providers to the composition of the committee,
- establishing that the quorum is based on the number of filled positions,
- renumbering as needed, and
- some clean-up language.

Public Health Significance:

Food establishments have fewer critical risk factors when there are employees who have a Food Protection Manager Certification in accordance with the Conference for Food Protection's *Standards*, according to the CDC as stated in the endorsement letter to the Conference dated April 5, 2006, and referenced on the Conference Website. (http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf)

Recommended Solution: The Conference recommends...:

adopting the Committee Bylaw revisions as proposed by the Food Protection Manager Training, Testing and Certification Committee. All new language is indicated in underline format; language to be deleted is in strike through.

Substantial revisions to the *Food Protection Manager Training, Testing, and Certification Committee Bylaws* are as follows:

Section 2. The Council II Chair shall select the Committee Chair and Vice-Chair ~~from the following groups that comprise the broad based representation of the Conference: regulatory agencies, industry, academia and consumer groups.~~ The Chair and Vice-Chair shall not be selected from the same group affiliation.

Section 3. The composition of the Committee is a balanced representation of industry, regulatory, academia, certification providers, training providers, and consumers. The Committee shall consist of twenty-eight (28) members in addition to the Chair and Vice-Chair.

Subsection 1. Nine (9) ~~Ten (10)~~ representatives from regulatory agencies:

- a. Two (2) ~~Three (3)~~ from State regulatory agencies;
- b. Two (2) ~~Three (3)~~ from local regulatory agencies;
- c. Two (2) from federal government agencies with retail food program responsibilities.
- d. Three (3) ~~Two (2)~~ "At Large" appointments. (*At Large representation - agencies with primary regulatory food safety responsibilities or professional organizations whose mission incorporates a significant public health protection focus.)

Subsection 2. Nine (9) ~~Ten (10)~~ industry representatives;

- a. Three (3) ~~Four (4)~~ from the foodservice (restaurant) industry;
- b. Three (3) ~~Four (4)~~ from the retail food store industry, and
- c. Three (3) ~~Two (2)~~ "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) ~~Four (4)~~ certification providers that are accredited by the Conference's accreditation process;

Subsection 4. Three (3) Food Protection Manager training providers:

Subsection 4 5. Two (2) representatives from academia, and

Subsection 5 6. Two (2) consumer/independent representatives/public members.

Section 9. A quorum to conduct Committee meetings and conference calls shall be the presence of one more than half of the filled fifteen (15) Committee positions members. 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.

Non-substantial revisions to Standards Section 5, such as renumbering, can be found in the FPMTTC Committee Final Report attachment, *Food Protection Manager Training, Testing, and Certification Committee Bylaws*.

NOTE: The revisions with this Issue do not include the proposed Committee name change; this change is presented in a separate Issue.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 078
Issue: 2010 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:

Report and Re-creation - Interdisciplinary FBI Committee

Issue you would like the Conference to consider:

Acceptance of the report from the Interdisciplinary Foodborne Illness Training Committee and Recommendation to re-create the Interdisciplinary Foodborne Illness Training Committee

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.

There are many disease training programs in development by a number of governmental and NGO agencies. The outcome of these endeavors may help shape the future of food safety training.

The Interdisciplinary Foodborne Illness Training Committee has value in considering essential components for certification of foodborne illness outbreak trainings , and making recommendations for establishing a standard for voluntary accreditation of same.

Recommended Solution: The Conference recommends...:

- 1) acceptance of the Report from the Interdisciplinary Foodborne Illness Training Committee,
- 2) thanking the Committee members for their work, and
- 3) 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.

Submitter Information:

Name: Michele Samarya-Timm, Chair
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Attachments:

- "Interdisciplinary FBI Committee Final Report"
- "Interdisciplinary FBI Committee Roster"

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**Conference for Food Protection 2008-2010
Interdisciplinary Foodborne Illness Training Committee
Final Report**

COMMITTEE NAME: Interdisciplinary Foodborne Illness Training Committee

COUNCIL: II

DATE OF COMMITTEE REPORT: December 1, 2009

SUBMITTED BY: Michéle Samarya-Timm, Chair
Elizabeth Bugden, Co-Chair

COMMITTEE CHARGE(S): To work with the Council to Improve Foodborne Outbreak Response (CIFOR) and investigate establishing standards for foodborne illness training programs and report back to the 2010 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The Interdisciplinary Foodborne Illness Training Committee created a regular schedule of quarterly conference calls to work in an expeditious manner toward meeting the committee charge.

Our committee has reviewed the potential synergy between CIFOR Training assessment, and this committee's charge. CIFOR is looking at *gaps* in training (accessibility, content). This CFP committee is looking at establishing a *standard* for programs for voluntary accreditation (more content based.)

This CFP committee challenged members with the following action items:

1. Identify principles that guide how standards are developed and any examples of how standards are developed.
2. Make a list of accreditations and certifications that are highly regarded and make a list of the essential components (what's needed, how often is it renewed, syllabus, etc.)
3. Consider essential components for certification of foodborne illness outbreak investigations

The committee began looking at the new CIFOR guidelines to help facilitate our efforts, and to also identify and consider what criteria could be used to approve food safety trainings, and how to determine if a program is qualified.

In conducting further research for this objective, our committee discovered that a number of entities are in the process of developing training standards for Food Safety professionals. AFDO, along with the FDA 50-State Training Workgroup are conducting a job task analysis to help identify essential trainings. These essential trainings are to encompass all stakeholders and all elements of food protection with the goal of credentialing attendees. As the outcome of these endeavors may help shape the future of food safety training – and foodborne illness training, this committee has concluded that we may be a committee ahead of its time. As there are many prominent disease training programs in development, the committee will continue to track the progress of these programs. The committee recommends that this committee be re-created and charged to track the progress of these programs and bring back additional guidance to the Conference.

COMMITTEE MEMBER ROSTER:

Interdisciplinary Foodborne Illness Training Committee Roster is attached.

Requested action:

The committee will submit 1 issue:

1. **Acknowledgement of the Committee Report**
2. **thanking committee members, and**
3. **Re-Creation of the Interdisciplinary Foodborne Illness Training Committee** with the following charges:
 - track the progress of the prominent disease training programs in development,
 - bring back additional guidance to the Conference.

Conference for Food Protection 2008-2010
 Interdisciplinary Foodborne Illness Training Committee
 Membership Roster

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	Email
Samarya-Timm	Michele	CHAIR	Regulatory LOCAL	Somerset County Department of Health	SamaryaTimm@co.somerset.nj.us
Budgen	Elizabeth	VICE CHAIR	INDUSTRY	Consultant	bugdene@comcast.net
Armatis	David	Member	INDUSTRY	Guckenheimer	darmatis@guckenheimer.com
Bacon	Brenda	Member	INDUSTRY -Retail Food Stores	Harris Teeter	bbacon@harristeeter.com
Bogard	April	Member	Regulatory STATE	Minnesota Department of Health	april.bogard@health.state.mn.us
Bullock	Teresa	Member	Regulatory STATE	Arkansas Department of Health	teresa.bullock@arkansas.gov
Carpenter	David	Member	ACADEMIA	CSTE	dcarpenter@siumed.edu
Checketts	Neil	Member	INDUSTRY - Retail Food Stores	Wal-Mart Stores, Inc.	neil.checketts@wal-mart.com
Coleman	Gary	Member	CONSUMER	Underwriter Laboratories	gary.coleman@us.ul.com
Cooper	Ivory	Member	Regulatory STATE	DC Department of Health	ivory.cooper@dc.gov
Davis	Douglas	Member	INDUSTRY - Foodservice	Marriott International	douglas.davis@marriott.com
Divine	Michael	Member	INDUSTRY - Retail Food Stores	H.E.B. Grocery	divine.michael@heb.com
Fear	Jim	Member	Regulatory FEDERAL	FDA	jfear@ora.fda.gov
Ferko	Frank	Member	INDUSTRY - Foodservice	US Foodservice	frank.ferko@USFood.com
Ford	Tom	Member	OTHER -	Ecolab	tom.ford@ecolab.com
Gerard	Lorna	Member	Regulatory - STATE	Minnesota Dept of Agri/Dairy and Food Inspection	lorna.girard@state.mn.us
Gordon	Christopher	Member	Regulatory - STATE	Virginia Department of Health	christopher.gordon@vdh.virginia.gov
Hilton	Debrena	Member	Regulatory - LOCAL	Tulsa Health Department	dhilton@tulsa-health.org
Hollingsworth	Jill	Member	INDUSTRY	Food Marketing Institute	jhollingsworth@fmi.org
LeMaster	Lori	Member	Regulatory - STATE	Tennessee Department of Health	lori.lemaster@state.tn.us
Mack	James	Member	Regulatory - STATE	Wisconsin Department of Health Services	james.mack@wisconsin.gov
Odette	Robert	Member	Regulatory - FEDERAL	Navy and Marine Corps Public Health Center	robert.odette@med.navy.mil
Ostertag	Elizabeth	Member	Association	National Environmental Health Association	eostertag@neha.org
Roughan	George	Member	OTHER - Testing/Training Services	TAP Series, LLC	groughan@chimsol.com
Sharp	Donald	Member	Regulatory - FEDERAL	CDC	das8@cdc.gov
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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 075
Issue: 2010 II-027**

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

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Title:

Change in Program Standard No. 6 and Appendix F, Compliance and Enforcement

Issue you would like the Conference to consider:

Currently for a jurisdiction to meet Standard No. 6, under Description of Requirement, 3., the program element needed is "documentation on the establishment inspection report form or in the establishment file showing compliance and/or enforcement action was taken to achieve compliance at least 80 percent of the time when out of control risk factors or interventions are recorded on a routine inspection measured using the procedures in Supplement to Standard 6, Appendix F." As more and more jurisdictions work toward meeting Standard No. 6, it has become apparent that the current sample size needs to be increased so that the probability of a jurisdiction passing and meeting the Standard accurately reflects the conditions experienced by enrolled jurisdictions. Based on an improved analysis of the requirements for a jurisdiction to pass, it is recommended that the minimum number of establishments chosen for file review be changed from 20 to 40 with the maximum number remaining at 70.

In addition the following phrase within the language of Requirement 3 needs clarification, "achieve compliance at least 80 percent of the time". The language change should be ". . . where at least 80 percent of sampled establishments . . ." (See the recommended solution below for full text changes). The change in wording clarifies the requirements for meeting the Standard.

Public Health Significance:

The number of establishments (file records) used in the calculation of the scoring affects the probability of a jurisdiction passing with a score of 80%. The recommendation is to increase the sample size in the Standard to improve the probability of a high-performing jurisdiction passing the Standard and to clarify the language to avoid confusion in the calculation of the scoring (or rating) of files as pass/fail.

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.

Modify Standard 6 so that it reads:

Description of Requirement

" . . . The essential program elements required to meet this standard are:

1. No Change.
2. No Change.
3. Documentation on the establishment inspection report form or in the establishment file using the statistical method for file selection in the Supplement to Standard 6, Appendix F, where at least 80 percent of sampled establishments meet the following conditions:

a) The inspection and enforcement staff takes compliance and enforcement action according to the procedures (i.e., the staff follows the step-by-step compliance and enforcement procedures when violations occur), and

b) Resolution was successfully achieved for all out-of-control risk factors or interventions that were recorded on the selected routine inspection.

~~3. Documentation on the establishment inspection report form or in the establishment file that compliance and/or enforcement action was taken to achieve compliance at least 80-percent of the time when out-of-control risk factors or interventions are recorded on a routine inspection measured using the procedures in Supplement to Standard 6, Appendix F.~~

- ~~1. Compliance and enforcement actions that follow the step-by-step procedure.~~

Documentation

" The quality records needed for this standard include:

1. No change.
2. No change.
3. Documentation that compliance and enforcement action was taken correctly for at least 80% of sampled establishments ~~80-percent of the time~~ using the worksheet and procedures in Supplement to Standard 6, Appendix F, when out-of-control risk factors or code interventions are recorded on routine inspections.
4. No change.

Modify Appendix F, Supplement to Standard 6 - Compliance and Enforcement so that it reads:

Selecting the Sample

Jurisdictions with under 800 total establishments will select 40 files for review, or if they have less than 40 establishments in the inventory, then all files are to be reviewed.

Jurisdictions with 800 or more establishments will select a sample equal to 5% of the total establishments up to a maximum of 70 files. This initial selection of sample files will be the initial sample and will be the first files reviewed. Sample selection using a table of random numbers or a random number generator is the preferred method of sample selection and can be used with a card file, ledger, list, or automated data system. However, two alternative sample selection techniques acceptable for retail food program self-assessments are presented here.

1. Method 1. No change.

2. Method 2. The second alternative technique to the use of a random number generator utilizes a card file, ledger, list or data processing record system. When this procedure is used, all the establishments in the program must be subject to sampling. The frequency interval may be determined by dividing the total number of retail food establishments by the number of files needed in the sample. (For example, if there are 800 establishments within

the jurisdiction, a sample of 40 would be needed (5% of ~~80~~ 800). The frequency interval would be 800 divided by 40, or 20. Thus every 20th establishment shall be selected to make up the initial sample.) To establish a starting point when using a frequency interval of 20, write numbers 1 - 20, inclusive, on separate strips of paper and draw one slip at random. The number appearing on that strip of paper represents the first establishment to be drawn. If a ledger or list is being used for sampling and the number drawn is 7, then the seventh entry in the ledger or list would be the first establishment in the sample. The second establishment would be the 27th entry, the third would be the 47th entry and so forth, until the sample of 40 is drawn.

Alternate Sample List

Paragraphs 1 -4: No Change.

Paragraph 5, Change to read:

If method 1 is used for the random selection, the alternate sample files will be the last files drawn. For example, if the sample size required is 40, then 52 files will be selected, and the last 12 files drawn will be designated as alternative files.

Paragraph 6 to end of Appendix F - No Change.

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Attachments:

- "Attachment A - Standard 6-Compliance and Enforcement"
- "Attachment B-APPENDIX F Supplement to Standard No. 6"

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STANDARD NO. 6 COMPLIANCE AND ENFORCEMENT

This standard applies to all compliance and enforcement activities used by a jurisdiction to achieve compliance with regulations.

REQUIREMENT SUMMARY

Compliance and enforcement activities result in follow-up actions for out-of-control risk factors and timely correction of code violations

DESCRIPTION OF REQUIREMENT

Compliance and enforcement encompasses all voluntary and regulatory actions taken to achieve compliance with regulations. Voluntary corrective action includes, but is not limited to, such activities as on-site corrections at time of inspection, voluntary destruction of product, risk control plans and remedial training. Enforcement action includes, but is not limited to, such activities as warning letters, re-inspection, citations, administrative fines, permit suspension and hearings. Compliance and enforcement options may vary depending on state and local law.

The program must demonstrate credible follow-up for each violation noted during an inspection, with particular emphasis being placed on risk factors that most often contribute to foodborne illness and *Food Code* interventions intended to prevent foodborne illness. The resolution of out-of-compliance risk factors and/or food code interventions must be documented in each establishment record. The essential program elements required to meet this standard are:

1. A written step-by-step procedure that describes how compliance and enforcement tools are to be used to achieve compliance.
2. Inspection report form(s) that record and quantify the compliance status of risk factors and interventions (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
3. Documentation on the establishment inspection report form or in the establishment file using the statistical method for file selection in the Supplement to Standard 6, Appendix F, where at least 80 percent of sampled establishments meet the following conditions:
 - a) The inspection and enforcement staff takes compliance and enforcement action according to the procedures (i.e. the staff follows the step-by-step compliance and enforcement procedures when violations occur), and
 - b) Resolution was successfully achieved for all out-of-control risk factors or interventions that were recorded on the selected routine inspection.

Attachment A – Standard 6

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~~3. Documentation on the establishment inspection report form or in the establishment file that compliance and/or enforcement action was taken to achieve compliance at least 80 percent of the time when out-of-control risk factors or interventions are recorded on a routine inspection measured using the procedures in Supplement to Standard 6, Appendix F.~~

~~4. — Compliance and enforcement actions that follow the step-by-step procedure.~~

OUTCOME

The desired outcome of this standard is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

DOCUMENTATION

The quality records needed for this standard include:

1. A copy of the written step-by-step enforcement procedures.
2. Inspection form that meets the criteria.
3. Documentation that compliance and enforcement action was taken correctly for at least 80 percent of sampled establishments ~~80 percent of the time~~ using the worksheet and procedures in Supplement to Standard 6, Appendix F, when out-of-control risk factors or code interventions are recorded on routine inspections.
4. A reference “Key” which identifies the major risk factors and Food Code interventions on the jurisdiction's inspection report form. [Note: A jurisdiction will not be penalized under Standard 6 for sections of the Food Code which have not yet been adopted].

Attachment A – Standard 6

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WORK SHEET INSTRUCTIONS

This Standard applies to all voluntary and regulatory activities used by a jurisdiction to achieve compliance with regulatory requirements. The desired outcome is an effective compliance and enforcement program that consistently follows through on documented violations and achieves compliance. The sequence and type of follow-up activity a particular jurisdiction elects to use may vary. However, when an out-of-control risk factor or intervention is documented on an inspection report, the expectation is that actions taken to correct the violation will also be documented in the establishment file. For the purposes of self-assessment, follow-up actions have been divided into three types.

- On-site corrective action that occurs at the time of a routinely scheduled inspection,
- Follow-up action that occurs after the routine inspection, such as re-inspections, training, risk control plans, and informal conferences, and
- Enforcement activities such as fines, permit suspension, hearings, mandated training, restriction of operations, embargo, etc.

The measure of success for a compliance and enforcement program under Standard 6 is based on a review of randomly selected establishment files to determine whether documented violations have been resolved satisfactorily in the establishment.

In order to track documented violations through the compliance and enforcement process for a period of time long enough to determine resolution, a fixed point in time must be chosen as the starting point. It is expected that follow-up or subsequent inspections of that facility should show correction of the violations documented at the starting point. The Standard 6 measure uses a concept called the ‘start-point inspection.’

The ‘start-point inspection’ will be the third oldest routine inspection in the establishment’s file if it shows a violation of one of the risk factors or *Food Code* interventions. If no risk factor or *Food Code* intervention violation is shown on that inspection, then the fourth oldest routine inspection may be used if it shows a risk factor or *Food Code* intervention violation. The third oldest routine inspection is determined by starting from the most recent routine inspection in the establishment’s file and working backward chronologically. The fourth oldest routine inspection would be the one prior to the third oldest. If no violation of a risk factor or *Food Code* intervention is documented on the third or fourth oldest routine inspection, then no ‘start-point inspection’ exists for that establishment.

A sampling of files will be reviewed for compliance and enforcement performance based on the ‘start-point inspection’ concept. The following section provides instructions for the proper construction of a list of sample files and a required alternate list of sample files.

SELECTING THE SAMPLE

Jurisdictions with under 800 total establishments will select 40 files for review, or if they have less than 40 establishments in the inventory, then all files are to be reviewed.

Jurisdictions with 800 or more establishments will select a sample equal to 5% of the total establishments up to a maximum of 70 files. This initial selection of sample files will be the initial sample and will be the first files reviewed. Sample selection using a table of random numbers or a random number generator is the preferred method of sample selection and can be used with a card file, ledger, list, or automated data system. However, two alternative sample selection techniques acceptable for retail food program self-assessments are presented here.

1. Method 1. The first alternative technique to the use of a random number generator requires that each establishment be identified by a card or strip of paper having the establishment's name and address, permit number, file number, or other means of positive identification. These identifying cards or slips of paper are thoroughly mixed and the establishment files to be reviewed are drawn one at a time until the required number is obtained.
2. Method 2. The second alternative technique to the use of a random number generator utilizes a card file, ledger, list or data processing record system. When this procedure is used, all the establishments in the program must be subject to sampling. The frequency interval may be determined by dividing the total number of retail food establishments by the number of files needed in the sample. (For example, if there are 800 establishments within the jurisdiction, a sample of 40 would be needed (5% of 800). The frequency interval would be 800 divided by 40, or 20. Thus every 20th establishment shall be selected to make up the initial sample.) To establish a starting point when using a frequency interval of 20, write numbers 1 – 20, inclusive, on separate strips of paper and draw one slip at random. The number appearing on that strip of paper represents the first establishment to be drawn. If a ledger or list is being used for sampling and the number drawn is 7, then the seventh entry in the ledger or list would be the first establishment in the sample. The second establishment would be the 27th entry, the third would be the 47th entry and so forth, until the sample of 40 is drawn.

ALTERNATE SAMPLE LIST

Deletion of an establishment from the sample of files to be reviewed will be limited to those establishments which have not been in business long enough to have at least three regularly scheduled inspections or those files where no risk factor or *Food Code* intervention violation is documented on the 'start-point inspection.'

When an establishment file is eliminated from the initial random draw, a new establishment file will be drawn from a pre-determined alternate sample list. Alternate files will be drawn in the same manner as the original sample and at the same time as the original sample selection. It is suggested that the number of alternate files selected be at least 30 percent of the original sample size. If a large number of files selected in the

initial draw do not have risk factor or *Food Code* intervention violations on the ‘start-point inspection,’ then a larger alternate sample will be needed.

The sample list of alternate files shall be kept separate from the original sample list. When an original selected file cannot be rated because it has not been in business long enough to have received at least three routine inspections or because it has no risk factor/intervention violation on the start-point inspection, a substitute file from the pre-selected alternate list will be reviewed. Substitute files from the alternate list will be used in the order in which the files were drawn.

If a random number generator or a table of random numbers is used for the initial sample selection, then this same method should be used to select the appropriate number of files for the alternate sample list. Again, this is the easiest and preferred method of sample selection.

If method 1 is used for the random selection, the alternate sample files will be the last files drawn. For example, if the sample size required is 40, then 52 files will be selected, and the last 12 files drawn will be designated as alternative files.

If method 2 is used for the random selection, a separate drawing of the alternate files will be made using an interval determined as follows: the number of establishments in the inventory, minus the number of files drawn for the original sample, divided by the number of alternate files needed. Using our example from method 2 above:

$$\mathbf{800 \text{ (inventory)} - 40 \text{ (files drawn in the original sample)} / 12 \text{ (30\% of the original sample)} = 63}$$

To establish a starting point for the new interval of 63, write the numbers 1 – 63 inclusively on separate slips of paper and draw one at random. The number drawn will be the first file selected for the alternate sample and every 63rd file afterward until 12 files are drawn.

REVIEWING AND RATING THE FILES

Step 1. Identify the items on the local inspection report that correspond to each of the risk factors and interventions on the worksheet. Record the local item numbers on the “reference key” line of the worksheet. If there is no corresponding local requirement for a particular *FDA Code* risk factor or intervention, record “NA” for not applicable. You may find the Standard No. 1, Appendix A Worksheets, helpful in making this comparison. Note that the program is not penalized under Standard No. 6 for sections of the *Food Code* that have not been adopted.

Step 2. Open the first establishment inspection file that was randomly selected in Step 1 above. Identify the third oldest routine inspection report in the file, starting at the current date and working back chronologically. This inspection will be the “start-point inspection” for the review of this file. Using the reference key line on the worksheet,

determine which risk factors and interventions were out of compliance at the time of this 'start-point inspection.' Place a check under each item that is out of compliance on the horizontal status line. If there is no risk factor/intervention that was out of compliance on the third oldest inspection in the file, you may move to the fourth oldest inspection in the file and use it for the 'start-point inspection' if it contains a risk factor/intervention that was out of compliance. If there is no risk factor/intervention that was out of compliance on the third or fourth oldest inspection, eliminate this file from the review and select a substitute file from the alternate list. ***[NOTE: Be sure to indicate the date of the start-point inspection on the Appendix F worksheet for each reviewed file. This will aid the reviewer during a validation audit.]***

Step 3. Review all of the documentation in the establishment file from the start-point inspection forward to the current date and determine whether follow-up action was taken and documented for each of the out-of-compliance risk factors and interventions that were out of compliance on the start-point inspection. Determine whether there was at least one type of follow-up activity for each item that was marked out of compliance. Place "Yes" in the appropriate line and column to indicate that follow-up action was documented in the establishment file. Make a notation below each "Yes" to indicate the type of action taken such as "RH" for Reheat, "WL" for warning letter or "RCP" for risk control plan. If there is no documentation in the establishment file to indicate that follow-up action was taken for each specific risk factor or intervention that was out of compliance, the presumption is that follow up did not occur. Indicate by "yes" or "no" in the last column whether follow-up actions complied with the jurisdiction's written step-by-step procedure for compliance and enforcement.

In order for an individual establishment file to pass, each column marked with a violation at the start-point inspection must have a subsequent "yes" answer to indicate that at least one type of follow-up action was taken. Actions must have complied with the jurisdiction's written step-by-step procedure for compliance and enforcement. A single start-point violation without a final resolution, either correction or a compliance/enforcement activity causes the file to fail. A single failure to follow the jurisdiction's written procedures also causes the file to fail. Circle the appropriate "pass" or "fail" notation at the bottom of the work sheet.

Repeat Steps 2 and 3 with each of the randomly selected establishment files. When all of the files have been reviewed, total the number of files that passed and divide by the total number of files that met the sample selection criteria that were reviewed. To meet Standard No. 6, eighty percent (80%) of the files must pass.

See the following example and blank Worksheet.

EXAMPLE:

SAMPLE WORK SHEET -COMPLIANCE AND ENFORCEMENT

File No: 1

Risk Factors and Food Code Interventions											
Establishment Name Seafood Palace	Unsafe Source	Inadequate Cooking	Hot & Cold Temperatures/Improper holding	Time/Temperature Parameters not met. (Time as a control, date marking, rapid cooling)	Bare hand contact with ready-to-eat PHF	Poor Personal Hygiene	Food Contact Surfaces & Equipment Contaminated	(when required) Consumer Advisory	Demonstration of Knowledge by PIC	implemented. Employee Health Control system or policy	Was the Written Procedure Followed?
Permit Number 339											
Inspection Date (start point) 3 May 2000											
Reference Key to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16	Circle One
Start Point Inspection Violations		X		X	X	X					<u>YES</u>
Was on site corrective action taken ?		Yes RH		YES EM	Yes Glove						or NO
Was follow up corrective action taken?				Yes RCP		Yes TR					
Was enforcement action taken?		Yes WL									
Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed.											Circle One <u>PASS/FAIL</u>

In this example, the file passes because each of the violations noted on the start point inspection, dated 3 May 2000, has documented follow-up action in the file. The "NA" under Consumer Advisory indicates that the jurisdiction does not have a requirement for

this intervention. The "yes" in the last column indicates that the compliance and enforcement procedure of the jurisdiction was followed.

*Define the acronyms and notations used to reflect follow-up action. **RH**= *Reheat to safe temperature*, **RCP**= *risk control plan successfully completed*, **WL**= *warning letter sent*, **EM** =*embargo*, **TR** = *training required*

WORK SHEET - COMPLIANCE AND ENFORCEMENT

File No. _____

Risk Factors and Food Code Interventions											
Establishment Name	Unsafe Source	Inadequate Cooking	Hot & Cold Temperatures/Improper holding	Time/Temperature Parameters not met. (Time as a control, date marking, rapid cooling)	Bare hand contact with ready-to-eat PHF	Poor Personal Hygiene	Food Contact Surfaces & Equipment Contaminated	(when required) Consumer Advisory	Demonstration of Knowledge by PIC	Employee Health Control system or policy implemented.	Was the Written Procedure Followed?
Permit Number											
Inspection Date (Start Point)											
Reference Key to local inspection items											<p style="text-align: center;">CIRCLE ONE</p> <p style="text-align: center;">YES</p> <p style="text-align: center;">or</p> <p style="text-align: center;">NO</p>
Start Point Inspection Violations											
Was on-site corrective action taken?											
Was follow up corrective action taken?											
Was enforcement action taken?											
Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed.											<p style="text-align: center;">Circle One</p> <p style="text-align: center;">PASS/FAIL</p>

*Define the acronyms and notations used to reflect follow up action.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 076
Issue: 2010 II-020**

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

All information above the line is for conference use only.

Title:

New or Continuation Charges for the renamed FPMTTC Committee

Issue you would like the Conference to consider:

The renamed CFP standing committee, the "Food Protection Manager Certification Committee" (FPMCC) 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.
- investigate if the *Standards for Accreditation of Food Protection Manager Certification Programs* should create more alignment with ISO17024 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.

Public Health Significance:

Food establishments have fewer critical risk factors when there are employees who have a Food Protection Manager Certification in accordance with the Conference for Food Protection's *Standards*, according to the CDC as stated in the endorsement letter to the Conference dated April 5, 2006, and referenced on the Conference Website. (http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf)

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.

- 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 2012 Biennial Meeting of the Conference for Food Protection.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 079
Issue: 2010 II-026**

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 for Food Protection (CFP) Program Standards requests that the committee be reinstated to 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
 - Mechanisms for making changes to the Program Standards documents.
- and present their findings at the 2012 CFP Biennial Meeting.

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 and management of a retail food program in our continued goal of reducing foodborne illnesses and the promotion of active managerial control of all factors that may cause foodborne illness. This committee was formed to work with the FDA Clearinghouse Committee to clarify and address language issues currently found in the Standards.

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.

Submitter Information:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 086
Issue: 2010 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:

Report - FPMTTC Committee

Issue you would like the Conference to consider:

Please acknowledge the final report as submitted and thank the 2008-2010 Food Protection Manager Training, Testing and Certification Committee members for their effort in addressing the charges from the 2008 Biennial Meeting.

Public Health Significance:

Food establishments have fewer critical risk factors when food there are employees who have a Food Protection Manager Certification in accordance with the Conference for Food Protection's *Standards*, according to the CDC as stated in the endorsement letter to the Conference dated April 5, 2006, and referenced on the Conference Website. (http://www.foodprotect.org/media/managercert/MTTC_cdc_endorse.pdf)

Recommended Solution: The Conference recommends...:

acknowledging the attached Committee report and extending thanks to the Committee members for their work.

Submitter Information:

Name: Joyce Jensen, REHS, CP-FS, Committee Chair
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Attachments:

- "Proposed Standards 2010"
- "Bylaw Revision 2010"
- "CFPMTTC Committee Membership"
- "Final Committee Report 2010"

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Conference for Food Protection

Standards for Accreditation of Food Protection Manager Certification Programs

As Amended by the ~~2008~~ 2010 Biennial 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 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 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 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 meet the following CFP standards and provide evidence of compliance through the documentation requested in the application. In addition, the *certification organization* must agree to abide by *certification* policies and procedures which are specified by the CFP Manager Training, Testing and Certification Committee, hereinafter referred to as the MTTC 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 MTTC 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 MTTC 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 *certificates* issued by an *accredited certification program* as one means of meeting the FDA Food Code's "Demonstration of Knowledge" requirement, as prescribed in Paragraph 2-102.11(B).

Modifications and Improvements

The MTTC 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 Biennial Conferences under the title, Standards for *Accreditation* of Food Protection Manager *Certification* Programs.

The revision and reformatting of the document were made after a comprehensive MTTC Committee review of each section. 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*.

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 organizations* and test providers responsible for the design of the assessment tool used to measure a candidate’s *competency*. *Certification organizations* have a responsibility to ensure that the *certification* process is fair to the candidates 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 *certificates* 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 Managers* provide regulatory authorities reliable and *legally defensible* criteria for evaluating *certification* programs. In addition, they eliminate duplication of testing and additional cost for the industry.

Regulatory authorities that may not be in a position to eliminate their existing programs are encouraged to recognize food protection managers certified in accordance with these standards as fulfilling their program requirements. Annex B provides additional guidance, developed through the CFP, for the implementation of these regulatory *certification* programs.

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SECTION 1.0 - DEFINITIONS

1.0 Definitions

- 1.1 Accreditation** means that an *accrediting organization* has reviewed a Food Protection Manager *Certification* Program and has verified that it meets standards set by the CFP (a review of a *certifying 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. 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 development and administration.
 - b. does not refer to training functions or educational programs.
- 1.4 Algorithm** means a set of procedures or rules pertaining to the selection of test questions on an exam.
- 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 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. responsibility for identifying hazards in the day-to-day operation of a *food establishment* that provides food for human consumption;
 - b. development or implementation of specific policies, procedures or standards aimed at preventing foodborne illness;

- c. coordination of training, supervision or direction of food preparation activities, and responsibility for taking corrective action as needed to protect the health of the consumer; and
 - d. responsibility for completion of in-house self-inspection of daily operations on a periodic basis to see that policies and procedures concerning food safety is 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 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 *algorithms* based on the statistics of the test 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 forms means alternate sets of test questions (with at least 25% alternate questions) to assess the same *competencies*, conforming to the same *examination specifications*.

1.19 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 Examination version means a test in which the exact set of items in an *examination form* is presented in another order, language, manner or medium.

1.21 Food establishment

- a. Food establishment means an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption:
 - i. 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. 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. Food establishment includes:
 - i. 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. 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. Food establishment does not include:
 - i. an establishment that offers only prepackaged foods that are not potentially hazardous;
 - ii. a produce stand that only offers whole, uncut fresh fruits and vegetables;
 - iii. a food processing plant;

- iv. 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. an area where food that is prepared as specified in Subparagraph (c) (iv) of this definition is sold or offered for human consumption;
- vi. 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. a private home that receives catered or home-delivered food.

1.22 Food safety certification examination means an examination in food safety approved in accordance with the provisions of this program.

1.23 Instructor means an individual who teaches a course that includes *competencies* in prevention of foodborne illness.

1.24 Item bank means all of the items that have been developed for the several forms of an examination. It includes all of the items available to create *examination forms*.

1.25 Item sequence means the presentation order of test items in an examination.

1.26 Job analysis means the description of functions or tasks required for an individual to perform to entry level standards in a specific job or occupation, including information about the attributes required for that performance. It defines the performance dimension of a job and includes knowledge, skills, and abilities necessary to carry out the tasks.

- a. **Tasks** are the individual functions, whether mental or physical, necessary to carry out an aspect of a specific job.
- b. **Knowledge, skills, and abilities (KSAs)** include the information and other attributes that the worker must possess in order to perform effectively and safely. They include information and understanding as well as learned behaviors and natural attributes.

1.27 Legal entity means an organization structured in a manner that allows it to function legally and be recognized as a responsible party within the legal system.

1.28 Legally defensible means the ability to withstand a legal challenge to the appropriateness of the examination for the purpose for which it is used. The challenge may be made by actual or potential examinees or on behalf of the public. Candidates' 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 knowledge, skills, and abilities required to protect the consumer from foodborne illness.

~~1.29~~ ~~**Monitor**~~ means the same as *Proctor*. (See *Proctor*.)

1.3029 Overexposure means the relative frequency in which a test item which is presented across all computerized tests has undermined the integrity of the tests. Whether a test item is overexposed or not is based upon the type of exam test item (pictorial vs. written) and its frequency of use.

1.3130 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 have the ability to observe examinee behaviors, accurately distribute and collect test materials, and assist the *test administrator* as assigned. They must have training or documented successful experience in monitoring procedures and must affirm in writing an agreement to maintain test security and to assure that they have no conflict of interest.

1.3231 Psychometric means scientific measurement or quantification of human qualities, traits or behaviors.

1.3332 Psychometrician means a professional with specific education and training in development and analysis of tests 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 development and a minimum of two in statistical methods.

1.3433 Regulatory authority means a government agency that has been duly formed under the laws of that jurisdiction to administer and enforce the law.

1.3534 Reliability means the degree of consistency with which a test measures the attributes, characteristics or behaviors that it was designed to measure.

1.3635 Retail food industry means those sectors of commerce that operate *food establishments*.

1.3736 Test 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 ~~monitor~~/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.

1.3837 Test encryption and decoding means the security aspects of a computer examination to prevent the test 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.

1.3938 Trainer, in this instance, means a professional with appropriate expertise who conducts a course in food safety for applicants for *certification* as Food Protection Managers.

1.4039 Validity means the extent to which a test score or other type of assessment measures the attributes it was designed to measure. In this instance, does the test 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 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. the availability of financial resources to effectively and thoroughly conduct regular and ongoing *certification* program activities.
 - b. that staff possesses the knowledge and skills necessary to conduct the *certification* program or has available and makes use of non-staff consultants and professionals to sufficiently supplement staff knowledge and skills.

SECTION 4.0 – FOOD SAFETY CERTIFICATION EXAMINATION DEVELOPMENT

4.0 *Food Safety Certification Examination Development*

4.1 *Food safety certification examinations* administered by *accredited certifying programs* must comply fully with all criteria set by the CFP and must meet explicit and implicit standards to protect the public from foodborne illness.

4.2 Each *certification organization* must provide evidence that it meets the following professional requirements:

- a. ability to conduct or otherwise use a *legally defensible* and psychometrically valid *job analysis*;
- b. demonstrated experience in the development of psychometrically valid *competency examinations*;
- c. demonstrated capability to develop and implement thorough procedures for security of the *item bank*, printed, taped or computerized examinations, exam answer sheets, and candidate scores;
- d. data handling capabilities commensurate with the requirements for effective processing, reporting, and archiving of candidate *food safety certification examination* scores; and
- e. demonstrated evidence of an understanding of and willingness to abide by the principles of fairness and due process.

4.3 The *certification organization* must 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. complete description of the scope and usage of the examination;
- b. *job analysis* task list, with knowledge, skills, and abilities (KSAs);
- c. *examination specifications*;
- d. the number of unduplicated items in the *item bank*;
- e. statistical performance of each item in the bank;
- f. number of *examination forms* and evidence of their *equivalence* to each other;

- g. description of method used to set passing score;
- h. copies of all logs, diaries, and personnel lists and descriptions kept as required in the development process;
- i. summary statistics (Section 4.16 Periodic Review) for each *examination form*;
- 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 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 be sufficiently diverse as to avoid cultural bias and ensure fairness in content according to all federal requirements.
- 4.5** The *job analysis* must 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 be derived from a valid study of the *job analysis* tasks and their accompanying knowledge, skills, and abilities (KSAs) and must be appropriate to all aspects of the *retail food industry*. The *job analysis* must 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 be available to candidates and to the public.
- 4.7** The *certification organization* or its contracted test provider must 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 be provided to the *accrediting organization* on demand.
- 4.8** *Certifying organizations* are required to systematically evaluate practices in the *retail food industry* to assure 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 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*.
- 4.11** The *food safety certification examination* must be based on psychometrically valid procedures to assure the relative equivalence of scores from various *examination forms*. The *certifying organization* must 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 be provided to assure 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 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 provide evidence of content *equivalency* of the translated version with the original *examination form* and/or *item bank*. The developer must provide a detailed description of the translation method(s), including the rationale for selecting the translation method(s), and must 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 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 items and of the full examination. Those materials must be provided to the *accrediting organization* on demand.
- a.** All examinations must be delivered and administered in a format that ensures the security of the examination (i.e. in a secured environment with a *proctor*.) Un-proctored examinations are not acceptable regardless of the mode of administration.

4.15 Security. The *certifying organization* will demonstrate that procedures are developed and implemented to assure that individual items, *item banks*, *food safety certification examinations* presented in all media (printed, taped and computerized), test answer sheets and candidate scores are and remain secure. Demonstration shall include an overall examination security plan that covers each step in the examination development 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 organization* must 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 used) administered during the preceding six months, as well as other information that may be reasonably requested by the *accrediting organization*:

- a. number of *food safety certification examinations* administered,
- b. mean,
- c. mode,
- d. standard deviation,
- e. range,
- f. *reliability* coefficient,
- g. number and percentage of candidates passing the examination, and
- h. the statistics describing the performance of each item used on *food safety certification examinations* administered during the six-month period.

4.17 Specific Procedures for Examination Administration. *Certification organizations* must specify procedures for administering all *food safety certification examinations* in a standard manner in order to assure that all candidates are provided with the opportunity to perform according to their level of *competency* and to assure comparability of scores. Procedures must include, but not be limited to:

- a. requirements for qualifications of *test administrators* and ~~*monitor/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,

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- 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,
- b. 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.

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- c. must be in a proctored environment where the interpreter and candidate are not a distraction to other candidates, and
- d. 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

5.0 *Food Safety Certification Examination Administration*

5.1 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 be accomplished in a manner that ensures fairness to all candidates.

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.

5.3 ~~*Instructor/Educator/Trainer as Test Administrator/Proctors*~~ **Proctoring *Food Safety Certification Examinations***. ~~When an~~ An instructor/educator/trainer of food safety training shall not be a test administrator or proctor ~~administers, proctors or monitors a food safety certification examination, from an accredited certification program, the accredited~~ *Instructor/educator/trainer and test administrator/proctor may exist in the same legal entity but shall be structurally and functionally separated to insure the confidentiality and security of the examination. The 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.~~

5.-84 *Test Administrator and ~~Monitors/Proctor~~ Qualifications, Training and Duties.* ~~Certifying~~ *Certification organizations* must specify the responsibilities of *test administrators* and of ~~monitors/~~ *proctors*, set minimum criteria for approval of *test administrators* and for ~~monitors/~~ *proctors*, and provide suitable programs of training to enable persons to meet those criteria. Responsibilities, duties, qualifications and training of *test administrators* and ~~monitors/~~ *proctors* must 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 ~~monitors/~~ *proctor* fails to meet job responsibilities must be implemented and documented. ~~Where instructors/educators/trainers are used as test administrators/proctors, the certifying organization shall enter into a formal contractual~~

~~relationship with the test administrators/proctors to ensure they follow all administrative procedures.~~

- 5.5** The certification organization shall define and provide descriptions for the roles of test administrators, proctors, and certification personnel that will clearly delineate the responsibilities of each role. The certification organization shall demonstrate how it ensures that all certification personnel, including test administrators and proctors, understand and practice the procedures identified for their roles.
- 5.6** The certification organization shall ensure that all test administrators and proctors meet the competency requirements established by the certification organization, comply with all requirements of the certification organization, and are not instructors, educators, or trainers participating in training for Certified Food Protection Managers.
- 5.7** The certification organization shall enter into a formal agreement with the test administrators/proctors and shall assess and monitor the performance of test administrators and proctors in accordance with all documented procedures and agreements. The formal agreement shall include, at a minimum, provisions that relate to code of conduct, conflict of interest and a statement of consequences for breach of the agreement.
- 5.8** **Item & 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.
- 5.49** Where special accommodations must be made for otherwise qualified candidates under provisions of the Americans with Disabilities Act, arrangements must 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 be provided to the ~~certifying~~ certification organization.
- 5.510** The ~~certifying~~ certification organization must provide procedures to be followed in any instance where the security of a *food safety certification examination* is, or is suspected to be, breached. Included must be specific procedures for handling and for reporting to the *accrediting organization*, any suspected or alleged cheating incidents, lost or stolen booklets, intentional or unintentional divulging of test items by examinees or test administration personnel, or any other incidents perceived to have damaged the security of the examination or any of its individual items. Corrective actions to guard against future security breaches must be established and implemented. Documentation of corrective actions and their effectiveness must be made available to the accreditation body.

5.611 Examination Administration Manual. The ~~certifying~~ *certification organization* must provide each *test administrator* with a manual detailing the requirements for all aspects of the *food safety certification examination* administration process.

5.712 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 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;
- b. shipping must be done by certifiable, traceable means so that its location can be determined at any given time; and
- c. the packing list must show the number of packages in the shipment and the exact contents of each.

The package(s) of examination booklets must be placed in secure storage immediately upon delivery. They must be kept in secure storage both before and after they are used.

5.913 *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 *monitors/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.~~

5.1014 *Monitors/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.

5.1115 The number of approved *monitors/proctors* assigned to a *test administrator* must be sufficient to allow each examinee to be observed and supervised to assure conformance to security requirements. There shall be no less than one *test administrator* for the first thirty-five examinees, plus one additional *test administrator* or *proctor* ~~or monitor~~ for each additional 35 examinees or fraction thereof.

5.1216 Site Requirements. Sites chosen for administering *food safety certification examinations* must conform to all legal requirements for safety, health, and accessibility for all qualified candidates. Additionally, the accommodations, lighting, space, comfort, and work space for taking the examination must allow all candidates to perform at their highest level of *competency*.

5.1317 Requirements at each site include but are not limited to:

- a. accessibility in accordance with requirements of the Americans with Disabilities Act must be 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;
- b. all sites must conform to all fire safety and occupancy codes of the jurisdiction in which they are located;
- c. there must be sufficient spacing between each examinee in the area in which the actual testing is conducted, or other appropriate and effective methods, to preclude any examinee from viewing another examinee's test;
- d. acoustics must allow each examinee to hear instructions clearly, using an electronic audio system if necessary;
- e. lighting at each examinee's work space must be adequate for reading fine print; and
- f. ventilation and temperature must be appropriate for health and comfort of examinees.

5.1418 Examination Scheduling. *Food safety certification examinations* must be scheduled far enough in advance to allow for timely shipment of supplies.

5.1519 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.

5.1620 Scoring will be done only by means authorized by the ~~certifying~~ certification organization and approved by the *accrediting organization*.

5.1721 *Food safety certification examination* scores will not be released as being official until verified and approved by the ~~certifying~~ certification organization.

5.1822 Examinee scores will be confidential, available only to the examinee and to persons or organizations approved in writing by the examinee.

5.1923 Score reports will be available to examinees in a time frame specified in the application, which will not be later than 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 ~~certifying~~ certification organization will have ongoing communication with examinees and with the *test administrator* until the scores are verified and released.

SECTION 6.0 – COMPUTER-BASED TESTING (CBT)

6.0 Computer-Based Test Development and Administration

- 6.1 Computer-Based Test Development.** *Examination specifications* for *computer-based testing* must describe the method for development, including the *algorithms* used for test item selection, the item response theory model employed (if any), and examination *equivalency* issues.
- 6.2** Items must be evaluated for suitability for computer delivery, be reviewed in the delivery medium, and be reviewed in the presentation delivery medium. Assumptions must 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 that the items are protected from *overexposure*. Item usage statistics must 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 be provided to demonstrate equivalence of the examinees' scores.
- 6.5** Tutorials and/or practice tests must 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 be demonstrated. Data must be gathered and continually analyzed to determine if scoring methods are comparable.
- 6.7** Evidence of security in the *computer-based testing* environment must 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 be provided.
- 6.9** Policies and procedures regarding the recording and retention of the *item sequence* and item responses for each examinee must be developed and followed. Computer examinations using a unique sequence of items for each examinee must record the information necessary to recreate the sequence of items and examinee responses on the computer examination.

- 6.10** Systems and procedures must be in place to address technical or operational problems in examination administration. For example, the examination delivery system must 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 be developed.
- 6.11 Due Process.** Candidates must 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 AND THE PUBLIC

7.0 *Certification Organizations Responsibilities to Candidates and the Public.*

7.1 **Responsibilities to Applicants for *Certification*.** A certifying organization shall:

- 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. 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. 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. provide evidence that competently proctored testing sites are readily accessible (Section 5.10);
- e. provide evidence of uniformly prompt reporting of *food safety certification examination* results to applicants (Section 5.19);
- f. provide evidence that applicants failing the *food safety certification examination* are given information on general areas of deficiency;
- g. provide evidence that each applicant's *food safety certification examination* results are held confidential (Sections 5.17 and 5.18); and
- 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 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.

- 7.4 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 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 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, or other matters involving potential legal defensibility of the examination or program. The protocol will include a published time frame for reporting findings to the User.
- 7.9 Misrepresentation.** Only Food Protection Manager *Certification Programs* that conform to all requirements of Standards for *Accreditation of Food Protection Manager Certification Programs* and are accredited by the agent selected by the CFP as the *accrediting organization* for such programs are allowed to refer to themselves as being accredited. Those programs may not make any other reference to the CFP in their publications or promotional materials in any medium.

SECTION 8.0 – CERTIFICATION ORGANIZATION RESPONSIBILITIES TO THE ACCREDITING ORGANIZATION

8.0 *Certification Organization Responsibilities to the Accrediting Organization.*

8.1 Certifying organizations seeking *accreditation* for development and/or administration of a *certification* program shall provide at least the following information, as well as other information that might be requested by the *accrediting organization*.

- a. The name and complete ownership of the *legal entity*.
- b. The address, telephone/fax number(s) and other contact information of the *certification organization's* headquarters.
- c. The name, position, address and telephone/fax/e-mail information of the contact person for projects related to the CFP Standards for *Accreditation of Food Protection Manager Certification Programs*.
- d. Such fiscal information as may be needed to establish evidence of ability to carry out obligations under these standards.

8.2 **Summary Information.** A certifying organization shall:

- a. provide evidence that the mechanism used to evaluate individual competence is objective, fair, and based on the knowledge and skills needed to function as a *Certified Food Protection Manager* (Sections 4.3 and 4.4);
- 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. 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. 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. provide evidence that appropriate measures are taken to protect the security of all *food safety certification examinations* (Sections 5.2 through and including 5.15)
- f. publish a comprehensive summary or outline of the information, knowledge, or functions covered by the *food safety certification examination* (Section 4.6);

- 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. 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. make available upon request to the *accrediting organization* copies of all publications related to the *certification* program,
- b. advise the *accrediting organization* of any proposed changes in structure or activities of the certifying organization,
- c. advise the *accrediting organization* of substantive change in *food safety certification examination* administration,
- d. advise the *accrediting organization* of any major changes in testing techniques or in the scope or objectives of the *food safety certification examination*,
- e. annually complete and submit to the *accrediting organization* information requested on the current status of the Food Protection Manager *Certification* Program and the *certification organization*,
- f. submit to the *accrediting organization* the report requirements information specified for the Food Protection Manager *Certification* Program, and
- g. be re-accredited by the *accrediting organization* at least every 5 years.

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 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 Managers* 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 that individuals have achieved mastery of the competencies;

therefore, professionals involved in the credentialing process for *Certified Food Protection Managers* 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 scores.

Actual or potential conflicts of interest that might influence judgment or performance of examination developers, *test administrators or proctors/monitors, instructors/trainers/educators*, 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.

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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 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.** ~~In order to~~ To become a *Certified Food Protection Manager*, an individual must pass a *food safety certification examination* from an accredited certifying program recognized by the CFP. ~~To prepare for certification, it is recommended that the individual obtain training. Based on the content of the areas of knowledge prescribed in Paragraph 2-102.11 (C) of the FDA Food Code.~~ 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*.

Food Protection Manager Training, Testing and Certification Committee Bylaws

Preamble

The Food Protection Manager ~~Training, Testing and~~ 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 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 F. 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 H. 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 charged to the Committee by the Board. The Committee 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.
- Section 5. All issues, intellectual properties, and/or inventions created by the Committee and approved by the voting assembly of the Conference become the property of the Conference.

Article ~~IV~~ III. 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. The Chair and Vice-Chair shall be 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, ~~from the following groups that comprise the broad based representation of the Conference: regulatory agencies, industry, academia and consumer groups.~~ The Chair and Vice-Chair shall not be selected from the same group affiliation.
- Section 3. The Chair and Vice-Chair shall serve until the conclusion of the next 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 4. The Committee Chair and Vice-Chair may serve consecutive terms 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~~ IV. Committee Structure and Representation.

- Section 1. To be eligible to serve on the Committee, individuals must commit in writing to active participation and be approved by the Conference Chair and the Board.
- Section 2. The Committee Chair, Vice-Chair, and/or Council II Chair will select committee members from the list of volunteers or recruit volunteers as appropriate to balance the committee as delineated under Article IV. Committee Structure and Representation.
- Section 3. The composition of the Committee is a balanced representation of industry, regulatory, academia, certification providers, training providers, and consumers. The Committee shall consist of twenty-eight (28) members in addition to the Chair and Vice-Chair.

Subsection 1. Nine (9) ~~Ten (10)~~ representatives from regulatory agencies:

- a. Two (2) ~~Three (3)~~ from State regulatory agencies;
- b. Two (2) ~~Three (3)~~ from local regulatory agencies;
- c. Two (2) from federal government agencies with retail food program responsibilities.

d. ~~Three (3) Two (2)~~ “At Large” appointments. (*At Large representation – agencies with primary regulatory food safety responsibilities ~~or professional organizations whose mission incorporates a significant public health protection focus.~~)

Subsection 2. ~~Nine (9) Ten (10)~~ industry representatives;

- a. ~~Three (3) Four (4)~~ from the foodservice (restaurant) industry;
- b. ~~Three (3) Four (4)~~ from the retail food store industry, and
- c. ~~Three (3) Two (2)~~ “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) Four (4)~~ certification providers that are accredited by the Conference’s accreditation process;

Subsection 4. Three (3) Food Protection Manager training providers;

Subsection ~~4~~ 5. Two (2) representatives from academia, and

Subsection ~~5~~ 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 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. An assessment by the 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.

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 Conference meetings.

Article ~~VI~~ V. Committee Organization, and Operation, and Meetings

- Section 1. The Committee shall receive its direction from the Board. The Board shall assign the Committee its charges as ratified 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 session until the confidential portion of the proceedings has ~~have~~ 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 7. In addition to the charges and issues received from the Board, Committee members may submit issues and alternative recommendations to the Committee. 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.

- Section 9. A quorum to conduct Committee meetings and conference calls shall be the presence of one more than half of the filled ~~fifteen (15)~~ Committee positions ~~members~~. 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.
- 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 11. Voting. 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.
- Section 12. The Vice-Chair may voice positions on issues. When the Committee Chair conducts a meeting, the Vice-Chair may vote on all matters before the Committee.
- Section 13. 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. 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 15. 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.

Article ~~VII~~VI. Duties of the Committee Chair

- Section 1. The Chair, with the approval of the Board and the Council II Chair, shall select Committee members in accordance with Article IV.
- 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 to the Committee in accordance with Article VIII.
- Section 3. The Chair shall preside at all meetings of the Committee, except as provided in Article VII, Section 1.
- Section 4. The Chair shall coordinate the arrangement of meetings and conference calls.
- 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 distributing written or oral reports to the Board detailing the activities of the Committee. The Chair shall be called upon to report at the biennial Conference meeting on the activities of the Committee.
- Section 9. The Chair shall provide an annual written Committee budget report to Committee members and the Board.

Article ~~VIII~~ VII. 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.
- Section 3. The Vice-Chair shall perform all duties assigned by the Chair.

Article ~~IX~~ VIII. Duties of Committee Members

- Section 1. A Committee member's tenure shall be carried out in accordance with Article IV, Section 2.
- Section 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. The member may submit in writing a designated representative in his/her place to the Chair. This designated representative may vote on issues before the committee.

- Section 3. Committee members or designated representative 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 4. Committee members or designated representative shall have the responsibility to complete work assignments within time frames designated by the Committee.
- Section 5. Committee members or designated representative shall have the responsibility to notify the Committee Chair or the Chair's designee of their inability to complete a work assignment.
- Section 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, shall require the concurrence of two-thirds (2/3) of the voting members of the Committee.

Article ~~X~~IX. Committee Consultants

- 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.
- 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.

Article ~~XI~~X. 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~~^{XI}. Committee Reports

Section 1. The Committee Chair shall submit a status report of the Committee's activities to the Council II Chair no later than thirty (30) days prior to the Board meetings.

Section 2. The Committee Chair shall coordinate the development of a final report of the Committee activities to the Council with recommended actions. The final report shall be done in advance of the Conference meeting as part of an Issue submission. 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 shall be in attendance when Council II meets during the Conference meeting to present and discuss the Committee's report and any issues submitted by the Committee.

Article ~~XIII~~^{XII}. Amendments

The Food Protection Manager ~~Training, Testing and~~ 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 group 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 ~~Training, Testing and~~ Certification Committee Bylaws
Revised Bylaws approved 2010~~2004~~ Conference
Revised 6/8/2004

CFP Food Manager Training, Testing & Certification Committee 2008-2010

Joyce Jensen, Chair	Lincoln-Lancaster Co. Health Dept	3140 N Street	Lincoln, NE 68510-1514	(402) 441-8033	jjensen@lincoln.ne.gov
Jeff Hawley, Vice-Chair	Harris Teeter, Inc.	701 Crestdale Road	Matthews, NC 28105	(704) 844-3098 (704) 236-0890 (C)	jhawley@harristeeter.com

Regulatory - 10

State Regulatory - 3

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Local Regulatory - 3

Vicki Everly	Santa Clara Co Dept of Environmental Health	1555 Berger Drive, Suite 300	San Jose, CA 95112-2716	(408) 918-3490	vicki.everly@deh.sccgov.org
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Federal Regulatory - 2

Lynn Hodges	USDA-Office of Outreach, Education & Employee Training	1100 Commerce St., Ste. 516	Dallas, TX 75242	(972) 937-7519	Lynn.Hodges@fsis.usda.gov
Laurie Williams	FDA/CFSAN/Office of Food Safety	5100 Paint Branch Pkwy	College Park, MD 20740	(301) 436-2938	Laurie.Williams@fda.hhs.gov
John Hicks (Alt)	Office of Policy, Program & Employment Dev. USDA-FSIS	1400 Independence Ave. SW	Washington, DC 20250	(202) 205-0210	john.hicks@fsis.usda.gov
Kristina Barlow (Alt)	Office of Policy, Program & Employment Dev. USDA-FSIS	1400 Independence Ave. SW	Washington, DC 20250	(202) 205-3872	kristina.barlow@fsis.usda.gov

At Large Regulatory - 2

Tony Carotenuto	Navy and Marine Corps Public Health Center	620 John Paul Jones Circle	Portsmouth, VA 23708	(757) 953-0712	anthony.carotenuto@med.navy.mil
Patricia Welch	Illinois Department of Public Health	525 West Jefferson Street, 2nd Floor	Springfield, IL 62761	(217) 782-4345	patricia.welch@illinois.gov

Industry - 10

Food Service Industry - 4

Douglas Davis	Marriott International	10400 Fernwood Road Dept. 51.932	Bethesda, MD 20817	(301) 380-5736	douglas.davis@marriott.com
Susan Quam	Wisconsin Restaurant Association Education Foundation	2801 Fish Hatchery Road	Madison, WI 53713	(608) 270-9950	squam@wirestaurant.org
Geoff Luebke	Florida Restaurant & Lodging Association	230 S. Adams Street	Tallahassee, FL 32301-7710	(850) 224-2250	geoff@frla.org

Retail Industry - 4

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Thomas McMahan	Supervalu, Inc.	250 Park Center Blvd.	Boise, ID 83706	(208) 395-3265	thomas.mcmahan@supervalu.com
Sharon Wood	H-E-B Grocery Company	5105 Rittman Rd.	San Antonio, TX 78218	(210) 938-6511	wood.sharon@heb.com

At Large Industry - 2

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Certification Providers - 4

Larry Lynch	Environmental Health Testing (National Registry)	5728 Major Blvd., Suite 750	Orlando, FL 32819	(800) 446-0257	llynch@nrfsp.com
Kate Piche'	National Restaurant Association Solutions	175 W. Jackson Blvd., Suite 1500	Chicago, IL 60604-2814	(312) 261-5348	kpiche@restaurant.org
Kenneth Walters	Prometric	1260 Energy Lane	St. Paul, MN 55108	(651) 603-3416	Kenneth.Walters@prometric.com
Rose Mary Ammons (alt)	Environmental Health Testing (National Registry)	3141 Lakestone Drive	Tampa, FL 33618	(813) 960-0103 (813) 494-5494 (C)	ammonsrm@verizon.net

Academia - 2

David McSwane	Indiana University	801 W. Michigan Street	Indianapolis, IN 46202	(317) 274-2918	dmcswane@iupui.edu
Julie Albrecht	Univ of Nebraska/Lincoln, Nutrition & Health	119 Ruth Leverton Hall	Lincoln, NE 68583-0808	(402) 472-8884	jalbrecht1@unl.edu

Consumer/Independent - 2

Cynthia D. Woodley	Professional Testing, Inc.	7680 Universal Drive, Suite 300	Orlando, FL 32819	(407) 264-2993	cdwoodley@proftesting.com
Christine Hollenbeck	NEHA Entrepreneurial Zone	720 S. Colorado Blvd., Ste. 1000N	Denver, CO 80246	(303) 756-9090	chollenbeck@neha.org
David Cox (Alt)	Professional Testing, Inc.	7680 Universal Drive, Suite 300	Orlando, FL 32819	(407) 264-2993	dcox@proftesting.com

ANSI Representative

Roy Swift	American National Standards Institute	1819 L Street, NW 6 th Floor	Washington, DC 20036	(202) 331-3617	rswift@ansi.org
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Accreditation Committee

Jim Lewis	NSF International	789 North Dixboro Road	Ann Arbor, MI 48105	(734) 769-5360	lewis@nsf.org
Lee Cornman	Florida Department of Agriculture & Consumer Services	3125 Conner Boulevard, Room 185	Tallahassee, FL 32399-1650	(850) 488-8434	cornmal@doacs.state.fl.us

updated 10-29-2009

Conference for Food Protection Committee FINAL Report

COMMITTEE NAME: Food Protection Manager Training, Testing, and Certification Committee

COUNCIL: Council II

DATE OF REPORT: January 8, 2010

SUBMITTED BY: Joyce Jensen, Committee Chair

COMMITTEE CHARGE(S):

2008 CFP Issue II-037

The Conference recommends this standing committee be charged to continue working with the Conference for Food Protection (CFP) Executive Board and the American National Standards Institute (ANSI)-CFP Accreditation Committee (ACAC) to maintain the standards in an up-to-date format.

2008 CFP Issue II-039

To evaluate Annex B Section B3, to consider incorporating the training recommendations suggested by the Committee as shown below.

Annex B Section B3: Qualifications for Certification. In order to become a Certified Food Protection Manager an individual must pass a food safety certification examination from an accredited certifying program recognized by the CFP. To prepare for certification, it is recommended that the individual obtain training based on the content of the areas of knowledge prescribed in Paragraph 2-102.11 (C) of the FDA Food Code and content outlined based on job task analyses developed by accredited certification organizations.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Following the 2008 CFP biennial meeting, the Food Protection Manager Training, Testing, and Certification Committee (FPMTTC) met in person twice and held several conference calls to address the charges and to review and revise the Committee Bylaws.

The Committee Chair would like to thank the Committee Vice-Chair, Jeff Hawley, for his valued assistance, and all of the Committee Members for their hard work and input on addressing the CFP charges. The Committee would like to thank: Jeff Hawley and Harris Teeter, Inc. for hosting the September 10, 2008 conference call; Dr. Cynthia Woodley and David Cox and Professional Testing for hosting the January 14 and 15, 2009 face-to-face meeting at in Orlando, Florida; Frank Ferko and US Foodservice for hosting the August 26 and 27, 2009 face-to-face meeting in Rosemont, Illinois; and Katie Piche and National Restaurant Association Solutions for hosting the November 19, 2009 Committee web conference call.

The Committee completed work on the two charges from the 2008 CFP Biennial Meeting. For the first charge (from 2008 Issue II-037), several concerns came up relative to the *Standards for Accreditation of Food Protection Manager Certification Programs* (hereafter referred to as *Standards*) that were discussed, and proposed revisions to the Standards have been submitted as Issues. For the second charge (from 2008 Issue II-039) to propose a revision to the Annex B Section B3, the Committee came up with alternative language that gives guidance on training; this language has been submitted as a separate Issue.

The proposed changes to the *Standards* Section 5 were the most challenging for the Committee. It is important to remember the history of Food Protection Manager Certification. This program had been thoroughly researched and debated over many years when the CFP determined that a legally defensible nationally recognized third party accreditation of certification programs was needed.

To have a certification program, standards are necessary, and then certification organizations would be accredited by an accrediting organization that would independently evaluate if the certification organization’s program meets the standards. A certification is not a record of training attended by an individual. A certification is the result of a legally defensible process based on a current job analysis that demonstrates an individual has the knowledge required to protect the public from foodborne illness.

It may help to refer to the attached *Standards for Accreditation of Food Protection Manager Certification Programs* in Annex A and the definitions in Section 1 to assist with understanding the accreditation and certification process. The following comparison table assists in clarifying the differences between “certification” programs and “certificate” programs.

CERTIFICATION Program	CERTIFICATE Program
Results from an assessment process	Results from an educational process
Awarded by a third party	Awarded by training and educational programs
Indicates mastery-demonstration of required competencies to practice	Indicates successful completion of a course/s
Has on-going requirements; holder must demonstrate s/he continues to meet the requirements	No on-going requirements. Individuals may or may not demonstrate knowledge of course at the end of a set period in time
Certification owned by the certification body- can be taken away	Certificate owned by the certificate holder.

A certification examination is developed and administered by an independent third party so that the outcome is valid. “Teaching to the test,” assisting in the “understanding” of the questions, or otherwise “helping” with the test by an instructor, trainer, or educator would invalidate the certification process, no matter how good the intentions. However, when the *Standards* were developed, it became evident a system to train and test thousands of food protection managers was already in place across the country, and that it would be a challenge to change the existing process. So to compromise, the CFP *Standards* included requirements to provide a “firewall” that separates “training” and “testing” while allowing an instructor, trainer, or educator to administer the test. Allowing a trainer to administer the examination is unique for a certification

process and has continually been the source of problems and/or concerns for food protection manager certification programs, ANSI, and ACAC.

To address this challenge, the FPMTTC Committee is proposing a change to the *Standards* Section 5 that would **NOT** allow an instructor, trainer, or educator to be a test administrator or proctor. The *Standards* Section 5, as proposed, would still allow an instructor, trainer, or educator and a test administrator or proctor to be part of the same organization/agency. Test administrators and proctors would, however, be restricted from participating with training.

This proposed change to the *Standards* Section 5 was not a unanimous decision by the Committee. The following are some advantages and concerns of the proposed revision as discussed by the Committee:

Advantages of separating the instructor/educator/trainer from the test administrator/proctor:

- CFP and FDA are supportive of a “certification” program which is legally defensible.
- It will be a step in the right direction, rather than forcing a total separation requiring a separate organization to administer the test.
- According to ANSI, typical certification programs beyond the food industry do not allow an instructor/educator/trainer to be a test administrator/proctor. Our current process blurs the lines and gives the appearance of a certificate program (take a course and an exam) rather than a certification program.
- Not taking action may result in jurisdictions dropping the certification requirement because of an invalid process.
- The current process has created opportunities for violation of exam security by allowing an instructor/educator/trainer to have direct contact with the exams.
- The credibility of the CFP and the *Standards for Accreditation of Food Protection Manager Certification Programs* will be jeopardized if this issue is not addressed.
- What a program is worth is the value it takes to achieve it. The expense, training, and degree of knowledge needed to be certified reflect the value of the certification. If the process is not valid or if there are opportunities in the process that allow individuals to get around the requirements, it devalues the programs for all others who have achieved the certification.
- The certification providers would have more control over the integrity and accountability of the exam administration process by restricting who has access to the examinations.
- There have been studies that indicate that when there is clear singular role identity (such as “test administrator” vs. “trainer”) there is better adherence to the rules and requirements for that specific role, and less chance of deviation from the role.

Concerns of separating the instructor/educator/trainer from the test administrator/proctor:

- Having an instructor/educator/trainer separate from a test administrator/proctor may add to the expense of the certification process. This may discourage access to manager certification rather than encourage it.
- When training and testing are not combined, there is additional time needed if the candidate has to take the exam at a different location.
- The separation could decrease in-person trainings and increase “online training” options, which may not be completely embraced by some regulatory jurisdictions.
- The separation could have a negative impact on the training and testing opportunities in rural and low population areas.
- The separation could have a negative impact on entities that currently have one person that both instructs a course and administers the test.
- There are alternatives to certification, including certificate programs where the manager would be trained and then pass a non-certified exam; however, the result may not have the same degree of assurance that a manager has the knowledge required to protect the public from foodborne illness.
- Dishonest people will always be a problem that has to be addressed and separating the roles may not necessarily add any greater security to the process.

The above concerns were discussed by the Committee and were found to be very legitimate but the overarching factor is maintaining the credibility of the Food Protection Manager Certification Program. The intent is to have a certification process that minimizes the chances of inappropriate activity and gives the certification organizations the ability to address situations of concern.

ANSI has recommended that the Committee look at how the *Standards* could be brought more in alignment with International Standard ISO17024 which sets out general requirements for an organization's certification program for individual persons.

In the continuing process to maintain the *Standards* in an up-to-date format per 2008 Issue II-037, the Committee completed draft revisions to the FPMTTC Committee Bylaws and is presenting the following proposals as Issues:

- To change and shorten the Committee name.
- To modify composition of the Committee to include representatives of training providers while not increasing the total number of Committee members.
- To define a quorum to be one (1) more than half of the filled Committee positions, rather than a specific number.
- To allow the Committee Chair and Vice-Chair to be selected from any representative group on the Committee.

- Other non-substantive clean-up bylaw changes.

The Committee agreed that a future charge is to determine how Committee membership vacancies and change of membership representation are addressed in the Committee bylaws and propose changes if needed.

REQUESTED ACTION:

The Committee submits the following Issues to the 2010 CFP Biennial Meeting:

1) **Report – FPMTTC Committee**

This Issue requests that the Conference acknowledge the final report as submitted, and thanks the Committee members for their effort in addressing the charges from the 2008 Biennial Meeting.

2) **Amend training language in *Standards for Accreditation***

This Issue addresses charge from 2008 CFP Issue II-039 with proposed clarification to Annex B Section B3 regarding training recommendations.

3) **Amend Section 5 of the *Standards for Accreditation***

This proposed Section 5 revision includes new and revised subsections establishing the following: an instructor, trainer, or educator cannot serve as test administrator, or proctor; roles and responsibilities for certification personnel; competency requirements for test administrators and proctors; item and examination exposure controls; and establishes formal agreements with test administrators/proctors that include a code of conduct, conflict of interest, and a statement of consequences for breach of the agreement. In addition, some of the subsections have been reorganized for clarity and renumbered accordingly.

4) **Remove reference to “monitor” in the *Standards for Accreditation***

The term monitor is not currently used by certification organizations and was defined as a proctor. The term is no longer applicable

5) **Change name of the “FPMTTC Committee”**

The proposed revision to change the Committee name from “Food Protection Manager Training, Testing and Certification Committee” to “Food Protection Manager Certification Committee” to more accurately reflect the actual food protection manager certification program as written by the standards.

6) **Revise Bylaws of the FPMTTC Committee**

This FPMTTC Committee proposed Bylaw revision includes: adding training providers to the composition of the Committee, establishing that a quorum is based on the number of filled positions, and some non-substantive clean-up language.

7) **New or Continuation Charges for the renamed Committee**

The Conference recommends that this standing committee 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.
- investigate if the *Standards for Accreditation of Food Protection Manager Certification Programs* should create more alignment with ISO17024 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.

ATTACHMENTS:

Standards for Accreditation of Food Protection Manager Certification Programs

Food Protection Manager Training, Testing, and Certification Committee Bylaws

Food Protection Manager Training, Testing, and Certification Committee Member Roster

COMMITTEE MEMBER ROSTER:

Attached

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 087
Issue: 2010 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:

Constitution - new article titled "Parliamentary Authority"

Issue you would like the Conference to consider:

Add a new article to the Constitution, titled "Parliamentary Authority", to be inserted before the current Article XIX of the Constitution

Public Health Significance:

The Constitution and Bylaws/Procedures Committee would like to clarify the parliamentary authority by which the Conference conducts its business.

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.

Submitter Information:

Name: Ruth N. Hendy, Chair
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City/State/Zip: Austin, TX 78714-9347
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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
2010 Issue Form**

**Internal Number: 088
Issue: 2010 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:

Report - Constitution and Bylaws Committee

Issue you would like the Conference to consider:

The 2008-2010 Constitution and Bylaws/Procedures Committee has addressed recommendations from the 2008 Biennial Meeting and 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 Committee members.

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.

Submitter Information:

Name: Ruth N. Hendy, Chair
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Attachments:

- "Final Report Constitution and Bylaws Committee"

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

Council: Executive Board

Date of Report: December 4, 2009

Submitted by: Ruth N. Hendy, Chair

Committee Charges:

The duties of the Constitution and Bylaws/Procedures Committee, as stated in Article XV, Section 3 of the CFP Constitution are to:

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 to the Committee, as presented in final issues from the 2008 Biennial Meeting (Issue 2008 II-001) are to:

1. Renumber, as necessary, the Constitution, Bylaws and Conference Procedures as accepted by the Assembly of Delegates.

Charges to the Committee from the Executive Board during the 2008-2010 biennium are to:

1. Review the Constitution and Bylaws provisions concerning definitions of membership categories.
2. Review Conference Procedures concerning voting rights of federal agency members of committees.

Committee Activities and Recommendations:

Specific Outcomes for Each Assigned Charge

1. Recommendations to improve Conference administrative functions:
 - A. Proposals to amend the Constitution and Bylaws:
 - 1) Parliamentary Authority. The Committee proposes a new article, to be inserted before the current Article XIX of the Constitution, to be entitled Parliamentary Authority that would read as follows:

“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.”

The Executive Board, at the August 25, 2009 Executive Board meeting, approved the wording for the amendment to the Constitution.

2) Establishment of a quorum for Executive Board meetings. The Committee recommends that the quorum for Executive Board meetings remain at a majority (half plus one). No action necessary by the Executive Board or the Conference.

3) Constitutional article concerning the name of the organization. The Conference for Food Protection Constitution does not have an article that specifies the name of the organization, although the name is mentioned in the Preamble. The Committee voted to take no action on the question.

B. Recommendations concerning Conference policies:

1) The Executive Board, at the April 30, 2009 Executive Board meeting, directed the Constitution/Bylaws Committee review and make recommendations for changes to the Conference Audit Policy. The Committee recommended to the Executive Board that the Conference Audit Policy be re-written as follows:

Purpose: Remain as currently written

Policy:

- The CFP Audit Committee, a standing committee, shall conduct an annual review of the CFP financial records and report their findings to the Executive Board.
- The CFP Executive Board, at the discretion of the Board, may request an external review of the CFP financial records, at the expense of the CFP.

The Executive Board, at the August 2009 meeting, adopted the Committee recommendation.

2. Review Proposed Memorandums of Understanding

There were no Memorandums of Understanding submitted to the Committee for review.

3. Renumber, as necessary the Constitution, Bylaws and Conference Procedures.

This was done by the CFP Executive Director.

4. Review Conference Procedures concerning the voting rights of federal agency members of committees.

The Executive Board, at the April 30, 2009 Executive Board meeting, directed the Constitution/Bylaws committee review the question of voting rights of federal agency members of committee. The Committee discussed whether standing committees with their own bylaws would be able to vary from Section VIII(D)(2) of the Conference

Procedures. The Committee's conclusion was that a federal agency can set its own policy of whether their employee could be a voting member. The Committee has not made a recommendation concerning clarification of the wording in the Procedures or the Constitution and Bylaws on voting rights of committee members.

5. Review the Constitution and Bylaws concerning definitions of membership categories.

The Committee held several discussions on the question of definition of membership categories. Currently:

- 1) The Constitution and Bylaws refers to members by their constituency (federal regulatory, state regulatory, local regulatory, academia, consumer, and food industry);
- 2) Food industry is further delineated into food processing, food service, retail food stores and food vending;
- 3) An element of the food industry not included in these categories is the food service support industry, currently addressed as "other";
- 4) There is not a category for retiree, other than moving from regulatory, academia or industry to consumer.

The Committee has no recommendations on this charge at this time.

Specific Recommendations

1. The Committee continues discussions on membership categories.

Requested Action:

Listing of all Committee-Submitted Issues

- Report —Constitution and Bylaws Committee
- CB2—CFP Constitution—Add a new article to be entitled "Parliamentary Authority"

Committee Member Roster

- Committee roster attached to this report

Constitution and Bylaws Committee

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
Hendy	Ruth	Chair	State	Texas DSHS	PO Box 149347	Austin	TX	78714	512-834-6753	ruth.hendy@dshs.state.tx.us
Cornman	Lee	Vice-Chair	State	Fla Dept Agriculture & Consumer Services		Tallahassee	FL	32399	850-488-0295	cornmal@doacs.state.fl.us
Owens	Jacqueline	Member	State	Wisconsin Dept Agriculture, Trade & consumer Protection		Madison	WI	53708	608-224-4734	jacqueline.owens@wi.gov
Laymon	Ellen	Member	State	Oregon Dept Agriculture		Salem	OR		503-986-4725	elaymon@oda.state.or.us
Everly	Vicki	Member	Local	Santa Clara Co EH		San Jose	CA	95112	408-918-1955	vicki.everly@deh.sccgov.org
Hardister	Bill	Member	Local	Mecklenberg Co HD		Charlotte	NC	28202	704-336-5533	bill.hardister@mecklenburgcountyNC.gov
Levee	Terry	Member	Industry	Winn-Dixie Stores	5050 Edgewood Court	Jacksonville	FL	32254	904-783-5229	terrylevee@winn-dixie.com
Rosenwinkel	Ken	Member	Industry	Jewel-Osco/Supervalu	1955 W. North Ave	Melrose Park	IL	60160	708-531-6787	ken.rosenwinkel@supervalu.com
Marcy	John	Member	Academia	University of Arkansas		Fayetteville	AR	72701	479-575-2211	jmarcy@uark.edu
Binkley	Margaret	Member	Academia	Ohio State University	264 Campbell Hall, 1784 Neil AVE	Columbus	Oh	43210	614-292-4529	mbinckley@ehe.osu.edu
Smith	Kevin	Member	Federal	FDA	5100 Paint Branch Pkwy	College Park	MD	20740	301-436-2149	kevin.smith@fda.hhs.gov

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 005
Issue: 2010 III-005**

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

All information above the line is for conference use only.

Title:

On-Site Generation of Antimicrobial Pesticides

Issue you would like the Conference to consider:

To accomplish its charge, the 2008-10 Sanitizer Committee thoroughly reviewed three specific aspects related to on-site generation and use of sanitizers and other antimicrobials. These included 1) the current federal regulatory requirements for on-site generators of antimicrobial pesticides and 2) unresolved questions related to on-site generators of antimicrobial pesticides, and 3) specific recommendations for language in the Food Code for on-site generation of antimicrobial solutions. The Committee would like the Conference to consider its recommended language related to on-site generation and use of antimicrobials.

Public Health Significance:

Proper use of sanitizers is an important step to prevent cross contamination and food safety failures. On-site generation of sanitizers and other antimicrobials is not addressed in the 2009 Food Code, and the regulatory process for sanitizers generated and used on-site varies considerably from the regulatory process for manufactured products. Clarification of the Food Code requirements for on-site generated sanitizers is essential to ensure proper use of these materials and to avoid unproductive confusion for inspectors and operators.

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.

The recommended new language is indicated below in underline format for additions and plain text for current 2009 Food Code language:

1. Adding §4-204.124 to address equipment requirements for on-site generators

"4-204.124 On-Site Devices for Generation of Sanitizing Solutions

"Devices for generation of sanitizing solutions shall meet the characteristics specified under §4-202.11 and

(A) Devices for generating pesticides must comply with regulations as established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10.

(B) Devices for generating pesticides shall display the manufacturing establishment's registration number."

2. Adding §4-501.114 (F) to address the sanitizing solutions generated on-site

"A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows ^P:

...

"(F) Any chemical substance produced and used on-site as a food contact surface SANITIZING solution shall have the concentration, temperature, pH and other conditions necessary to meet the definition of SANITIZATION in §1-201.10."

3. Insert the following in Annex 3 for §4-501.114 to address FIFRA requirements for on-site generators, as indicated in the attachment.

"...section 7-204.11 would be violated.

"A variety of sanitizers can be generated on-site, including chlorine, hypochlorous acid (generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), chlorine dioxide, ozone, and others. EPA does not require the registration of pesticidal devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to:

- The name, brand, or trademark under which the product is sold
- An ingredient statement
- Statements concerning effectiveness of the product
- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

"Because there is no EPA registration of solutions generated and used on-site, either the equipment manufacturer or the user of the equipment must generate data to validate the efficacy of the solution the device produces as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site. Section 4-703.11 requires that the conditions of use yields SANITIZATION as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

"EPA Disinfectant - Technical Science Section (DIS-TSS) 4 describes efficacy data requirements for sanitizing rinses for previously cleaned food-contact surfaces http://www.epa.gov/oppad001/dis_tss_docs/dis-04.htm. Chlorine equivalent testing is used for halide-based biocides (chlorine bearing chemicals, iodophors, and mixed halides) and a minimum of 99.999% reduction of *E. coli* and *S. aureus* for non-chlorine biocides. These procedures are required for EPA-registered sanitizers (e.g., bottled chlorine, iodine, quats, etc.), but modification is needed for on-site generated sanitizers. For example, the procedures specify that 3 different batches are to be tested, one of which must be 60 days old. A 60 day sample would not be relevant for on-site generated sanitizers because they should be used shortly after generation. Validation testing for on-site generated product should include a time element, because efficacy can reduce with time. Testing should

include all factors that could impact the efficacy of the pesticide solution including water hardness, pH and temperature. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices.

"Some technologies generate chemicals that are addressed in the Code, such as chlorine or hypochlorous acid. Verifying performance of these chlorine-based solutions can be accomplished by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using test methods and equipment that is currently used.

"However, some on-site generators produce chemicals that are not listed as sanitizers in the Code (e.g. ozone, chlorine dioxide, hydrogen peroxide, etc.). The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment continues to generate the solution at the same concentration on-site.

"Some solutions, such as ozone, chlorine dioxide, and hypochlorous acid, may lose concentration more quickly than other solutions. Therefore, it is necessary to verify concentration on an on-going basis, and to comply with section 4-501.116.

"...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..."

4. Adding ¶7-204.11 (B) and inserting a reference to on-site generated antimicrobials to address pesticides that may not require a tolerance. The section to read as follows.

"Chemical SANITIZERS, including those generated on-site, and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall:

(A) meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions)^P, or

(B) be listed in 40 CFR 180.2020 Pesticide Chemicals Not Requiring a Tolerance or an Exemption From Tolerance - Non-food determinations."

5. Adding the following at the end of existing Annex 3 for §7-204.11 to address OSHA limits for gases dissolved in solution.

"...The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

"Some SANITIZERS produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. OSHA limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000. Although the amount of dissolved gas in solution may be very low when evenly distributed throughout all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility.

The permit holder using a pesticide device is responsible for being in compliance with 40 CFR 180.940. Because no process for regulatory review of the output of a pesticide device exists, no standard method for checking compliance exists. As such, a potential user of a pesticide device needs to look elsewhere for evidence of compliance. This may include a statement from the device manufacturer, an analysis of the MSDS ingredient statement or a third party chemical analysis of the device output."

6. Update ¶7-204.12 (A) to address on-site generation of chemicals to wash vegetables.
"(A) Chemicals including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. P"

Submitter Information:

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Attachments:

- "Food_Code_Recommendations_for_On-site_Generation_of_Antimicrobials"

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.

Food Code recommendations for on-site generation of antimicrobials
(Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

Table 1 Recommended Food Code modification to address on-site generation of antimicrobial pesticides
[original 2009 Food Code text in plain font; underline is an insertion; strikethrough is a deletion]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
4-204.124 On-Site Devices for Generation of Sanitizing Solutions new section	None	Chapter 4 of the Food Code addresses equipment for use in food establishments, and Part 4-2 specifically addresses the design and construction of such equipment. This section covers the equipment itself, NOT the solutions that the devices generate. It is important to address the equipment in the Food Code because FIFRA regulations require registration of the device manufacturer and not the resulting solution. The solutions are covered in subsequent sections.	<u>4-204.124 On-Site Devices for Generation of Sanitizing Solutions</u> <u>Devices for generation of sanitizing solutions shall meet the characteristics specified under §4-202.11 and</u> (A) <u>Devices for generating pesticides must comply with regulations as established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10.</u> (B) <u>Devices for generating pesticides shall display the manufacturing establishment's registration number.</u>
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness (F) new paragraph	A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows P: ... A-E unaltered	A sanitizer generated on-site should provide the same level of biocidal efficacy as a sanitizer manufactured in a different facility. A manufactured sanitizer must meet EPA testing and performance standards outlined in the Disinfectant – Technical Science Section DIS-TSS 4. Currently, no similar regulatory standard for solutions generated and used on-site exists. Pesticide devices and the sanitizers they produce for application on-site are exempt from registration requirements according to 40 CFR 152.500. At this point the EPA has not mandated registration of solutions produced by a pesticide device unless distributed or sold, but EPA does require that statements of performance, safety and efficacy related to the solution be true. ¶4-501.114 (D) refers to the use of chlorine, quats, or iodine based sanitizers at conditions and concentrations outside those specified in ¶¶ 4-501.114 (A)-(C). ¶4-501.114 (D) permits the use of those biocides if the permit holder demonstrates efficacy. ¶4-501.114 (E) allows the use of biocides other than chlorine, quats, or iodine, when used according to EPA-registered use instructions, which requires demonstration of efficacy by the supplier, which is accomplished by the EPA-registered label. This paragraph is not applicable to solutions generated on-site because there is no EPA-registered label, no efficacy standard and no regulatory oversight for such solutions that are generated and used on-site. New ¶4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and defines an efficacy standard that those solutions can be validated against. Guidance to the field regulatory personnel on how to verify that efficacy is proven is provided in Annex 3 for §4-501.114 (suggested language is below).	*A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows P: ... <u>(F) Any chemical substance produced and used on-site as a food contact surface SANITIZING solution shall have the concentration, temperature, pH and other conditions necessary to meet the definition of SANITIZATION in §1-201.10.</u>

Food Code recommendations for on-site generation of antimicrobials
(Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

[original 2009 Food Code text in plain font; underline is an insertion; strikethrough is a deletion]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
Annex 3 Public Health Reasons/ Administrative Guidelines Chemicals 4-501.114	New paragraphs within that section	The inclusion of ¶ 4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and provides an efficacy standard for those solutions. The field regulatory personnel may require guidance on how to verify that efficacy is met, which is addressed in the added paragraphs.	See below <u>underlined section below</u> .
<p>Annex 3. 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.</p> <p>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 quats) are not included on the label, that the solutions meet the standards required in the Code.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 further 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.</p> <p><u>A variety of sanitizers can be generated on-site, including chlorine, hypochlorous acid (generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), chlorine dioxide, ozone, and others. EPA does not require the registration of pesticidal devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to:</u></p> <ul style="list-style-type: none"> o <u>The name, brand, or trademark under which the product is sold</u> o <u>An ingredient statement</u> o <u>Statements concerning effectiveness of the product</u> o <u>Hazard and precautionary statements for human and domestic animals</u> o <u>Environmental and exposure hazards</u> o <u>The directions for use</u> <p><u>Because there is no EPA registration of solutions generated and used on-site, either the equipment manufacturer or the user of the equipment must generate data to validate the efficacy of the solution the device produces as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site. Section 4-703.11 requires that the conditions of use yields SANITIZATION as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.</u></p>			

Food Code recommendations for on-site generation of antimicrobials
 (Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

[original 2009 Food Code text in plain font; underline is an insertion; strikethrough is a deletion]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
7-204.11 Sanitizer, Criteria	<p>Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall meet the requirements specified in 40 CFR 180.940</p> <p>Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).^P</p>	<p>§7-204.11 addresses the toxicity of solutions used as sanitizers and requires them to comply with the EPA tolerance exemptions outlined in 40 CFR 180.940. Solutions generated on-site should comply with the same tolerance exemptions.</p> <p>The one exception to this is ozone, which is not addressed in 40 CFR 180.940. However, ozone is approved as a secondary food additive in 21 CFR 173.368 so ozone solutions generated on-site comply with the intent of that regulation.</p> <p>Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns. Verification of compliance with 40 CFR 180.940 also requires some clarification. Annex 3 §7-204.11 should address this (suggested language is below).</p>	<p>Chemical SANITIZERS, <u>including those generated on-site</u>, and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall:</p> <p>(A) meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions)^P, <u>or</u></p> <p>(B) <u>be listed in 40 CFR 180.2020 Pesticide chemicals not requiring a tolerance or an exemption from a tolerance - Non-food determinations.</u></p>

Food Code recommendations for on-site generation of antimicrobials
 (Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
<p>Annex 3 – Public Health Reasons/ Administrative Guidelines Chemicals 7-204.11 Sanitizers, Criteria.</p>	<p>7-204.11 Sanitizers, Criteria.</p> <p>See explanation in § 4-501.114</p> <p>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.</p>	<p>Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples of these technologies are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns and Annex 3 § 7-204.11 should address them.</p>	<p>7-204.11 Sanitizers, Criteria.</p> <p>See explanation in § 4-501.114</p> <p>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.</p> <p><u>Some SANITIZERS produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. OSHA limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility.</u></p> <p><u>The permit holder using a pesticide device is responsible for being in compliance with 40 CFR 180.940. Because no process for regulatory review of the output of a pesticide device exists, no standard method for checking compliance exists. As such, a potential user of a pesticide device needs to look elsewhere for evidence of compliance. This may include a statement from the device manufacturer, an analysis of the MSDS ingredient statement or a third party chemical analysis of the device output.</u></p>

Food Code recommendations for on-site generation of antimicrobials
 (Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
<p>7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.</p>	<p>(A) Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. ^P</p> <p>(B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.</p>	<p>§7-204.12 also addresses chemicals used for washing fruits and vegetables and requires them to comply with 21 CFR 173.315. Solutions generated on-site should comply with the same CFR.</p>	<p>(A) Chemicals <u>including those generated on-site</u>, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. ^P</p> <p>(B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.</p>

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 004
Issue: 2010 III-004**

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

All information above the line is for conference use only.

Title:

Report - Sanitizer Committee

Issue you would like the Conference to consider:

At the 2008 Conference for Food Protection, the FDA posed questions related to on-site generators of antimicrobial pesticides. The Sanitizer Committee was formed to address the following charge:

"to work with the FDA, EPA and other stakeholders to develop appropriate language for the Food Code addressing on-site generation of pesticides in food establishments and report back to the 2010 CFP Council III."

The 2008-10 Sanitizer Committee is submitting two issues to the 2010 Conference for Food Protection:

1. Report - Sanitizer Committee
2. On-Site Generation of Antimicrobial Pesticides

The following attachments are also submitted:

1. '2008-10_Sanitizer_Committee_Final_Report'
2. '2008-10_Sanitizer_Committee_Roster'
3. 'Food_Code_Recommendations_for_On-site_Generation_of_Antimicrobials'
(extracted from Committee Report)

Public Health Significance:

Proper use of sanitizers is an important step to prevent cross contamination and food safety failures. On-site generation of sanitizers and other antimicrobials is not addressed in the 2009 Food Code, and the regulatory process and requirements for sanitizers generated and used on-site varies considerably from the regulatory process for manufactured products. Clarification of the Food Code requirements for on-site generated sanitizers is essential to ensure proper use of these materials and to avoid unproductive confusion for inspectors and operators.

Recommended Solution: The Conference recommends...:

acknowledgment of the 2008-10 Sanitizer Committee Report, with thanks to the members of the Sanitizer Committee for completing their task, and disbanding the committee.

Submitter Information:

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Attachments:

- "2008-10_Sanitizer_Committee_Final_Report"
- "2008-10_Sanitizer_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: 2008-10 Sanitizer Committee

COUNCIL (I, II, III): III

DATE OF REPORT: 22 December 2009

SUBMITTED BY: Katherine MJ Swanson & Tressa Madden, Co-Chairs

COMMITTEE CHARGE(S): to work with the FDA, EPA and other stakeholders to develop appropriate language for the Food Code addressing on-site generation of pesticides in food establishments and report back to the 2010 CFP Council III.

The term "pesticides" in the context of this charge was considered by the committee to mean sanitizers and potentially other antimicrobial solutions, but not rodenticides or agricultural pesticides. This is consistent with the name of the committee; i.e., the "Sanitizer" Committee.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Specific Activities

Committee completed the charge through 12 conference calls, a few sub-committee conference calls, and email comments on working drafts. See Appendix 1 for dates and activity on conference calls. The work of the Committee focused on three (3) specific activities:

1. Describing the current federal regulatory requirements for on-site generators of antimicrobial pesticides
2. Addressing unresolved questions related to on-site generators of antimicrobial pesticides
3. Developing specific recommendations for language in the Food Code for on-site generation of antimicrobial solutions.

This report addresses each of these activities.

Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments

Background

- The *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) of 1947 was enacted to regulate the marketing of pesticides and devices, and for other purposes.
- By law, the Environmental Protection Agency (EPA) is authorized to register a pesticide for sale and distribution in the United States only if it will not cause unreasonable adverse effects on human health or the environment when used according to its label.
- FIFRA provides EPA with the authority to oversee the registration, distribution, sale, and use of pesticides. FIFRA applies to all types of pesticides (unless exempt), including but not limited to antimicrobials. The antimicrobial class of pesticides includes disinfectants, sanitizers and other substances that are intended to control microorganisms in or on various surfaces or media. FIFRA requires sellers, distributors and users of registered pesticide products to follow the labeling directions on each product explicitly.
- Under FIFRA, no one may sell or distribute or use a pesticide or an article containing a pesticide, including but not limited to an antimicrobial pesticide, unless it is registered by EPA, or unless it is exempted by the regulations.

On-site Generator Status

- On-site generators of hard surface sanitizers/disinfectants, such as chlorine dioxide, ozone, hypochlorous acid (HOCl, generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), are currently classified by EPA as devices.
- EPA does not currently require the registration of pesticidal devices; however, devices are not exempt from other pesticide requirements under FIFRA particularly with regards to labeling as defined in the Code of Federal Regulations (CFR) 40 CFR 156.10.

FIFRA Requirements

- All on-site generating devices are subject to a number of FIFRA's provisions, including labeling standards and production in registered establishments.
- On-site generators are subject to EPA device labeling requirements. No person may sell or distribute a pesticide device that is misbranded.
- The requirements for device labels are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to, the following:
 - The name, brand, or trademark under which the product is sold
 - An ingredient statement
 - Statements concerning effectiveness of product
 - Hazard and precautionary statements for human and domestic animal hazards
 - Environmental and exposure hazards
 - The directions for use
- This provision of FIFRA is critical because it deals with statements of composition, antimicrobial effectiveness and safety of a pesticide or device.
 - Because there has been no requirement for device registration, what we see in the marketplace tends to be self certification of the performance, safety and efficacy of pesticide devices.
 - Third party data is presently acceptable to demonstrate due diligence in making pesticide claims on on-site generated and applied sanitizers. A certified lab is not required, and EPA fees are not assessed for each claim made.
 - EPA expects a device manufacturer to be able to substantiate claims. A device making a sanitizer claim is expected to meet the same performance standard using the same testing methodology as that of a registered pesticide product making a sanitizer claim.
- On-site generators may also be subject to state regulation. Each state can have its own statutes and regulations concerning pesticide and pest control device registration and regulation.

2009 Food Code Recommendations

- On-site generators of antimicrobial solutions are not specifically mentioned in the Food Code under Equipment or other provisions.
- Equipment must meet the recommendations of Food Code Parts 4-1 "Materials for Construction and Repair" and 4-2 "Design and Construction". According to § 4-205.10, equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program are deemed to comply with Parts 4-1 and 4-2 of this chapter. As an example, an NSF Certification process includes:
 - Physical evaluations of design and construction, material evaluation and performance testing (when required).

- Material requirements, including specifications that all materials that have contact, or potential contact, with food must not contribute contaminants of toxicological significance to the food.
- Performance testing to verify that equipment conforms to all performance requirements of the standard. Note – Many products are certified to NSF Standard 169 for Special Purpose Food Equipment and Devices. This standard includes requirements for design, construction and materials but not efficacy of microbial claims.
- Equipment must meet the recommendations of § 4-402.11 “Fixed Equipment, Spacing or Sealing”.

Resolution of 2008 Questions on On-site Generators of Antimicrobial Pesticides

At the 2008 Biennial Meeting of the Conference for Food Protection, the FDA posed questions related to on-site generators of antimicrobial pesticides. The Sanitizer Committee was formed, in part, to address these questions. The following questions (in ***bold and italics***) were posed to the committee. The Sanitizer Committee answered the questions in a general manner, rather than focusing on specific generators. This will hopefully allow for introduction of new antimicrobials in the future, as long as they meet the general requirements.

1. Does the chemical produced comply with §7-204.11 “Sanitizers, Criteria,” which states that the sanitizer shall meet the requirements of 40 CFR §180.940?

- Of the on-site generated chemistries that the Committee considered (e.g., chlorine dioxide, hypochlorous acid, sodium hypochlorite, ozone), only chlorine dioxide, hypochlorous acid, hydrogen peroxide, and sodium hypochlorite are listed in 40 CFR 180.940 “Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).” Ozone is not listed in 40 CFR 180.940, but it is approved under 21 CFR 173.368 as a secondary food additive. The 2009 Food Code also includes a new approved use of ozone in §7-204.12 as follows: “Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.”
- In the opinion of the majority of the Committee based on science, it seems reasonable that ozone and other secondary food additives should be allowed for sanitization of a food contact surface, if efficacy can be demonstrated and levels used are below those listed for secondary food additives.
- EPA’s position is that any chemical used on a food contact surface for sanitization purposes must be listed in 40 CFR 180.940 unless data are submitted showing there is no residue. If there is no residue, EPA would likely list the ingredient in 40 CFR 180.2020. Ozone is not listed in either reference. EPA procedures exist to add other sanitizers to the list if providers chose to do so, although this may not be a rapid process.

2. Does the unit comply with the requirements of FIFRA as implemented in 40 CFR §152.500?

- 40 CFR 152.500 addresses EPA requirements for pesticide devices, but no list of “approved” sanitizer generating devices currently exists. Further, the regulation does not specifically indicate whether an ozone, chlorine dioxide or electrolytic chlorine generator, as a class, falls under this regulation. Rather, the regulation specifies the requirements that a manufacturer must meet for an on-site generating device to comply with the regulation. The committee cannot determine if any or all on-site generators would meet this regulation. Compliance with the regulation falls to the specific pesticide device and the device manufacturer.

- The manufacturer of the generator should provide documentation that the device complies with 40 CFR 152.500 and the manufacturing establishment's registration number should be on the device. Compliance with 40 CFR 152.500 goes beyond labeling of the device with an EPA establishment number. The device must also comply in regard to how it is "labeled and marketed." Language regarding labeling and marketing for both pesticides and devices in 40 CFR 156.10 reads as follows:

"5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

"(i) A false or misleading statement concerning the composition of the product;

"(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

"(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

"(iv) A false or misleading comparison with other pesticides or devices;

"(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;"

- Other provisions related to claims as to the safety of the pesticide or its ingredients are addressed in 40 CFR 156(a)(5)(ix). For example, "including statements such as 'safe', 'nonpoisonous,' 'noninjurious,' 'harmless' or 'nontoxic to humans and pets' with or without such a qualifying phrase as 'when used as directed' " may also be considered false or misleading.
- No regulatory body oversees testing that a device is in compliance with its labeling, therefore a user of an on-site generator or an inspector must rely on the manufacturer to self affirm that the device complies with the regulation when used according to the manufacturer's instructions. Compliance would involve validation that the output of a device is effective for its claimed uses and verification that the output of the device is within the required concentration, pH, oxidation reduction potential (ORP), or other parameters required to be effective at the point of use.

3. ***Are there occupational exposure concerns that make the unit unsuitable for a retail/foodservice setting?***

Depending upon the on-site generator being considered, there may or may not be occupational exposure concerns for a unit. The Committee believes that addressing this question in detail is outside of the scope of the original charge; i.e., "to develop appropriate language for the Food Code addressing on-site generation of pesticides in food establishments." Historically, the Food Code has not been a vehicle to address occupational safety issues; rather it provides guidance to address food safety issues. For example, slicers have occupational safety issues, which are not reviewed in great depth in the Food Code. Should FDA wish to address occupational safety issues, OSHA limitations such as those in 29 CFR 1910.1000 could be referenced. Manufactures should include information based on

occupational issues and include appropriate sensors, timers, or shut off devices, as appropriate, to protect workers.

4. *Are there operational and user training issues, such as ability to adjust and maintain proper output concentrations that make it unsuitable for retail/foodservice?*

The Committee cannot answer this question for all potential devices available now or in the future, as the level of operational and training issues will vary. In general, the equipment must be installed properly, with sufficient capacity to produce the volume of sanitizer required. This will vary by location and use requirements. Food workers must know how to use the equipment properly, how to verify that the output is at the proper concentrations, and how to maintain the equipment. This is similar to other devices that may be used in a foodservice or retail establishment.

An example of information that is provided on certain devices is the following UL 979 disclaimer for "Water Treatment Appliances":

"This category covers water treatment equipment employing ozone generation, investigated with respect to mechanical, electric shock, and fire hazards only. Maximum ozone threshold limit recommendations are set by the American Conference of Governmental Industrial Hygienists as found in 21 CFR 801.415 "Maximum Acceptable Level of Ozone." Compliance with the applicable regulations under conditions of normal and abnormal operation has not been investigated. The methods for controlling ozone release or the effectiveness of the water treatment have not been investigated."

- Visible onboard indicator of in-spec operation. Many ozone generators are adjustment free. When activated, they simply turn the supply of ozonated water on or off. Detailed installation and operating instructions should be concise and appropriate for the target audience.
- Emergency shut-off is recommended.

Both ozone and chlorine dioxide generators produce a gas dissolved in water, and the level present in the water is impacted by temperature of the water and mechanical agitation. Therefore, the concentration and potential efficacy of a solution of ozone or chlorine dioxide can change depending on how the solution is used. For example, a solution containing 5 ppm active ozone or chlorine dioxide in a spray bottle may have less than 1 ppm when that solution is sprayed onto a surface. A solution of ozone or chlorine dioxide made in 35°C water will have a lower active concentration than the same solution generated in 25°C water because of the potential for off-gassing. This phenomenon impacts both the safety and efficacy of the solution. Because of the potential for diffusion of the gas out of water, the concentration of the active ingredient is most accurately verified on the surface being sanitized, rather than in the stock solution prior to application (e.g., spraying the solution on a test strip rather than dipping the strip into the solution). This is unique to a gas dissolved in water because chemical solutions are not subject to the same type of activity loss through spraying. Users need to be trained on this to ensure proper operation.

The chemistries produced by an on-site generator can be tested for microbial efficacy under the same Association of Official Analytical Chemists (AOAC) standard used by the EPA for sanitizer registration. There is need for training of inspectors and users to understand how to determine if the solution generated has antimicrobial efficacy consistent with these standards. Unlike EPA-registered sanitizers, there is no list or registration number that the user or inspector can use to make this determination.

Because pesticidal devices are exempt from registration, EPA cannot require that efficacy data be submitted and will not approve a label for these devices for the same reason. The Committee suggests that data be developed under Good Laboratory Practices (GLP) using accepted AOAC methods specific to the active species produced by the given pesticide device.

Under proper concentration, contact time, temperature and pH, these chemistries can be effective sanitizers for food contact surfaces. There is need to validate and verify that the output of one of these systems can meet the definition of sanitization defined in §1.201 of the Food Code. No standard process exists to achieve this; however, it may be possible to require manufacturers to provide information on how they demonstrated effectiveness if they market the product for the purpose of generating a sanitizing solution.

Test strips as well as colorimetric and titrimetric methods exist for ozone, chlorine dioxide and HOCl/NaOCl, therefore the concentration can be verified on-site for any of these technologies. These should be used operationally to verify that the proper concentration is used and training is needed to ensure that the test methodology is used correctly.

Environmental monitors exist for ozone and chlorine dioxide that could provide background surveillance of the environment. Currently these devices may be prohibitively expensive and thus may not be practical in a food service or retail setting. Monitoring devices may not be necessary if it can be shown that the device cannot produce an output level considered by OSHA to be hazardous.

Other operational considerations include:

- Chlorine dioxide and ozone are minimally impacted by pH and hardness.
- The efficacy of HOCl/NaOCl is impacted by pH in a manner that is consistent with pH and temperature already identified in the Food Code, but it is minimally impacted by water hardness.
- In cases of water treatment, all of these oxidizers should be dosed at a concentration that overcomes the organic demand, leaving some residual active to provide kill. It is reasonable to think the same approach could be used for hard surface sanitization.
- An additional issue exists around controlling the concentration of ozone and chlorine dioxide in variable water conditions (temperature and agitation). This should be addressed by the manufacturer's instructions.

For the technologies considered, the potential for corrosion appears to be minimal under anticipated use conditions. For ozone and chlorine dioxide, the levels of active ingredient that would be required to achieve sanitization are in the single to tens of ppm levels. Further, ozone and chlorine dioxide disperse into the air as a water solution dries on a surface, making corrosion potential at typical use dilution levels minimal. However, in a closed space, chlorine dioxide has been known to cause corrosion on the top of a stainless steel container. With HOCl/NaOCl there is a breadth of historical experience of compatibility over the slightly alkaline pH ranges typically seen with commercial chlorine bleach (pH 8-10 in use dilution). An on-site generated solution with an equivalent pH and available chlorine content would likely have a similar performance profile. Acidic solutions of HOCl/NaOCl in the pH range of 2-4 could be more problematic over extended periods of time because of the high potential for chloride ion pitting on stainless steel under low pH high

chloride conditions. Any surface that is incompatible with bleach would also be incompatible with a generated solution of HOCl/NaOCl. The manufacturer's information should provide guidance on material compatibility for the product to assist with proper training and operation.

5. *Has the device been accepted for use in other non-retail applications? By whom?*

As previously mentioned, on-site generation of ozone, chlorine dioxide and HOCl/NaOCl are being used industrially for water treatment, bleaching, waste water recovery, and poultry washing. Ozone, chlorine dioxide and HOCl/NaOCl have also been used for laundry applications. Additionally, on-site generated HOCl/NaOCl and chlorine dioxide are used as high level disinfectants to decontaminate medical devices such as heat flexible endoscopes. On-site generators are used in dental applications to decontaminate dental unit waterlines, sanitize/disinfect dental office surfaces and as endodontic cleansers. HOCl/NaOCl on-site generators are used to treat acute and chronic wounds. On-site generators of chlorine dioxide and HOCl/NaOCl are used in agricultural applications to generate disinfecting agents. Furthermore, HOCl/NaOCl on-site generators have been approved by FDA as high level disinfectants, as a wound care irrigants and also as endodontic cleansers. There may be other applications.

6. *Does the manufacturer, the device and/or the sanitizer produced need to be EPA registered?*

There are FIFRA requirements that apply to the manufacturers of pesticidal devices. Also, the need for sanitizer registration depends on the nature of the sanitizer produced, by whom it is applied and whether there is intent to package/sell/distribute it.

Refer to the previous section on 'Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments.'

Recommended Food Code Language for On-site Generation of Antimicrobial Solutions

Based on the Committee's deliberations and the specific charge to identify language related to on-site generation of antimicrobial pesticides, the Committee identified several sections of the Food Code where on-site generators should be addressed. These are discussed in Table 1, which includes rationale for the change and specific language recommendations.

Specific Recommendations:

1. *Consider the recommended language in Table 1, including:*
 - a. Adding §4-204.124 to address equipment requirements for on-site generators
 - b. Adding ¶4-501.114 (F) to address the sanitizing solutions generated on-site
 - c. Updating Annex 3 for §4-501.114 to address FIFRA requirements for on-site generators
 - d. Adding ¶7-204.11 (B) to address pesticides that may not required a tolerance
 - e. Updating Annex 3 for §7-204.11 to address OSHA limits for gases dissolved in solution
 - f. Update §7-204.12 to address on-site generation of chemicals to wash vegetables.
2. *The Committee requests that the Sanitizer Committee be disbanded and note that the assigned charges are completed.*

REQUESTED ACTION:

The 2008-10 Sanitizer Committee is submitting two issues to the 2010 Biennial Meeting of the Conference for Food Protection:

1. **Report – Sanitizer Committee**
2. **On-Site Generation of Antimicrobial Pesticides**

The following attachments are also submitted:

1. '2008-10 Sanitizer Committee Final Report'
2. '2008-10 Sanitizer Committee Roster'
3. 'Food Code recommendations for on-site generation of antimicrobials' (extracted from Committee Report)

COMMITTEE MEMBER ROSTER

An abbreviated list of committee members follows, and a detailed list with contact information is attached. The Co-Chairs wish to thank these active committee members for their expertise and dedication to understanding this complex issue.

Name	Employer	City	State
Brania, Jonathan	Underwriters Laboratories, Inc.	Research Triangle Park	NC
Brickey, Matthew	National Restaurant Association	Washington	DC
Edwards, Dennis	Environmental Protection Agency	Washington	DC
Gordon, Christopher	Virginia Health Department	Richmond	VA
Grinstead, Dale	Johnson Diversey	Sturtevant	WI
Harris, Tanya	Tulsa Health Department	Tulsa	OK
Hepp, Mark	FDA Center for Food Safety & Applied Nutrition	College Park	MD
Herd, Brandon	Ecolab	Eagan	MN
Hipp, Joel	Hobart Corp.	Troy	OH
Johnson, Thomas	Johnson Diversified Products, Inc.	Mendota Heights	MN
Kundurur, Mahipal	Safeway, Inc.	Pleasanton	CA
Lhotka, Lorinda	Alaska Dept. Environ. Conservation Food & Sanitation	Fairbanks	AK
Madden, Tressa (Co-Chair)	Oklahoma State Dept. of Health	Oklahoma City	OK
McMahan, Thomas	SuperValu, Inc.	Boise	ID
Moore, Veronica	FDA Center for Food Safety & Applied Nutrition	College Park	MD
Sampson, Mark	PuriCore	Malvern	PA
Schwarz, Thomas	International Flight Services Association	Burke	VA
Swanson, Katherine (Co-Chair)	Ecolab	Eagan	MN

The Sanitizer Committee thanks the Conference for Food Protection for the opportunity to explore this topic and hopes that the work of our Committee will benefit CFP and public health at large by harmonizing the language and clarifying jurisdictional authority for sanitizer use in retail and food service settings.

Respectfully submitted by,

Katherine MJ Swanson and Tressa Madden, Co-Chairs for the 2008-10 CFP Sanitizer Committee

Table 1 Recommended Food Code modification to address on-site generation of antimicrobial pesticides
 [original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
<p>4-204.124 On-Site Devices for Generation of Sanitizing Solutions</p> <p>new section</p>	<p>None</p>	<p>Chapter 4 of the Food Code addresses equipment for use in food establishments, and Part 4-2 specifically addresses the design and construction of such equipment. This section covers the equipment itself, NOT the solutions that the devices generate. It is important to address the equipment in the Food Code because FIFRA regulations require registration of the device manufacturer and not the resulting solution. The solutions are covered in subsequent sections.</p>	<p><u>4-204.124 On-Site Devices for Generation of Sanitizing Solutions</u></p> <p><u>Devices for generation of sanitizing solutions shall meet the characteristics specified under §4-202.11 and</u></p> <p>(A) <u>Devices for generating pesticides must comply with regulations as established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10.</u></p> <p>(B) <u>Devices for generating pesticides shall display the manufacturing establishment's registration number.</u></p>
<p>4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness (F)</p> <p>new paragraph</p>	<p>A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows ^P:</p> <p>...</p> <p>A-E unaltered</p>	<p>A sanitizer generated on-site should provide the same level of biocidal efficacy as a sanitizer manufactured in a different facility. A manufactured sanitizer must meet EPA testing and performance standards outlined in the Disinfectant – Technical Science Section DIS-TSS 4. Currently, no similar regulatory standard for solutions generated and used on-site exists. Pesticide devices and the sanitizers they produce for application on-site are exempt from registration requirements according to 40 CFR 152.500. At this point the EPA has not mandated registration of solutions produced by a pesticide device unless distributed or sold, but EPA does require that statements of performance, safety and efficacy related to the solution be true.</p> <p>¶4-501.114 (D) refers to the use of chlorine, quats, or iodine based sanitizers at conditions and concentrations outside those specified in ¶¶ 4-501.114 (A)-(C). ¶4-501.114 (D) permits the use of those biocides if the permit holder demonstrates efficacy.</p> <p>¶4-501.114 (E) allows the use of biocides other than chlorine, quats, or iodine, when used according to EPA-registered use instructions, which requires demonstration of efficacy by the supplier, which is accomplished by the EPA-registered label. This paragraph is not applicable to solutions generated on-site because there is no EPA-registered label, no efficacy standard and no regulatory oversight for such solutions that are generated and used on-site.</p> <p>New ¶4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and defines an efficacy standard that those solutions can be validated against. Guidance to the field regulatory personnel on how to verify that efficacy is proven is provided in Annex 3 for §4-501.114 (suggested language is below).</p>	<p>*A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows ^P:</p> <p>...</p> <p><u>(F) Any chemical substance produced and used on-site as a food contact surface SANITIZING solution shall have the concentration, temperature, pH and other conditions necessary to meet the definition of SANITIZATION in §1-201.10.</u></p>

2008-2010 Sanitizer Committee Final Report

[original 2009 Food Code text in plain font; underline is an insertion; strikethrough is a deletion]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
Annex 3 Public Health Reasons/ Administrative Guidelines Chemicals 4-501.114	New paragraphs within that section	The inclusion of ¶ 4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and provides an efficacy standard for those solutions. The field regulatory personnel may require guidance on how to verify that efficacy is met, which is addressed in the added paragraphs.	See below <u>underlined section below</u> .
<p>Annex 3. 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.</p> <p>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 quats) are not included on the label, that the solutions meet the standards required in the Code.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 further 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.</p> <p><u>A variety of sanitizers can be generated on-site, including chlorine, hypochlorous acid (generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), chlorine dioxide, ozone, and others. EPA does not require the registration of pesticidal devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to:</u></p> <ul style="list-style-type: none"> o <u>The name, brand, or trademark under which the product is sold</u> o <u>An ingredient statement</u> o <u>Statements concerning effectiveness of the product</u> o <u>Hazard and precautionary statements for human and domestic animals</u> o <u>Environmental and exposure hazards</u> o <u>The directions for use</u> <p><u>Because there is no EPA registration of solutions generated and used on-site, either the equipment manufacturer or the user of the equipment must generate data to validate the efficacy of the solution the device produces as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site. Section 4-703.11 requires that the conditions of use yields SANITIZATION as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.</u></p>			

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Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
7-204.11 Sanitizer, Criteria	<p>Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall meet the requirements specified in 40 CFR 180.940</p> <p>Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).^P</p>	<p>§7-204.11 addresses the toxicity of solutions used as sanitizers and requires them to comply with the EPA tolerance exemptions outlined in 40 CFR 180.940. Solutions generated on-site should comply with the same tolerance exemptions.</p> <p>The one exception to this is ozone, which is not addressed in 40 CFR 180.940. However, ozone is approved as a secondary food additive in 21 CFR 173.368 so ozone solutions generated on-site comply with the intent of that regulation.</p> <p>Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns. Verification of compliance with 40 CFR 180.940 also requires some clarification. Annex 3 §7-204.11 should address this (suggested language is below).</p>	<p>Chemical SANITIZERS, <u>including those generated on-site</u>, and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall:</p> <p>(A) meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions)^P, <u>or</u></p> <p>(B) <u>be listed in 40 CFR 180.2020 Pesticide chemicals not requiring a tolerance or an exemption from a tolerance - Non-food determinations.</u></p>

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[original 2009 Food Code text in plain font; underline is an insertion; strikethrough is a deletion]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
<p>Annex 3 – Public Health Reasons/ Administrative Guidelines Chemicals 7-204.11 Sanitizers, Criteria.</p>	<p>7-204.11 Sanitizers, Criteria.</p> <p>See explanation in § 4-501.114</p> <p>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.</p>	<p>Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples of these technologies are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns and Annex 3 § 7-204.11 should address them.</p>	<p>7-204.11 Sanitizers, Criteria.</p> <p>See explanation in § 4-501.114</p> <p>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.</p> <p><u>Some SANITIZERS produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. OSHA limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility.</u></p> <p><u>The permit holder using a pesticide device is responsible for being in compliance with 40 CFR 180.940. Because no process for regulatory review of the output of a pesticide device exists, no standard method for checking compliance exists. As such, a potential user of a pesticide device needs to look elsewhere for evidence of compliance. This may include a statement from the device manufacturer, an analysis of the MSDS ingredient statement or a third party chemical analysis of the device output.</u></p>

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Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
<p>7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.</p>	<p>(A) Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. ^P</p> <p>(B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.</p>	<p>§7-204.12 also addresses chemicals used for washing fruits and vegetables and requires them to comply with 21 CFR 173.315. Solutions generated on-site should comply with the same CFR.</p>	<p>(A) Chemicals <u>including those generated on-site</u>, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. ^P</p> <p>(B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.</p>

Appendix 1. Conference Call Dates and Accomplishments

1. December 8, 2008 – Reviewed FDA questions and identified electrolyzed water, ozone, and chlorine dioxide as the primary on-site generated antimicrobials to consider. Broke into sub-groups to address technologies.
2. January 28, 2009 – A draft of the “regulatory status” of on-site generators was introduced to provide the committee with background on the regulatory framework involved with these devices. This was the starting point for the “Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments” section of this report.
3. March 6, 2009 – Chlorine dioxide was removed from the list of antimicrobials because no one was aware of commercial applications for retail and food service. Examples of labeling for on-site generated sanitizers were provided.
4. April 17, 2009 – Continued to refine the “regulatory status” draft, limited work progressed on individual technologies; group formed to identify areas of the Food Code with language to be addressed.
5. June 1, 2009 – “Regulatory status” draft discussed, but lack of quorum prevented finalization.
6. June 27, 2009 – “Regulatory status” draft finalized after moving 6 former members to “inactive” status. This allowed the committee to achieve quorum.
7. July 31, 2009 – Began review of citations in the Food Code that could be addressed related to on-site generation of sanitizers. The complexity of the issue stimulated a request to review the initial questions of FDA. Co-chairs reviewed alternative to proceed. The charge specifically directed the committee to develop language for the Food Code, but the questions deal with general terms that may or may not be relevant to Food Code language.
8. September 25, 2009 – Draft answers to FDA’s questions were provided to the committee for discussion and comment. A sub-committee was appointed to further refine the answers to FDA’s questions.
9. October 19, 2009 – The sub-committee focused on potential language for recommended changes to Food Code language rather than addressing FDA’s questions. This work addressed the specific charge to the committee, but did not address original questions posed at the 2008 CFP related to on-site generated sanitizers. A work group was formed to draft a final report that addressed:
 - a. Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments (based on the “regulatory status” draft finalized June 27 by the committee),
 - b. Resolution of 2008 Questions on On-site Generators of Antimicrobial Pesticides (to address FDA concerns) and
 - c. Recommended Food Code Language for On-site Generation of Antimicrobial Solutions (to address the Committee charge).
10. November 12, 2009 – Draft final report discussed up to citation recommendations
11. November 17, 2009 – Draft final report discussed – Draft 3 of final report
12. November 23, 2009 – Draft final report discussed – Draft 4 of final report – consensus reached

Committee Name:

Council III
Sanitizer

30-Nov-09

Last Name	First Name	Position (Chair/ Member)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
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Schwarz	Thomas	member	Industry - food service	International Flight Services Association	5700 Waters Edge Landing Court	Burke	VA	22015	703-250-5445	TLS4HACCP@aol.com
Kunduru	Mahipal	member	Industry - retail food stores	Safeway, Inc.	5918 Stoneridge Mall Roadc	Pleasanton	CA	94588	925-226-9393	mahipal.kunduru@safeway.com
McMahan	Thomas	member	Industry - retail food stores	SuperValu, Inc.	250 E. Parkcenter Blvd.	Boise	ID	83706	208-395-3265	Thomas.A.McMahan@supervalu.com
Grinstead	Dale	member	Other - sanitation services	Johnson Diversey	8310 16th Street	Sturtevant	WI	53177	262-631-4433	dale.grinstead@johnsondiversey.com
Herd	Brandon	member	Other - sanitation services	Ecolab, Inc.	655 Lone Oak Drive	Eagan	MN	55121	651-795-5828	brandon.herd@ecolab.com
Johnson	Thomas	member	Other - sanitation services	Johnson Diversified Products, Inc.	1408 Northland Drive, #407	Mendota Heights	MN	55120	651-587-0418	tomj@jdpinc.com
Sampson	Mark	member	Other - sanitation services	PuriCore	508 Lapp Road	Malvern	PA	19355	484-321-2719	msampson@puricore.com
Swanson	Katherine	Co chair	Other - sanitation services	Ecolab, Inc.	655 Lone Oak Drive	Eagan	MN	55121	651-975-5943	katie.swanson@ecolab.com
Brania	Jonathan	member	Other -services	Underwriters Laboratories, Inc.	12 Laboratory Drive	Research Triangle Park	NC	27709	919-549-1768	jonathan.brania@us.ul.com
Edwards	Dennis	member	Regulatory - federal	Environmental Protection Agency	7510C Ariel Rios Building, Pennsylvania Ave NW	1200 Washington	DC	20460	703-308-8087	edwards.dennis@epamail.epa.gov
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Moore	Veronica	member	Regulatory - federal	FDA/CFSAN	5100 Paint Branch Parkway	College Park	MD	20740	301-436-1409	Veronica.moore@fda.hhs.gov
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Madden	Tressa	Co chair	Regulatory - state	Oklahoma State Dept. of Health	1000 NE 10th	Oklahoma City	OK	73117	405-271-5243	tressam@health.ok.gov

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 014
Issue: 2010 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 - Blade Tenderization Committee

Issue you would like the Conference to consider:

Acknowledgement of the Blade Tenderization Committee final report.

Public Health Significance:

The Blade Tenderization Committee was charged with reviewing the guidance document "Guidelines on Injected and Mechanically Tenderized Beef Steak for Retail and Food Service Establishments" submitted to Council III at the 2008 CFP Biannual Meeting and making a revised document that would be reported back to CFP at the 2010 Biannual Meeting. The Committee:

- a. Provided peer review of the "Guidelines on Blade Tenderized Beef for Restaurants and Retail Food Establishments" submitted at the 2006 and 2008 meetings,
- b. Recommended changes to improve the document and possible changes to the Food Code, and
- c. Considered recent scientific research and any new data of contamination by *Escherichia coli* O157:H7 and the impact on this by various processes including injected and mechanically tenderized beef steaks.

Recommended Solution: The Conference recommends...:

acknowledgement of the Final Committee Report from the Blade Tenderization Committee, with thanks to the committee for completing their work and disbanding the committee.

Submitter Information:

Name: Robert G Reinhard, Co-Chair
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Attachments:

- "Blade Tenderization Committee Report"

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

COMMITTEE NAME: Blade Tenderization Committee

COUNCIL: III

DATE OF REPORT: December 4, 2009

SUBMITTED BY: Robert G. Reinhard

COMMITTEE CHARGE:

1. The Blade Tenderization Committee guidance document “Guidelines on Injected and Mechanically Tenderized Beef Steak for Retail and Food Service Establishments” submitted to Council III at the 2008 CFP Biennial Meeting should be reviewed with comments and a revised document be reported back to CFP at the 2010 meeting. The Committee should:
 - a. Provided peer review of the “Guidelines on Blade Tenderized Beef for Restaurants and Retail Food Establishments” submitted at the 2006 and 2008 Biennial Meetings,
 - b. Recommend changes to improve the document and possible changes to the Code, and
 - c. Considered recent scientific research and any new data of contamination by *Escherichia coli* O157:H7 and the impact on this by various processes including injected and mechanically tenderized beef steaks.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The Committee is submitting two issues to the 2010 CFP Biennial Meeting: 1) modified peer-reviewed guidance document, “Guidelines for Injected and Mechanically Tenderized Beef Steak for Retail and Food Service Establishments” (re-titled “Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments”), and 2) Final Report of the Blade Tenderization Committee. With the submission of the issues, the work of the committee is finished.

The committee met on nine separate occasions from April to November 2009 and attendance at each of the meetings ranged from five to fifteen members. In addition, on one occasion, seven members from the committee with two members from the Food and Drug Administration on a conference line met in person in Washington D.C. with the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS). The purpose of this face-to-face meeting with FSIS was to discuss the committee’s activities, numerous issues on the labeling of raw blade tenderized beef and the requirements for controlling the hazard and the most recent activities FSIS has initiated in federally inspected meat establishments that produce raw blade tenderized and injected beef.

In each of the meetings the committee discussed the Guidance document we were charged to review, recent scientific research and any new data of contamination by *Escherichia coli* O157:H7 and the impact on this by various processes including injected and mechanically tenderized beef steaks and/or made draft edits on the guidance

document. The committee recognized that other pathogens could have the same impact on the safety of non-intact beef but limited the discussion to *E. coli* O157:H7 since the outbreaks to date have been associated with *E. coli* O157:H7 and the controls for *E. coli* O157:H7 would also control other pathogens. The committee discussions and comments were generally focused on the various guidance document drafts; review and inclusion of the foodborne illness information in the guidance document as found in the original report; the type of tenderization, mechanically or injection, involved in each reported outbreak; the extent retail and food service establishments tenderize beef at their locations; the use of the consumer advisory in food service establishments; if the hazard is significant given recent research on translocation during blade tenderization and cooking/inactivation of the organism; and, whether the guidance document should address labeling, especially labeling that is not a regulatory requirement.

The committee reached a consensus that the guidelines would help retail and food service establishments limit and control contamination by *E. coli* O157:H7 in tenderized and injected beef. There was one committee member who suggested that the guidance document may no longer be needed since the recommendations have now been incorporated into the 2009 Food Code. However, the committee members agreed by consensus that the guidance document would provide useful information to retail and food service establishments that are specifically seeking information on producing and cooking mechanically tenderized or injected beef.

REQUESTED ACTION:

The Committee is submitting two Issues for consideration:

1. Requesting acknowledgement of the Committee report (see attachment titled: “Blade Tenderization Committee Report”)
2. The Committee requests Council III acceptance of the new revised guidance document: “Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments” with a request that the guidance document be made available to interested stakeholders on CFP’s web site or as an addendum to the Food Code. (see attachment titled: “Guidelines for Producing or Cooking Mechanically Tenderized Beef...”)

COMMITTEE MEMBER ROSTER:

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 015
Issue: 2010 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:

Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail

Issue you would like the Conference to consider:

The Blade Tenderization Committee submits up-dated "Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments".

Public Health Significance:

The submitted guidelines are intended to control contamination by *Escherichia coli* (*E. coli*) O157:H7 and other pathogenic Shiga-toxin producing *E. coli* [STEC] *E. coli* and *Salmonella* species during the production, handling, or preparation of mechanically tenderized or injected beef at food service establishments and retail food stores. Since control procedures for *E. coli* O157:H7, and other pathogenic *E. coli* also control *Salmonella* and other microbiological pathogens, these recommended guidelines will refer specifically to the control of *E. coli* O157:H7 but will be inclusive of these additional foodborne pathogens. *E. coli* O157:H7 is a significant public health concern in raw ground beef and the meat industry has implemented a variety of procedures to control this hazard. However, several recent *E. coli* O157:H7 outbreaks and resulting recalls linked to non-intact tenderized beef have raised concern about the safety of these products. The relatively recent recalls and outbreaks of non-intact tenderized beef products have also caused great interest in: 1) determining the potential risk these products pose to public health; and 2) the development of food safety preventive measures to control such risks during the production and preparation of non-intact beef products.

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 .
Additionally, the Conference recommends that a letter be sent to the FDA requesting that this guidance document be made available as an addendum to the Food Code.

Submitter Information:

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Attachments:

- "Guidelines for Producing or Cooking Mechanically Tenderized 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.

1 **Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and**
2 **Food Service Establishments**

3 **The following guidelines are intended to control contamination by**
4***Escherichia coli* (*E. coli*) O157:H7 and other pathogenic Shiga-toxin producing *E.***
5***coli* [STEC] *E. coli* and *Salmonella* species during the production, handling, or**
6**preparation of mechanically tenderized or injected beef at food service**
7**establishments and retail food stores. Since control procedures for *E. coli* O157:H7,**
8**and other pathogenic *E. coli* also control *Salmonella* and other microbiological**
9**pathogens, these recommended guidelines will refer specifically to the control of *E.***
10***coli* O157:H7 but will be inclusive of these additional foodborne pathogens.**

11 *E. coli* O157:H7 is a significant public health concern in raw ground beef and the
12meat industry has implemented a variety of procedures to control this hazard. However,
13several recent *E. coli* O157:H7 outbreaks and resulting recalls linked to non-intact
14tenderized beef have raised concern about the safety of these products. The relatively
15recent recalls and outbreaks of non-intact tenderized beef products have also caused great
16interest in: 1) determining the potential risk these products pose to public health; and 2)
17the development of food safety preventive measures to control such risks during the
18production and preparation of non-intact beef products.

19 These guidelines have been developed for limiting contamination by *E. coli*
20O157:H7 during the production, handling, or preparation of mechanically tenderized beef
21(e.g., blade-tenderized beef, pinned beef) and in the production and preparation of
22injected mechanically tenderized beef. Tenderization is the process of treating whole
23muscle tissue by either a mechanical or chemical method to soften the beef tissues,
24primarily to enhance product quality. Mechanical tenderization uses blades, needles, or

25pounding devices (e.g., blade-tenderized beef, pinned beef) to soften the beef tissue.
26Other forms of tenderization use chemicals or enzymes and a mechanical processing step
27(e.g. scoring of the muscle and tumbling, needle tenderization).

28 Blade tenderized and other mechanically tenderized beef is a significant portion
29of the beef supplied to and used by the restaurant and food service industry. In 1975, it
30was estimated that over 90% of hotel, restaurant, and institutional (HRI) operations
31utilized blade tenderization (10) and in a 2003 survey conducted on behalf of the National
32Cattlemen’s Beef Association, 94% of manufactures indicated they used mechanical
33tenderization to improve product quality (13).

34 Regardless of why blade tenderization is utilized, mechanically tenderized beef is
35not required to be labeled by either the USDA’s Food Safety and Inspection Service or
36the Food and Drug Administration. While labeling may be seen as a value to inform a
37small proportion of consumers, labeling has never been documented as an effective way
38to appreciably affect consumer behavior broadly when it comes to cooking. All
39mechanically tenderized beef products, like all raw beef, must be labeled with “safe
40handling” instructions for consumers. Producers of beef injected with tenderizers or
41flavoring marinades are required to include the term “(solution or tenderizer) added (or
42injected)” on the principal display panel and to list the added ingredients on the
43ingredient statement of the label.

44 Scientific studies have shown a very low prevalence of *E. coli* O157:H7 on the
45surface of intact beef primals, ranging from 0.083 to 0.2% incidence (1). However,
46research has also demonstrated that when the product is mechanically tenderized, the
47blades or needles used in the mechanical process can transfer microorganisms from the

48 surface of the beef to the interior (6, 7, 8, 10, 13). At high surface inoculation levels for
49 *E. coli* O157:H7, after one-pass blade tenderization of beef only 3-4% of the initial
50 inoculum was internalized into deeper parts/geometric center of the muscle (10, 13). In
51 addition, in those studies that have quantified the surface inoculate (4 log CFU/g) versus
52 those cells translocated after tenderization, very low levels of *E. coli* O157:H7 were
53 transferred to the geometric center of the product; counts ranging from 0 to 0.83 CFU/g.
54 This research indicates that adequate cooking temperatures targeted for the center of a
55 product would effectively eliminate the levels of *E. coli* O157:H7 expected to be found in
56 mechanically tenderized beef products. However, surface searing of a non-intact steak
57 may not deliver enough lethality heat treatment to pathogens that may be present in the
58 interior of the non-intact steak.

59 Guidelines for the production and handling of tenderized (mechanical or injected)
60 meat at Federally Inspected meat processing facilities already exist. The meat processing
61 guidelines are designed to prevent, eliminate or reduce contamination by *E. coli* O157:H7
62 during the production, handling, and preparation of mechanically tenderized and injected
63 beef. Recognizing that the guidelines for meat processors may not be applicable in retail
64 and food service facilities, this document provides specific guidelines for the production
65 and preparation of mechanically tenderized or injected beef that focus on measures to
66 reduce the risk of contamination. A preventive control-based approach is reasonable
67 given the expected low levels of contamination from *E. coli* O157:H7 in source materials
68 and the current regulatory requirements on product labeling. Best practices should focus
69 on controls that prevent the cross-contamination of source materials or product surfaces
70 and minimize risks through application of an intervention prior to tenderization. In

71 addition, the use of some of these guidelines on the receipt and holding of blade
72 tenderized beef products from a manufacture assures the controls implemented in the
73 production of that product are maintained at the retail or food service establishment.

74 **Guidance for Retail Establishments That Only Repackage Beef For Sale**

75 Since mechanically tenderized beef is not required to be labeled differently from
76 intact beef, the retail establishment may not be able to distinguish mechanically
77 tenderized beef from intact beef cuts. Therefore, retail establishments should use a
78 preventive control approach in the repackaging process and set up purchase specifications
79 with their suppliers.

80 Purchase specifications should require a continuing letter of guarantee from the
81 supplier that:

- 82 1. Assures the beef product they purchase is inspected and passed according to the
83 Meat Inspection Act.
- 84 2. Includes a provision indicating that the product was produced following a food
85 safety preventive control program (e.g. HACCP) in which *E. coli* O157:H7 is
86 identified as a hazard likely to occur and that has a control step to eliminate the
87 hazard or reduce it to an acceptable level.

88 In addition to purchase requirements, the retail establishment should have in place
89 control measures to reduce the risk of cross-contamination with *E. coli* O157:H7 and the
90 proliferation of the organism in the packaging process. These controls include product
91 temperature control, sanitation, and product control.

92

93

- 94 1. Product Temperature Control – To limit proliferation of *E. coli* O157:
- 95 a. Verify temperature of refrigerated beef at delivery is 41°F or less [Food
- 96 Code 3- 202.11(A)]
- 97 b. Control cold holding temperature of product from delivery to sale by
- 98 refrigerating immediately at 41°F or less [Food Code 3-501.16(A)(2)]
- 99 Maintain frozen products prior to processing at a frozen state [Food Code
- 100 3-501.11]. Temper, thaw or slack frozen beef appropriately so product
- 101 does not exceed the minimum growth temperatures for *E. coli* O157:H7
- 102 (less than 44.6 °F). [Food Code 3-501.12]
- 103 c. Maintain temperature control in the processing and storage areas such that
- 104 the product being processed does not exceed the minimum growth
- 105 temperature for *E. coli* O157:H7 (less than 44.6 °F)
- 106 d. Rotate product on first in-first out (FIFO) or first expired first out (FEFO)
- 107 basis as a good retail practice.
- 108 e. Verify temperature of beef in retail case/display is 41°F or less [Food
- 109 Code 3- 202.11(A)].
- 110 2. Sanitation Program – A system for monitoring the completeness and effectiveness
- 111 of the sanitation procedures.
- 112 a. Should be a written document that is designed to ensure sanitary
- 113 conditions both before and during operations
- 114 b. Should describe procedures for employee hygiene or these procedures
- 115 should be described in a separate program [Food Code Chapter 2

116 Management and Personnel; FDA Employee Health and Personal Hygiene
117 Handbook]

118 c. Should include proper cleaning and sanitizing procedures that describe the
119 procedure for equipment breakdown to ensure effective and thorough
120 cleaning and sanitizing [Food Code Chapter 4, Parts 4-6 and 4-7].

121 d. Verify effectiveness of the sanitizing procedures

122 e. Prevent cross-contamination [Food Code Chapter 3, Part 3-3]

123 f. Make the sanitation program available to appropriate employees
124 responsible for managing or implementing these programs

125 g. Train all employees responsible for the sanitation procedures

126 3. Employee Health

127 a. A written employee health policy is recommended to be in place to
128 exclude ill food workers from the establishment. [Food Code Annex 3,
129 Part 2-2 Employee Health]

130 4. Product Traceability

131 a. Code the product and maintain sufficient documentation to allow trace
132 back for a time period to include any potential frozen storage that may
133 occur prior to consumption of the finished product.

134 5. Labeling

135 a. For beef products that are injected, identify any added marinade,
136 antimicrobial ingredient, flavoring or tenderizers in the ingredient
137 statement [Food Code 3-602.11]. Antimicrobial agents approved as

138 processing aides are exempted from labeling requirements (21 CFR §
139 101.100).

140 b. Provide required labeling for safe handling/cooking instructions [Food
141 Code 3-201.11(F)].

142

143 **Guidance for Retail and Food Service Establishments That Tenderize or Inject Beef**

144 Retail and Food Service establishments that mechanically tenderize or inject meat
145 products should apply measures to reduce the risk of contamination with *E. coli* O157:H7
146 and other pathogens during the processing of the product and particularly in the
147 mechanical tenderization or injection step of the process. These preventive controls
148 include, but are not limited to, product temperature control, sanitation, and product
149 traceability, labeling, and interventions. It is recommended that retail and food service
150 operations develop a specific written plan, such as a risk-based or HACCP plan to define
151 their preventive controls. Only employees trained to implement these procedures in
152 accordance with the written plan should be permitted to tenderize or inject beef products.
153 Procedures for tenderizing and injecting meat should include:

154 1. Product and Solution Temperature Controls to limit proliferation of *E. coli* O157:

155 a. Verify temperature of beef at delivery is 41°F or less [Food Code 3-
156 202.11(A)]

157 b. Control cold holding temperature of product from delivery to sale by
158 refrigerating immediately at 41°F or less [Food Code 3-501.16(A)(2)].

159 Maintain frozen products prior to processing at a frozen state. Temper,
160 thaw or slack frozen beef appropriately so product does not exceed the

- 161 minimum growth temperatures for *E. coli* O157:H7 (less than 44.6 °F)
162 [Food Code 3-501.12]
- 163 c. Maintain temperature control in the processing and storage areas such that
164 the product being processed does not exceed the minimum growth
165 temperature for *E. coli* O157:H7 (less than 44.6 °F) [Food Code 3-501.12]
- 166 d. Maintain the time and temperature relationship on all re-used or re-
167 circulated injected fluids or marinade so that they do not allow the
168 outgrowth of *E. coli* O157:H7 [Food Code 3-501.16(A)(2)].
- 169 e. Rotate product on first in-first out (FIFO) or first expired first out (FEFO)
170 basis as a good retail practice.
- 171 f. Verify temperature of beef at in retail case/display is 41°F or less [Food
172 Code 3- 501.16(A)(2)]
- 173 2. Sanitation Program – A system for monitoring the completeness and effectiveness
174 of the sanitation procedures.
- 175 a. Should be a written document that is designed to ensure sanitary
176 conditions both before and during operations.
- 177 b. Should describe procedures for employee hygiene or these procedures
178 should be described in a separate program [Food Code Chapter 2
179 Management and Personnel; FDA Employee Health and Personal Hygiene
180 Handbook].
- 181 c. Should include specific procedures for proper cleaning and sanitizing that
182 include the procedures for equipment breakdown to ensure effective and

183 thorough cleaning and sanitizing [Food Code Chapter 4, Parts 4-6 and 4-
184 7].

185 d. Should include specific procedures for the disassembly, cleaning and
186 sanitizing of the equipment used for the mechanical tenderization or
187 injection process. These procedures are outlined below:

188 i. Cleaning and sanitizing of equipment before operation and during
189 operation, especially reservoirs, and piping associated with
190 mechanical tenderizing/flavoring operations.

191 ii. Cleaning and sanitizing procedures for blades or needles that
192 include frequency of procedures, and methods and chemical
193 concentrations used.

194 e. Verify effectiveness of the sanitizing procedures

195 f. Prevent cross-contamination [Food Code Chapter 3, Part 3-3]

196 g. Make the sanitation program available to appropriate employees
197 responsible for managing or implementing these programs

198 h. Train all employees responsible for the sanitation procedures

199 3. Employee Health

200 a. A written employee health policy is recommended to be in place to
201 exclude ill food workers from the establishment [Food Code Annex 3, Part
202 2-2 Employee Health].

203 4. Product Control

204 a. Code the product and provide sufficient documentation to allow trace back
205 if necessary.

206 b. Develop purchase specifications for the suppliers to ensure that the beef to
207 be tenderized or injected has been tested negative for *E. coli* O157:H7
208 using N=60 sampling methodology.

209 c. Consider the use of approved antimicrobial agents as a surface treatment
210 prior to tenderization/injecting and/or an antimicrobial agent (e.g., lactic
211 acid) in the solution injected into the beef. A list of Safe and Suitable
212 Antimicrobial Agents Used in the Production of Meat and Poultry
213 Products is available from FSIS [FSIS Directive 7120.1;
214 [http://www.fsis.usda.gov/Regulations_&_Policies/7000_Series-](http://www.fsis.usda.gov/Regulations_&_Policies/7000_Series-Processed_Products/index.asp)
215 [Processed_Products/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/7000_Series-Processed_Products/index.asp)

216 5. Labeling

217 a. For beef products that are injected, identify any added marinade,
218 antimicrobial ingredient, flavoring or tenderizers in the ingredient
219 statement. Antimicrobial agents approved as processing aides are
220 exempted from labeling requirements (21 CFR § 101.100).

221 b. Provide required labeling for safe handling/cooking instructions.

222

223 **For Retail or Food Service Establishments That Cook or Thermally-Process**
224 **Mechanically Tenderized or Injected Beef Steaks**

225 Injected and other mechanically tenderized beef products are considered non-
226 intact products. Time and temperatures for cooking non-intact products differ from those
227 for cooking intact products [Food Code 3-401.11(A)(2), (C) and (D)]. Intact steaks may
228 have contamination on the cut surfaces, and therefore cooking both the top and bottom to

229a surface temperature of 63°C (145°F) or above can inactivate pathogens on the surface.
230However, mechanically tenderized or injected steaks could have contamination below the
231surface, where the needles, blades or pins penetrate and therefore need more rigorous
232cooking.

233 The final internal temperature that must be achieved for blade-tenderized steaks,
234comminuted beef and injected beef, which are all considered non-intact, is 155°F (68°C)
235for 15 seconds or other times and temperatures combinations listed in Section 3-
236401.11(A)(2) of the Food Code. When a retail or food service establishment knows that
237meat is non-intact, they should follow these cooking procedures. Those establishments
238that cook these products at a lower internal temperature, e.g., as requested by the
239consumer, must provide a consumer advisory with a disclosure and reminder [Food Code
2403-603.11]. However, this alternative may not be used by food establishments that serve
241highly susceptible populations, such as nursing homes, hospitals, schools or daycare
242facilities [Food Code 3-801.11(C)]. Additionally, the Food Code [3-401.11(D)(2)] does
243not allow under-cooked comminuted meat to be served off a children's menu. A whole-
244muscle, intact steak as identified by labeling or letter of guarantee may be served or
245offered for sale in a ready-to-eat form by cooking to a surface temperature of 145°F
246(63°C) or above and a cooked color change is achieved on all external surfaces[Food
247Code 3-401.11(C)(3)]. It is best to always use a calibrated thermometer to ensure that
248correct temperature is achieved during cooking.

249 This guidance on cooking of mechanically tenderized beef is applicable to beef
250with ingredients added to induce tenderization, such as injected beef [as defined in Food

251Code 1-201.10(B)]. The guidelines provided above for cooking of mechanically
252tenderized beef also apply to injected/tenderized beef.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 016
Issue: 2010 III-025**

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

All information above the line is for conference use only.

Title:

Specialized Processing Methods

Issue you would like the Conference to consider:

Removing section 3-502.11 (variance requirements) from the Retail / Restaurant License. The special processing methods should require a Food Processor License.

Public Health Significance:

The special processing methods require additional initial training as well as continual training for the inspector to maintain the technical proficiency required for these facilities. Many jurisdictions have only a few facilities requiring a variance (1-2 per inspector). The inspector may miss critical violations and spend extra time reviewing the requirements.

Recommended Solution: The Conference recommends...:

that a Committee be established to investigate and recommend specific requirements for specialized processing methods such as brewing beer, wine production, smoking and curing, acidifying foods, and sprouts, and removing these processes from variance requirements as stated in Food Code Section 3-502.11.

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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
2010 Issue Form**

**Internal Number: 017
Issue: 2010 III-002**

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Delegate Action:	Accepted _____	Rejected _____	

All information above the line is for conference use only.

Title:

Allergen Ingredients and Allergen Cross-contamination.

Issue you would like the Conference to consider:

Expand section 3-101.11 to provide greater guidance on food allergens. Also expand section 3-602.11 to reflect the existing labeling requirement to include the common name in plain English of all allergens in the ingredient section.

Public Health Significance:

Six to seven million people in the United States have food allergies. Food allergens cause an estimated 30,000 ER visits with 150-200 deaths yearly.

Recommended Solution: The Conference recommends...:

charging the Allergen Committee with the following:

- to develop recommended Food Code language changes to Section 3-101.11 and 3.602.11 to list possible cross-contamination sources (such as common hot-oil fryers, sanitized surfaces that have not been cleaned, dish machines with food debris, product thermometers, wiping cloth sanitizer solutions, airborne wheat flour, and ingredients such as barley, oats, and rye (which may be cross-contaminated with wheat during harvest and storage)).
- to work with the FDA to finalize a definition for "gluten-free" and provide clarification for facilities that identify an allergen-free food and any necessary verification to their nutritional claims.
- to report back to the 2012 Biennial Meeting of the Conference for Food Protection.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 018
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Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

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Title:

Drying Agents

Issue you would like the Conference to consider:

Clarification to the 2009 US Food Code section 7-204.14 Drying Agents, Criteria, and the associated section in Annex 3 is needed to account for other regulatory procedures that can be used to clear food additives for their use in drying agents. Due to the absence of specific regulations in FDA's 21 Code of Federal Regulations (CFR) for drying agents, the FDA Food Code serves as the sole guidance for the use of drying agents in food facilities. The Food Code does not include use of Generally Recognized as Safe (GRAS) self-determinations by a panel of experts as specified in 21 CFR 170.30 or using the Food Contact Notification (FCN) process, which is included in the Federal Food Drug and Cosmetic Act (FFDCA) Section 409, and 21 CFR Parts 174.5 (d) (5). Both of these processes are appropriately used to qualify suitable components for drying agents and other chemicals associated with production and preparation of food.

Public Health Significance:

Some chemicals may be poisonous or toxic if not used properly and in accordance with FDA regulations. The lack of clear and explicit guidance surrounding drying agents not only creates confusion and allows for misinterpretation. Lack of clear and explicit guidance can also lead to the improper use of chemicals and may subsequently cause public health issues such as the adulteration of food, or potentially acute and chronic health effects to both the consumer and the employees of the food facilities.

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

Drying agents used in conjunction with sanitization shall:

(A) Contain only components that are listed as one of the following:

(1) Generally recognized as safe for use in food as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, ^P

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe, ^P

(3) Generally recognized as safe (GRAS) as determined by independent GRAS self-determinations by a panel of experts as specified in 21 CFR 170.30. ^P

(4) Subject of a Food Contact Notification (FCN) that is effective in accordance with the Federal Food Drug and Cosmetic Act (FFDCA) Section 409. ^P

FDA publishes the effective FCN's on their website at:

<http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm>

~~(53)~~ Approved for use as a drying agent under a prior sanction specified in 21 CFR 181 - Prior-Sanctioned Food Ingredients, ^P

~~(64)~~ Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts ~~174~~~~175~~-178, ^P or

~~(75)~~ Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; ^P and

(B) When sanitization is with chemicals, the approval required under Subparagraph (A)(3) or (A)(5) of this section or the regulation as an indirect food additive required under Subparagraph (A)(4) of this section, shall be specifically for use with chemical sanitizing solutions. ^P

2) Annex 3. Chapter 7- Part 204.14 Sanitizers, 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 or are appropriately cleared as food additives can be used.

"Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition, a Food Contact Notification (FCN), have GRAS clearance, or meet the Threshold of Regulation (TOR) requirements. 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.

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**Conference for Food Protection
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Title:

Updating ROP Criteria with regard to Cook Chill and Sous Vide

Issue you would like the Conference to consider:

Section 3-502.12 Reduced Oxygen Packaging without a Variance, Criteria.

Section 3.502.12 (B)(2) currently specifies four food intrinsic properties that permit ROP without a variance: (a) Has an a_w of 0.91 or less, (b) Has a pH of 4.6 or less, (c) Is a cured meat or poultry product, and (d) Is a food with a high level of competing organisms. These criteria were meant to be barriers or hurdles to the growth of psychrotrophic *Clostridium botulinum* and *Listeria monocytogenes*. As currently written the first two criteria represent the A_w growth minima for *L. monocytogenes* and the pH minima for *Clostridium botulinum* (non-psychrotrophs). For example a food product fully cooked in its bag to proper Food Code temperatures with a pH of 4.9 would not qualify despite destruction of *Listeria monocytogenes* via cooking and inhibition of psychrotrophic *C. botulinum* with a pH under 5.0. This issue seeks to clarify this section with regard to ensuring operations have at least one science-based barrier to growth (in addition to refrigeration) individually, of both psychrotrophic *Clostridium botulinum* and *Listeria monocytogenes*.

Public Health Significance:

When properly performed cook-chill and sous vide processing minimizes many risks of foodborne illness. When performed improperly, these processes may lead to growth of the foodborne pathogens *Clostridium botulinum* (psychrotrophic strains) or *Listeria monocytogenes*.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending that changes be made to the Food Code Section 3-502.12 Reduced Oxygen Packaging without a Variance, Criteria

To:

3.502.12 (B)(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 for each pathogen: psychrotrophic *Clostridium botulinum* and *Listeria monocytogenes*:^{Pf}

(a) Has an a_w of 0.91 or less for *Listeria monocytogenes* or 0.97 or less for psychrotrophic *C. botulinum*,^{Pf}

(b) Has a pH of 4.6 or less for *Listeria monocytogenes* or 5.0 or less for psychrotrophic *C. botulinum*,^{Pf}

(c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact package,^{Pf} or

(d) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables;^{Pf}

(e) Is a food that has received a cooking step of 90°C for 10 minutes to destroy psychrotrophic *C. botulinum*

(f) Is a food that has been ROP packaged and subsequently cooked in the package as specified in FC 3-401 or FC 3-403.11 for *Listeria monocytogenes*.

(An alternative Table format of the above suggested change is included in the attachment).

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Attachments:

- "Table format and references"

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Attachment 1 - Updating ROP Criteria with regard to Cook Chill and Sous Vide

Suggested change to Food Code using a Table Format

3.502.12 (B)

(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 each for psychrotrophic *Clostridium botulinum* and *Listeria monocytogenes*:^{Pf}

<u>Barriers to Growth or Thermal Destruction</u>	<u>ROP pathogens of Concern</u>	
	<u>psychrotrophic <i>Clostridium botulinum</i></u>	<u><i>Listeria monocytogenes</i></u>
<u>Aw</u>	<u>≤ 0.97</u>	<u>≤ 0.91</u>
<u>pH</u>	<u>≤ 5.0</u>	<u>≤ 4.6</u>
<u>Cured Meat product</u>	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	
<u>Competing Microflora</u>	Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables	
<u>Thermal Destruction</u>	<u>90°C for 10 minutes (or equivalent as specified in the US FDA 2001 Appendix 4 - Bacterial Pathogen Growth and Inactivation. In: Fish and Fisheries Products Hazards and Controls Guidance).</u>	<u>Cooking in a sealed bag as specified in 3-401 or reheating as specified in 3-403.11</u>

Science-based references summary

Psychrotrophic *C. botulinum* cook 90°C for 10 minutes.

1. Michael W. Peck. *Clostridium botulinum* and the safety of refrigerated processed foods of extended durability. See Box 2. Line 4.

Quote Box 2: It is recommended that the heat treatments or combination processes reduce the number of viable spores of non-proteolytic *C. botulinum* by a factor of 10^6 (a 6-decimal process). The Advisory Committee on the Microbiological Safety of Food (ACMSF) concluded that the safety of REPFEDs with respect to non-proteolytic *C. botulinum* could be ensured by one of the following:

...(4) storage at chill temperature combined with a heat treatment of 90°C for 10min or equivalent lethality [e.g. 70°C for 675 min, 75°C for 464 min, 80°C for 129min, 85°C for 36min] (the European Chilled Food Federation recommended alternative equivalent heat treatments, e.g. 80°C for 270min, 85°C for 52 min.)”

2. Betts. 1995. Growth and heat resistance of psychrotrophic *Clostridium botulinum* in relation to sous vide products.

Quote Page 61, “It can be seen from table 5. That the highest D90 value obtained in the CFDR studies was 1.1 min: a process of 6.6 min at 90°C should therefore be sufficient to achieve a 6 log reduction for these strains of psychrotrophic *C. botulinum*. Based on these data, it is recommended that building in a safety margin to allow for variation in heat resistance between strains and in different food products a process of 10 min at 90°C could be given to all sous vide products with a shelf life of greater than 10 days”.

3. 2008. Food Standards Agency guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*.

Quote Page 9: “The ACMSF recommended that, in addition to chill temperatures which should be maintained throughout the food chain, the following controlling factors should be used singly or in combination to prevent growth and toxin production by non-proteolytic *C. botulinum* in chilled foods with a shelf-life of more than 10 days: a heat treatment of 90°C for 10 minutes or equivalent lethality”.

4. 2001. FDA Appendix 4 - Bacterial Pathogen Growth and Inactivation. Fish and Fisheries Products Hazards and Controls Guidance. Third Edition.

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Appendix 4 - Bacterial Pathogen Growth and Inactivation

June 2001

Fish and Fisheries Products Hazards and Controls Guidance Third Edition

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Bacterial Pathogen Growth and Inactivation

This appendix contains information on the growth and inactivation of bacterial pathogens.

Table #A-1 contains information on: the minimum water activity (a_w), acidity (pH), and temperature; the maximum, pH, water phase salt, and temperature; and oxygen requirements that will sustain growth for the bacterial pathogens that are of greatest concern in seafood processing. Data shown are the minimum or maximum values, the extreme limits reported among the references cited. These values may not apply to your processing conditions.

Table #A-2 contains information on maximum, cumulative time/internal temperature combinations for exposure of fish and fishery products that, under ordinary circumstances, will be safe for the bacterial pathogens that are of greatest concern in seafood processing. These maximum, cumulative exposure times are derived from published scientific information. Because the nature of bacterial growth is logarithmic, linear interpolation using the time/temperature guidance is not appropriate.

In summary, the table indicates that:

- If the product is held at internal temperatures above 70°F (21°C) during processing, exposure time should ordinarily be limited to two hours (three hours if *Staphylococcus aureus* is the only pathogen of concern);
- If the product is held at internal temperatures above 50°F (10°C), but not above 70°F (21°C), exposure time should ordinarily be limited to six hours (twelve hours if *Staphylococcus aureus* is the only pathogen of concern);
- If the product is held at internal temperatures both above and below 70°F (21.1°C), exposure times above 50°F (10°C) should ordinarily be limited to 4 hours, as long as no more than 2 of those hours are above 70°F (21.1°C).

It is not possible to furnish recommendations for each pathogen, process, type of seafood, and temperature or combination of temperatures. Programmable models to predict growth rates for certain pathogens associated with various foods under differing conditions have been developed by the U.S. Department of Agriculture ("Pathogen Modeling Program" [PMP]) and the United Kingdom ("Food MicroModel" [FMM]). These programs can provide growth curves for selected pathogens. You indicate the conditions, such as pH, temperature, and salt concentration that you are interested in and the models provide pathogen growth predictions (e.g., growth curve, time of doubling, time of lag phase, generation time). FDA does not endorse or require the use of such modelling programs, but recognizes that the predictive growth information they provide may be of assistance to some processors. However, you are cautioned that significant deviations between actual microbiological data in specific products and the predictions do occur, including those for the lag phase of growth. Therefore, you should validate the time-temperature limits derived from such predictive models.

Table #A-3 contains information on the destruction of *Listeria monocytogenes*. Lethal rate, as used in this table, is the relative lethality of one minute at the designated internal product temperature as compared to the lethality of one minute at the reference internal product temperature of 158°F (70°C) (i.e. $z = 13.5^\circ\text{F}$ [7.5°C]). For example, one minute at 145°F (63°C) is 0.117 times as lethal as one minute at 158°F (70°C). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *L. monocytogenes*. The length of time at a particular internal product temperature needed to accomplish a six logarithm reduction in the number of *L. monocytogenes* (6D) is, in part, dependent upon the food in which it is being heated. The values in the table are generally conservative and apply to all foods. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal inoculum in the food.

Table #A-4 contains information on the destruction of *Clostridium botulinum* type B (the most heat resistant form of nonproteolytic *Clostridium botulinum*). Lethal rate, as used in this table, is the relative lethality of one minute at the designated internal product temperature as compared to the lethality of one minute at the reference product internal temperature of 194°F (90°C) (i.e. for temperatures less than 194°F [90°C] $z = 12.6^\circ\text{F}$ [7.0°C]; for temperatures above 194°F [90°C] $z = 18^\circ\text{F}$ [10°C]). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *C. botulinum*. The values in the table are generally conservative. However, they may not be sufficient for the destruction of nonproteolytic *C. botulinum* in dungeness crabmeat, because of the potential protective effect of lysozyme. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal inoculum in the food.

Table A-1
Limiting Conditions for Pathogen Growth

<i>Pathogen</i>	<i>min. a_w</i> <i>(using salt)</i>	<i>min. pH</i>	<i>max. pH</i>	<i>max. % water phase salt</i>	<i>min. temp.</i>	<i>max. temp.</i>	<i>oxygen requirement</i>
<i>Bacillus Cereus</i>	.92	4.3	9.3	10	39.2°F 4°C	131°F**** 55°C	aerobe
<i>Campylobacter jejuni</i>	.987	4.9	9.5	1.5	86°F 30°C	113°F 45°C	micro-aerophilic*
<i>Clostridium botulinum</i> , type A, and proteolytic B and F	.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe**
<i>Clostridium botulinum</i> , type E, and nonproteolytic B and F	.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe**
<i>Clostridium perfringens</i>	.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe**
pathogenic strains of <i>Escherichia coli</i>	.95	4	9	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe***
<i>Listeria monocytogenes</i>	.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe***
<i>Salmonella</i> spp.	.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe***
<i>Shigella</i> spp.	.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe***
<i>Staphylococcus aureus</i> -growth	.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe***
<i>Staphylococcus aureus</i> -toxin	.85	4	9.8	10	50°F 10°C	118°F 48°C	
<i>Vibrio cholerae</i>	.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe***
<i>Vibrio parahaemolyticus</i>	.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe***
<i>Vibrio vulnificus</i>	.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe***
<i>Yersinia enterocolitica</i>	.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe***

* requires limited levels of oxygen ** requires the absence of oxygen *** grows either with or without oxygen. **** growth significantly delayed (>24 hr.) at 131°F (55°C)

Table A-2
Time/Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Seafoods

<i>Potentially Hazardous Condition</i>	<i>Product Temperature</i>	<i>Maximum Cumulative Exposure Time</i>
Growth and toxin formation by <i>Bacillus cereus</i>	39.2-43°F (4-6°C) 44-50°F (7-10°C)	5 days 17 hours*

	51-70°F (11-21°C) Above 70°F (above 21°C)	6 hours* 3 hours
Growth of <i>Campylobacter jejuni</i>	86-93°F (30-34°C) Above 93°F (above 34°C)	48 hours 12 hours
Germination, growth, and toxin formation by <i>Clostridium botulinum</i> type A, and proteolytic B and F	50-70°F (10-21°C) Above 70°F (above 21°C)	11 hours 2 hours
Germination, growth, and toxin formation by <i>Clostridium botulinum</i> type E, and nonproteolytic B and F	37.9-41°F (3.3-5°C) 42-50°F (6-10 °C) 51-70°F (11-21°C) Above 70°F (above 21°C)	7 days >2 days 11 hours 6 hours
Growth of <i>Clostridium perfringens</i>	50-54°F (10-12°C) 55-57°F (13-14 °C) 58-70°F (15-21°C) Above 70°F (above 21°C)	21 days 1 day 6 hours* 2 hours*
Growth of pathogenic strains of <i>Escherichia coli</i>	44.6-50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	14 days 6 hours 3 hours
Growth of <i>Listeria monocytogenes</i>	31.3-41°F (-0.4-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	7 days 2 days 12 hours* 3 hours*
Growth of <i>Salmonella</i> species	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	14 days 6 hours 3 hours
Growth of <i>Shigella</i> species	43-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	14 days* 12 hours* 3 hours*
Growth and toxin formation by <i>Staphylococcus aureus</i>	44.6-50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	14 days 12 hours* 3 hours
Growth of <i>Vibrio cholerae</i>	50°F (10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	21 days 6 hours* 2 hours*
Growth of <i>Vibrio parahaemolyticus</i>	41-50°F (5-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	21 days 6 hours* 2 hours*
Growth of <i>Vibrio vulnificus</i>	46.4-50°F (8-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	21 days 6 hours 2 hours
Growth of <i>Yersinia enterocolitica</i>	29.7-50°F (-1.3-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	1 days 6 hours 2.5 hours
* Additional data needed.		

Table A-3
Inactivation of *Listeria monocytogenes*

<i>Internal Product Temperature (°F)</i>	<i>Internal Product Temperature (°C)</i>	<i>Lethal Rate</i>	<i>Time for 6D Process (minutes)</i>
145	63	0.117	17.0
147	64	0.158	12.7
149	65	0.215	9.3

151	66	0.293	6.8
153	67	0.398	5.0
154	68	0.541	3.7
156	69	0.736	2.7
158	70	1.000	2.0
160	71	1.359	1.5
162	72	1.848	1.0
163	73	2.512	0.8
165	74	3.415	0.6
167	75	4.642	0.4
169	76	6.310	0.3
171	77	8.577	0.2
172	78	11.659	0.2
174	79	15.849	0.1
176	80	21.544	0.09
178	81	29.286	0.07
180	82	39.810	0.05
182	83	54.116	0.03
183	84	73.564	0.03
185	85	100.000	0.02
Note: z = 13.5°F (7.5°C)			

Table A-4
Inactivation of nonproteolytic *Clostridium botulinum* type B

<i>Internal Product Temperature (°F)</i>	<i>Internal Product Temperature (°C)</i>	<i>Lethal Rate*</i>	<i>Time for 6D Process (minutes)</i>
185	85	0.193	51.8
187	86	0.270	37.0
189	87	0.370	27.0
190	88	0.520	19.2
192	89	0.720	13.9
194	90	1.000	10.0
196	91	1.260	7.9
198	92	1.600	6.3
199	93	2.000	5.0
201	94	2.510	4.0
203	95	3.160	3.2

205	96	3.980	2.5
207	97	5.010	2.0
208	98	6.310	1.6
210	99	7.940	1.3
212	100	10.000	1.0

Note: for temperatures less than 194°F (90°C) z = 12.6°F (7.0°C); for temperatures above 194°F (90°C) z = 18°F (10°C).

*Note: these lethal rates and process times may not be sufficient for the destruction of nonproteolytic *C. botulinum* in dungeness crabmeat, because of the potential that substances that may be naturally present, such as lysozyme, may enable the pathogen to more easily recover from heat damage.

Page Last Updated: 11/10/2009

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**Conference for Food Protection
2010 Issue Form**

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Title:

3-302.11 Packaged and Unpackaged Food - Separation

Issue you would like the Conference to consider:

Currently Annex 3 gives guidance on separating raw animal foods during storage, preparation, holding, and display that is "...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." Because of this guidance, many jurisdictions prohibit packaged ground beef (cook to 155°F) from being stored, held, or displayed above whole muscle beef products (cook to 145 °F) even though 3-302.11(A)(4) recognizes that storing the FOOD in packages or wrappings is an exception to separating raw animal FOODS. Ground beef is cooked to a higher temperature to kill potential internal contamination. Whole muscle beef can be cooked to kill surface contamination only. If the packaged whole muscle beef were to be cross-contaminated from the packaged ground beef, it would still only be a surface contaminant and normal cooking temperature of 145 °F would render the product safe. This fact is supported by 3-302.11(A)(2) which allows combining certain types of raw animal FOODS as ingredients. Request the Conference to consider amending Section 3-302.11 of the Food Code along with Annex 3 (Public Health Reasons/Administrative Guidelines) to recognize that packaged ground meat displayed for sale over packaged whole muscle cuts is an acceptable practice that has minimal risk.

Public Health Significance:

In the unlikely event the juice or pieces of ground beef products from a packaged product were to get onto a piece of packaged whole muscle beef, the normal cooking requirements for the whole muscle product would be adequate to render the food safe based in part on similar information applicable to seared steak found in the 2009 Food Code Annex which states:

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee for Microbiological Criteria on 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."

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 packaged whole muscle beef

and Annex 3 (Public Health Reasons/Administrative Guidelines) be amended by adding the following at the end of the paragraph.

Annex 3 - 3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.

"...from these products packaged in-house. Another exception is permitted for packaged raw ground beef to be stored or displayed adjacent to or above packaged whole muscle beef since the packaging is an acceptable barrier for separating and if there were leakage in both packages, the surface of the whole muscle cuts would receive sufficient heat treatment similar to searing a steak and make the whole muscle cut safe when standard cooking instructions are followed. "

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 021
Issue: 2010 III-019**

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

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Title:

Reduce confusion in ROP Criteria with regard to Cook Chill and Sous Vide

Issue you would like the Conference to consider:

The current section on ROP criteria with regard to cook-chill or sous vide without a variance (3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria) has two items that may be misinterpreted by regulators and operators. One section, 3-502.12 (B)(2) specifies conditions that permit storage of ROP at 41°F for up to 14 days. Another section, 3.502.12 (D)(2)(e) specifies holding temperature options of 38°F and 34°F. This section does not provide for a 41°F option at 14 days, yet does not exclude instructions provided in 3-502.12 (B)(2). Clarity is needed in the intent and wording of this section of the food code.

Public Health Significance:

When properly performed cook-chill and sous vide processing minimizes many risks of foodborne illness. When performed improperly, these processes may lead to growth of the foodborne pathogens *Clostridium botulinum* (psychrotrophic strains) or *Listeria monocytogenes*.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the FDA make changes to the Food Code Parts 3-502.12 Reduced Oxygen Packaging without a Variance, to clarify original storage temperature and shelf life intent to users by adding a new subsection (v) to Section 3-502.12. (D)(2)(e) as follows:

(v) maintained at 41°F for foods that meet criteria specified in 3-502.12 (B)(2).

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Attachments:

- "Food Code Section 3.502.12"

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(C) If time without temperature control is used as the public health control up to a maximum of 6 hours:

Time – maximum up to 6 hours

- (1) The FOOD shall have an initial temperature of 5°C (41°F) or less when removed from temperature control and the FOOD temperature may not exceed 21°C (70°F) within a maximum time period of 6 hours; ^P
- (2) The FOOD shall be monitored to ensure the warmest portion of the FOOD does not exceed 21°C (70°F) during the 6-hour period, *unless an ambient air temperature is maintained that ensures the FOOD does not exceed 21°C (70°F) during the 6-hour holding period;* ^{Pf}
- (3) The FOOD shall be marked or otherwise identified to indicate: ^{Pf}
 - (a) The time when the FOOD is removed from 5°C (41°F) or less cold holding temperature control, ^{Pf} and
 - (b) The time that is 6 hours past the point in time when the FOOD is removed from cold holding temperature control; ^{Pf}
- (4) The FOOD shall be:
 - (a) Discarded if the temperature of the FOOD exceeds 21°C (70°F), ^P or
 - (b) Cooked and served, served at any temperature if READY-TO-EAT, or discarded within a maximum of 6 hours from the point in time when the FOOD is removed from 5°C (41°F) or less cold holding temperature control; ^P and
- (5) The FOOD in unmarked containers or PACKAGES, or marked with a time that exceeds the 6-hour limit shall be discarded. ^P

(D) A FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION may not use time as specified under ¶¶ (A), (B) or (C) of this section as the public health control for raw EGGS.

Specialized Processing Methods

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: ^{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}
- (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;* ^{Pf}
- (E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption; ^{Pf}
- (F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; ^{Pf}
- (G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; ^{Pf} or
- (H) Sprouting seeds or beans. ^{Pf}

Clostridium botulinum and Listeria monocytogenes Controls

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

- (A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES 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**. ^P
- (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}
 - (1) Identifies the FOOD to be PACKAGED; ^{Pf}

(2) Except as specified under ¶¶ (C) - (E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: Pf

(a) Has an A_w of 0.91 or less, Pf

(b) Has a pH of 4.6 or less, Pf

(c) Is a MEAT OR POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, Pf or

(d) Is a FOOD with a high level of competing organisms such as RAW MEAT, RAW POULTRY, or raw vegetables; Pf

(3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: Pf

(a) Maintain the FOOD at 5°C (41°F) or below, Pf and

(b) Discard the FOOD if within 14 calendar days of its PACKAGING it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption; Pf

(4) Limits the refrigerated shelf life to no more than 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; P

(5) Includes operational procedures that:

(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶ 3-301.11(B), Pf

(b) Identify a designated work area and the method by which: Pf

(i) Physical barriers or methods of separation of RAW FOODS and READY-TO-EAT FOODS minimize cross contamination, Pf and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, Pf and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; Pf and

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the: Pf

(a) Concepts required for a safe operation, Pf

(b) EQUIPMENT and facilities, Pf and

(c) Procedures specified under Subparagraph (B)(5) of this section and ¶ 8-201.14(D). Pf

(C) Except for FISH that is frozen before, during, and after PACKAGING, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method. P

Fish

(D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES FOOD using a cook-chill or sous vide process shall:

Cook-Chill or Sous Vide

(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, 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, at which time the FOOD must be consumed or discarded;^P

(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

(iv) Held frozen with no shelf life restriction while frozen until consumed or used.^P

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,^{Pf}

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation,^{Pf} and

(h) Labeled with the product name and the date PACKAGED;^{Pf} and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP PLAN and:

(a) Make such records available to the REGULATORY AUTHORITY upon request,^{Pf} and

(b) Hold such records for at least 6 months;^{Pf} and

(4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.^{Pf}

(E) A FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:

Cheese

(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;^P

(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;^{Pf}

(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;^{Pf} and

(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.^{Pf}

3-6 Food Identity, Presentation, and On-premises Labeling

Subparts

3-601 Accurate Representation

3-602 Labeling

3-603 Consumer Advisory

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and standards of identity or composition, and the general requirements in 21 CFR 130 – Food Standards: General and 9 CFR 319 Subpart A – General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD OR COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 - Food labeling, and 9 CFR 317 Labeling, marking devices, and containers.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient (Effective January 1, 2006).^{Pf}

(6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3) - (5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(7) For any salmonid FISH containing canthaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

(1) The manufacturer's or processor's label that was provided with the FOOD; or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.

(D) Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:

(1) A health, nutrient content, or other claim is not made;

(2) There are no state or local LAWS requiring labeling; and

(3) The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT OF manufacturers' dating information on FOODS may not be concealed or altered.

Consumer Advisory

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

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

(B) DISCLOSURE shall include:

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

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

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

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

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

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

conditions. ^{Pf}

3-7 Contaminated Food

Subparts

3-701 Disposition

Disposition

3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

- (A) A FOOD that is unsafe, ADULTERATED, or not honestly presented as specified under § 3-101.11 shall be discarded or reconditioned according to an APPROVED procedure. ^P
- (B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 - .17 shall be discarded. ^P
- (C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been RESTRICTED OR EXCLUDED as specified under § 2-201.12 shall be discarded. ^P
- (D) FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, OR OTHER PERSONS through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded. ^P

3-8 Special Requirements For Highly Susceptible Populations

Subparts

3-801 Additional Safeguards

Additional Safeguards

3-801.11 Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

- (A) The following criteria apply to JUICE:
 - (1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;
 - (2) PREPACKAGED JUICE or a PREPACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a PACKAGED JUICE OR BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale; ^P and
 - (3) UNPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(B) - (E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls. ^P
- (B) Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of: ^P
 - (1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, EGGNog, ice cream, and EGG-fortified BEVERAGES, ^P and
 - (2) Except as specified in ¶ (F) of this section, recipes in which more than one EGG is broken and the EGGS are combined; ^P
- (C) The following FOODS may not be served or offered for sale in a READY-TO-EAT form: ^P
 - (1) Raw animal FOODS such as raw FISH, raw-marinated FISH, RAW MOLLUSCAN SHELLFISH, and steak tartare, ^P
 - (2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw EGGS, and meringue; ^P and
 - (3) Raw seed sprouts. ^P
- (D) FOOD EMPLOYEES may not CONTACT READY-TO-EAT FOOD as specified under ¶¶ 3-301.11(B) and (D). ^P
- (E) Time only, as the public health control as specified under ¶ 3-501.19(D), may not be used for raw EGGS. ^P
- (F) Subparagraph (B)(2) of this section does not apply if:
 - (1) The raw EGGS are combined immediately before cooking for one CONSUMER'S serving

at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled EGGS;

(2) The raw EGGS are combined as an ingredient immediately before baking and the EGGS are thoroughly cooked to a READY-TO-EAT form, such as a cake, muffin, or bread; or

(3) The preparation of the food is conducted under a HACCP PLAN that:

(a) Identifies the FOOD to be prepared,

(b) Prohibits contacting READY-TO-EAT FOOD with bare hands,

(c) Includes specifications and practices that ensure:

(i) **Salmonella Enteritidis** growth is controlled before and after cooking, and

(ii) **Salmonella Enteritidis** is destroyed by cooking the EGGS according to the temperature and time specified in Subparagraph 3-401.11(A)(2),

(d) Contains the information specified under ¶ 8-201.14(D) including procedures that:

(i) Control cross contamination of READY-TO-EAT FOOD with RAW EGGS, and

(ii) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES, and

(e) Describes the training program that ensures that the FOOD EMPLOYEE responsible for the preparation of the FOOD understands the procedures to be used.

(G) Except as specified in paragraph (H) of this section, FOOD may be re-served as specified under Subparagraph 3-306.14(B)(1) and (2).

Re-service of Food

(H) FOOD may not be re-served under the following conditions:

Prohibited Re-service of Food

(1) Any FOOD served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside.

(2) Packages of FOOD from any patients, clients, or other CONSUMERS should not be re-served to PERSONS in protective environment isolation.

Page Last Updated: 11/05/2009

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 035
Issue: 2010 III-022**

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

All information above the line is for conference use only.

Title:

Antimicrobial Treatments for Washing Fruits & Vegetables

Issue you would like the Conference to consider:

Approved antimicrobial treatments for washing fruits and vegetables can be useful to reduce the risk of cross contamination, particularly for produce that will be served without cooking. Language in Annex 3 §3-302.15 Washing Fruits and Vegetables may cause confusion regarding when antimicrobial treatments can be used for washing fruits and vegetables in retail and food service establishments, and do not clearly convey the potential benefit of these treatments. Additionally, some antimicrobial treatments that are approved for washing fruits and vegetables contain surfactants and statements in Annex 3 §3-302.15 could be misinterpreted to exclude these as acceptable solutions.

Public Health Significance:

Antimicrobial treatments used for washing fruits and vegetables must be used at the correct concentration to assure that no harmful residues are transferred to foods. When used at appropriate concentrations, antimicrobial treatments can reduce the risk of cross contamination through wash water. Recent, peer reviewed research (e.g. Zhang et. al 2009) demonstrates the potential benefit of using several antimicrobials to reduce transfer of a pathogen from contaminated produce to uncontaminated produce, as compared to using water alone.

FDA Guidance to the Industry (February 2008), which is included as a reference in Annex 3, includes the following statement, which clearly recognizes that sometimes temperature differentials may not be practical and alternative methods to reduce risk do exist.

"When it is not practical to reduce the temperature differential between the wash/cooling water and the produce, it is especially important that processors follow practices to minimize pathogens in the water or on the surface of produce. Such practices may include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce."

Providing practical alternative approaches for washing produce is important to protect public health at the retail level as well.

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.

"... All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed using under-running, potable water, with or without antimicrobial treatments, before eating, cutting or cooking. ..."

"... 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. When it is not practical to reduce the temperature differential between the wash/cooling water and the produce, it is especially important to follow practices to minimize pathogens in the water or on the surface of produce. Such practices may include using antimicrobial chemicals in the wash water or using spray type wash treatments. 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."

"... Washing fresh fruits and vegetables with unapproved soap, detergent or other surfactants that do not have antimicrobial properties should be avoided as they facilitate infiltration ~~and may not be approved for use on food.~~ ... "

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Attachments:

- "Zhang, et al. 2009 antimicrobial transfer reference"
- "FDA 2008 Guidance to Industry on fresh cut Fruits and Vegetables."

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.

Efficacy of Antimicrobial Agents in Lettuce Leaf Processing Water for Control of *Escherichia coli* O157:H7

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ABSTRACT

The objectives of this research were to study transfer and control of *Escherichia coli* O157:H7 during simultaneous washing of inoculated and uninoculated lettuce pieces and to determine the efficacy of antimicrobial agents (peroxyacetic acid, mixed peracid, and sodium hypochlorite) on reducing the transfer of *E. coli* O157:H7 through processing water with or without organic load. Lettuce leaf pieces (5 by 5 cm) were inoculated with a five-strain mixture of green fluorescent protein–labeled *E. coli* O157:H7 at 5.6 log CFU per piece. One inoculated lettuce piece was added to five uninoculated leaves during washing. Peroxyacetic acid and mixed peracid were tested at 10, 20, and 30 ppm, and chlorine was tested at 30 and 50 ppm. No organic load (liquefied lettuce leaves) and 10% organic load in processing water were compared. Without organic load, peroxyacetic acid at 30 ppm, mixed peracid at 10, 20, and 30 ppm, and chlorine at 30 and 50 ppm all significantly reduced *E. coli* O157:H7 in processing water by 1.83, 1.73, 1.50, 1.83, 1.34, and 1.83 log CFU/ml, respectively, compared with washing with water alone. These antimicrobials at all concentrations tested also significantly reduced transfer of the bacteria from an inoculated leaf to uninoculated leaves in the processing water by 0.96 to 2.57 log CFU per piece. A 10% organic load in the processing water reduced efficacy of antimicrobial agents. In this contaminated water, peroxyacetic acid at 10 and 20 ppm and chlorine at 30 ppm produced effects not significantly different from those of water alone. Therefore, it is important to understand the impact of organic load when validating the effectiveness of antimicrobial treatments.

Lettuce is one of the most commonly consumed leafy greens, with a farm value of over \$1.5 billion in 2005 in the United States (10). Lettuce is perceived by consumers as healthful and nutritious. Contamination of vegetables by human pathogens can occur at many locations in the farm-to-fork continuum, including contamination of seeds and of product during production, harvesting, postharvest handling, transport distribution, storage, processing, and preparation (13). Survival and growth of foodborne human pathogens on fresh and fresh-cut produce has been widely reported (3–5, 12, 14, 15, 21). The efficacy of different antimicrobials used to kill foodborne pathogens on fresh and fresh-cut produce has been studied extensively, and most antimicrobials are minimally effective, reducing pathogen contamination by only 1 to 2 log CFU/g (3, 5, 9, 21).

Antimicrobial agents often are added to water in flumes that convey or wash fresh fruits and vegetables. The addition of these agents reduces the number of microorganisms in fruit and vegetable processing water. Reducing the number of microorganisms in recycled processing water helps prevent the water from becoming a vehicle of cross-contamination (7, 8, 11, 16, 18, 19). Antimicrobial chemicals in processing water also can reduce microorganisms on the surfaces of fruits and vegetables. However, processing water antimicrobials are more effective for reducing microorganisms in water suspensions than on fruit and vegetable surfaces (1, 2, 6, 11, 18–20).

This study was conducted (i) to investigate transfer of *Escherichia coli* O157:H7 from an inoculated lettuce leaf piece to uninoculated lettuce leaf pieces during washing, (ii) to determine the efficacy of peroxyacetic acid, mixed peracid, and chlorine for reducing the transfer of *E. coli* O157:H7 under conditions of high organic load, and (iii) to determine the efficacy of peroxyacetic acid, mixed peracid, and chlorine for reducing *E. coli* O157:H7 in lettuce processing water.

MATERIALS AND METHODS

Bacterial strains and culture conditions. Five strains of *E. coli* O157:H7 were used: ATCC 43888 (human feces), EO122 (cattle isolate), K3995 (spinach isolate), K4492 (lettuce, clinical isolate), and F4546 (alfalfa sprout outbreak isolate). A plasmid (pGFPuv) containing a *gfp* gene was introduced into each strain using a CaCl₂ heat shock method (17). Expression of green fluorescent protein (GFP) in labeled cells was evaluated by epifluorescence microscopic examination of colonies. The five strains were cross-streaked onto tryptic soy agar (Difco, Becton Dickinson, Sparks, MD) to confirm lack of cross-inhibitory activity. All strains were grown at 37°C for 24 h on brain heart infusion agar (BHIA; Difco, Becton Dickinson) or in brain heart infusion broth (BHIB; Difco, Becton Dickinson) supplemented with ampicillin (Roche Diagnostics, Indianapolis, IN) at a concentration of 100 µg/ml (BHIA-amp and BHIB-amp, respectively). Colonies of these GFP-labeled strains were viewed under a 396-nm wavelength UV lamp for enumeration.

All *E. coli* O157:H7 strains were transferred to BHIB-amp three times at 24-h intervals before they were used as inocula. Cells from overnight culture (10 ml) were sedimented by centri-

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fugation at $5,000 \times g$ for 10 min and resuspended in 10 ml of 0.1% sterile peptone water (Difco, Becton Dickinson). Approximately equal populations of each of the five strains were combined. Dilutions were made in 0.1% sterile peptone water to create a culture suspension for inoculation of approximately 10^6 CFU/ml.

Antimicrobial agents. Peroxyacetic acid (Tsunami 100), mixed peracid (Tsunami 200), and sodium hypochlorite (XY-12) were provided by Ecolab, Inc. (St. Paul, MN).

Preparation of lettuce for inoculation. Iceberg lettuce (*Lactuca sativa* L.) was purchased from a grocery store (Griffin, GA). Two or three layers of outer leaves were removed from each head of lettuce, and inner leaves were aseptically cut into pieces (ca. 5 by 5 cm), using as much of the leaf portion as possible and avoiding stem areas.

Inoculation of lettuce leaves. Lettuce leaf pieces were placed on a sterile surface in a laminar flow biosafety cabinet, and 100 μ l of the five-strain mixture of culture suspension was spot inoculated with a micropipettor onto the adaxial side of each leaf piece to achieve an initial *E. coli* O157:H7 population of 5.6 log CFU per inoculated lettuce piece. The inoculated leaf pieces were placed in a sterile plastic container with a lid and held at 4°C for approximately 2 h to allow bacterial attachment before treatment. A minor cut (ca. 2 mm) on one side was made on all inoculated leaf pieces to differentiate these pieces from uninoculated leaf pieces during treatment.

Organic load preparation. Two outer layers of iceberg lettuce leaves were discarded. Green leaves (100 g) were placed in a sterile blender jar with 100 g of sterile water tempered to 4°C. Leaves were blended on high speed until they were liquefied and particulates were small enough to be suctioned through a pipette. This organic load preparation was blended immediately before use.

Antimicrobial use solution: chemistry without organic load. The appropriate amount of test antimicrobial was pipetted into 250 ml of sterile deionized water in a 500-ml volumetric flask, and additional sterile deionized water was added to the 500-ml mark.

Antimicrobial use solution: chemistry with 10% organic load. The appropriate amount of test antimicrobial was pipetted into 250 ml of sterile deionized water as above, 50 ml of the organic load preparation was added, and additional sterile deionized water was added to the 500-ml mark.

Antimicrobial use solution: concentration of antimicrobial agent. Concentrations of free chlorine and total peracid in use solutions were determined by an iodine–sodium thiosulfate redox titration (Oxidizer Kit 322, Ecolab). The following antimicrobial agents were evaluated: water; peroxyacetic acid at 10, 20, and 30 ppm; mixed peracid at 10, 20, and 30 ppm; and sodium hypochlorite at 30 and 50 ppm at pH 6.8. All antimicrobials were evaluated without organic load and with a 10% organic load preparation.

Treatment of lettuce leaves with antimicrobial agents. All testing was conducted in a refrigerated room (4 to 5°C). The use solutions (with or without organic load) were poured into the mixing vessel (modified version of the CDC Biofilm Reactor, Bio-Surface Technologies Corp., Bozeman, MT) and stirred at 125 rpm with a magnetic stir bar on a stir plate. Five uninoculated lettuce pieces and one inoculated lettuce piece were placed in the

mixing vessel and agitated for 1.5 min treatment. Lettuce pieces were then removed aseptically and separately placed into Whirl-Pak bags (Nasco, Fort Atkinson, WI) containing 10 ml of 0.5% sodium thiosulfate neutralizing agent (Fisher Scientific, Fair Lawn, NJ). Lettuce pieces were then individually macerated at 230 rpm for 30 s, and serial dilutions were plated in duplicate on BHIA-amp and incubated at $35 \pm 2^\circ\text{C}$ for 48 h.

One milliliter of each treated use solution from the mixing vessel was pipetted into 9 ml of 0.5% sodium thiosulfate. Serial dilutions were plated in duplicate and incubated under the conditions described above.

Control: test substance neutralization. Triplicate neutralization checks were performed on each type of chemistry. If more than one use solution concentration was used, the most concentrated solution was tested. For control A, an uninoculated lettuce piece was dipped into the test substance use solution for 1.5 min and then removed and placed into a small Whirl-Pak bag containing 10 ml of the neutralizing agent (0.5% sodium thiosulfate). Subsequently, 0.1 ml of *E. coli* O157:H7 test system suspension (10^5 CFU/ml) was added and mixed. For control B, an uninoculated lettuce piece was dipped into the test substance diluent (sterile deionized water) for 1.5 min and then removed and placed into a small Whirl-Pak bag containing 10 ml of the neutralizing agent. Subsequently, 0.1 ml of *E. coli* O157:H7 test system suspension (10^5 CFU/ml) was added and mixed. For control C, 0.1 ml of *E. coli* O157:H7 test system suspension (10^5 CFU/ml) was added to 10 ml of sterile peptone water and mixed. Leaf pieces from controls A, B, and C were held at room temperature for 30 min before the microbiological assay. Portions (0.25 ml in quadruplicate and 0.1 ml in duplicate) of each control were plated on BHIA-amp and incubated at $35 \pm 2^\circ\text{C}$ for 48 h.

The neutralizing agent was considered to have effectively neutralized the test substance when the average plate count from control C equaled that of control A $\pm 10\%$. The neutralizing agent was not detrimental to the culture suspension when the average plate count from control C equaled that of control B $\pm 10\%$.

Control: test substance diluent (sterile deionized water) sterility. Portions (0.25 ml in quadruplicate and 0.1 ml in duplicate) of sterile deionized water were plated on BHIA-amp and incubated at $35 \pm 2^\circ\text{C}$ for 48 h.

Control: *E. coli* O157:H7-free lettuce pieces. An uninoculated lettuce piece was aseptically placed into a Whirl-Pak bag, 10 ml of neutralizing agent was added, and the bag contents were homogenized in a laboratory blender (Stomacher 400, Seward, Worthington, UK) at 230 rpm for 30 s. Portions (0.25 ml in quadruplicate and 0.1 ml in duplicate) of homogenate were plated on BHIA-amp and incubated at $35 \pm 2^\circ\text{C}$ for 48 h.

Control: *E. coli* O157:H7-free organic load. Portions (0.25 ml in quadruplicate and 0.1 ml in duplicate) of organic load were plated on BHIA-amp and incubated at $35 \pm 2^\circ\text{C}$ for 48 h.

All chemical solutions were stored at 4°C 1 day before the experiment. The entire experiment was conducted in a room with temperature set at 4°C.

Statistical analysis. Data were analyzed using the general linear models procedure of SAS (SAS 9.1.3; SAS Institute, Inc., Cary, NC at $\alpha = 0.05$). Duncan's multiple range tests were used to determine significant differences ($\alpha = 0.05$) between mean values. The entire study was repeated three times.

TABLE 1. *E. coli* O157:H7 on lettuce leaves and in processing water with and without antimicrobials and without organic load^a

Antimicrobial agent	Concn (ppm)	Mean (\pm SD) <i>E. coli</i> O157:H7 population ^b		
		Inoculated leaves after treatment (log CFU/piece)	Posttreatment processing water (log CFU/ml)	Uninoculated leaves after treatment (log CFU/piece)
Peroxyacetic acid	10	3.31 \pm 0.11 AB	0.88 \pm 0.84 AB	0.20 \pm 0.34 BC
	20	3.21 \pm 0.36 ABC	0.76 \pm 1.32 AB	0.44 \pm 0.27 B
	30	2.38 \pm 0.18 BC	ND B	ND C
Mixed peracid	10	2.27 \pm 0.55 BC	0.10 \pm 0.17 B	0.07 \pm 0.12 BC
	20	2.10 \pm 1.84 C	0.33 \pm 0.58 B	0.18 \pm 0.18 BC
	30	ND D	ND B	ND C
Chlorine	30	3.42 \pm 0.35 AB	0.49 \pm 0.84 B	0.19 \pm 0.32 BC
	50	2.60 \pm 0.44 ABC	ND B	0.07 \pm 0.11 BC
Water		3.68 \pm 0.23 A	1.83 \pm 0.24 A	2.54 \pm 0.19 A

^a *E. coli* O157:H7 population on inoculated untreated leaves was at 5.6 log CFU per piece.

^b Within a column, means with the same letter are not significantly different at $\alpha = 0.05$. ND, not detected. Detection limits were 1 CFU/ml of processing solution and 10 CFU per leaf piece.

RESULTS

E. coli O157:H7 populations for control A were 2.97, 2.92, and 2.98 log CFU/ml for 30 ppm of peracetic acid, 30 ppm of mixed peracid, and 50 ppm of chlorine, respectively, and 2.98 and 2.96 log CFU/ml for controls B and C, respectively. These values were approximately the same, indicating that the neutralizing agent effectively neutralized the test substance and was not detrimental to *E. coli* O157:H7. The sterile deionized water used for all solutions, the lettuce leaves, and the prepared organic load were all negative for *E. coli* O157:H7.

A single lettuce leaf piece inoculated with *E. coli* O157:H7 at 5.6 log CFU transferred contamination in 500 ml of water at approximately 2 log CFU/ml with or without the presence of organic material. Although the contamination levels were not significantly different, peroxyacetic acid at 10 and 20 ppm held the level of contamination in the solution to 1 log CFU/ml less than that of water when no additional organic material was present. All other antimicrobial solutions had significantly less *E. coli* O157:H7 than did water when no additional organic material was present. In posttreatment solutions without organic load containing mixed peracid at 10 and 20 ppm, *E. coli* O157:H7 levels were 1.5 log CFU/ml less than those in water. *E. coli* O157:H7 was not detected (detection limit of 1 CFU/ml) in posttreatment solutions when mixed peracid and peroxyacetic acid were at 30 ppm or chlorine was at 50 ppm. The average *E. coli* O157:H7 population detected was 0.5 log CFU/ml after chlorine treatment at 30 ppm, which was more than 1 log CFU/ml less than that for water alone (Table 1).

The presence of 10% organic material reduced the effectiveness of several antimicrobial treatments for control of *E. coli* O157:H7 transfer to the washing solutions. There were no significant differences between *E. coli* O157:H7 levels in water and in chlorine at 30 ppm, mixed peracid at 10 ppm, and peroxyacetic acid at 10 and 20 ppm. In posttreatment solutions with 10% organic load, *E. coli* O157:H7 was not detected in mixed peracid at 20 and 30 ppm. Peroxyacetic acid at 30 ppm had *E. coli* O157:H7

levels that were significantly less than those in water ($\alpha = 0.05$) by 1.7 log CFU/ml. Chlorine at 30 ppm and 50 ppm had *E. coli* O157:H7 levels that were 0.8 and 1.3 log CFU/ml, respectively, less than those in water only (Table 2).

In contrast to the results for the posttreatment solutions, the *E. coli* O157:H7 populations transferred to uninoculated leaves were significantly smaller for all antimicrobial treatments than for water only with or without added organic material. When one leaf piece inoculated with *E. coli* O157:H7 at 5.6 log CFU was mixed with five uninoculated leaf pieces in 500 ml of untreated water, the mean population on the uninoculated leaves after treatment was greater than 2.5 log CFU per leaf piece. When no added organic material was present, the mean population on uninoculated leaves in antimicrobial solutions was at least 2 log units less than that for water only, and no *E. coli* O157:H7 was detected on uninoculated leaves treated with peroxyacetic acid or mixed peracid at 30 ppm. There was no significant difference between the results for those treatments and the leaf results for mixed peracid at 10 and 20 ppm and chlorine at 30 or 50 ppm (Table 1).

The presence of 10% organic material added to the antimicrobial solutions reduced the effectiveness of limiting transfer of *E. coli* O157:H7 to uninoculated leaves; however, all antimicrobial treatments resulted in significantly lower cell numbers on uninoculated leaves compared with the numbers on leaves in untreated water. Chlorine at 30 and 50 ppm and peroxyacetic acid at 10 ppm had mean cell numbers 1 log or more lower than those for untreated water. Peroxyacetic acid at 20 and 30 ppm and mixed peracid at 10, 20, and 30 ppm had mean cell numbers >2 log less than those in untreated water (Table 2).

For *E. coli* O157:H7 on inoculated lettuce leaves after treatment without organic load, a significant reduction ($\alpha = 0.05$) of 1.9 log CFU per leaf piece was achieved by washing with water alone. A reduction of 3.2, 3.5, and >4.6 log CFU per leaf piece was achieved by peroxyacetic acid at 30 ppm, mixed peracid at 20 ppm, and mixed peracid at 30 ppm, respectively, and this reduction was significantly different from that achieved with water alone.

TABLE 2. *E. coli* O157:H7 on lettuce leaves and in processing water with and without antimicrobials and in the presence of 10% organic load^a

Antimicrobial agent	Concn (ppm)	Mean (\pm SD) <i>E. coli</i> O157:H7 population ^b		
		Inoculated leaves after treatment (log CFU/piece)	Posttreatment processing water (log CFU/ml)	Uninoculated leaves after treatment (log CFU/piece)
Peroxyacetic acid	10	3.99 \pm 0.45 A	1.61 \pm 0.09 AB	1.26 \pm 0.70 BC
	20	3.25 \pm 0.69 A	1.27 \pm 0.63 AB	0.68 \pm 0.79 CD
	30	1.66 \pm 1.47 BC	0.10 \pm 0.17 CD	0.07 \pm 0.12 D
Mixed peracid	10	3.42 \pm 0.43 A	1.24 \pm 0.81 AB	0.57 \pm 0.39 CD
	20	2.57 \pm 0.46 AB	ND D	0.27 \pm 0.31 D
	30	0.90 \pm 0.85 C	ND D	0.13 \pm 0.12 D
Chlorine	30	2.86 \pm 0.41 AB	1.15 \pm 1.00 ABC	1.68 \pm 1.00 B
	50	2.88 \pm 0.29 AB	0.59 \pm 1.02 BCD	0.80 \pm 1.39 BCD
Water		3.93 \pm 0.56 A	1.96 \pm 0.26 A	2.64 \pm 0.15 A

^a *E. coli* O157:H7 population on inoculated untreated leaves was at 5.6 log CFU per piece.

^b Within a column, means with the same letter are not significantly different at $\alpha = 0.05$. ND, not detected. Detection limit was 1 CFU/ml of processing water.

The 2.18-log reduction achieved by washing with chlorine at 30 ppm and the 3.0-log reduction with 50 ppm of chlorine was not significantly different than that achieved with water alone. The reduction of *E. coli* O157:H7 on inoculated leaves was significantly greater for the mixed peracid solution at 30 ppm than for any other treatment. When no added organic material was present, *E. coli* O157:H7 was not detected, representing a >5-log reduction from the initial level of 5.56 log CFU per leaf piece. A similar trend was observed for treatments with 10% organic load, with slightly lower efficacy of all antimicrobial agents (Table 2).

DISCUSSION

Compared with water without antimicrobial agents, peroxyacetic acid and mixed peracid at 30 ppm were more effective for reducing the numbers of *E. coli* O157:H7 cells in processing water, with or without 10% organic load, and

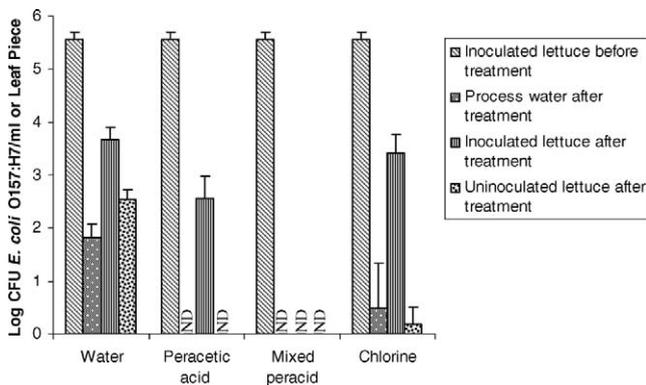


FIGURE 1. Comparison of antimicrobial agents at 30 ppm in processing water without organic load for their effect on *E. coli* O157:H7 in processing water and on inoculated and uninoculated lettuce leaves. ND, not detected. The experiment was repeated three times. One sample was evaluated for inoculated lettuce before treatment, processing water after treatment, and inoculated lettuce after treatment in each replicate. Five samples were evaluated for uninoculated lettuce after treatment in each replicate. Error bars represent the standard deviation.

on inoculated lettuce leaves. However, peracid agents at 10 and 20 ppm (which are below the specified label use concentration) were much less effective than 30 ppm for reducing *E. coli* O157:H7 in processing water and on inoculated lettuce leaves (Tables 1 and 2). According to the Federal Insecticide, Fungicide and Rodenticide Act (<http://www.epa.gov/oecaagct/lfra.html>), it is a violation of Federal Law to use an Environmental Protection Agency-registered product in a manner that is inconsistent with its labeling. The results of this study demonstrate that improper use of antimicrobial agents (e.g., reduced concentration) under produce processing conditions will not achieve the intended purpose of controlling pathogenic microorganisms in processing water.

E. coli O157:H7 on inoculated leaves contaminated processing water and was transferred to uninoculated leaves in the processing water for all treatments except 30 ppm of mixed peracid and 30 ppm of peroxyacetic acid. *E. coli* O157:H7 contamination reached 2.5 and 2.6 log CFU per leaf piece on uninoculated leaf pieces when they were washed with leaf pieces inoculated at 5.6 log CFU per leaf piece in water without and with 10% organic load, respectively (Tables 1 and 2). In comparison with washing with water only, peroxyacetic acid, mixed peracid, and chlorine treatments at all concentrations resulted in significantly lower numbers of *E. coli* O157:H7 cells on uninoculated leaves (Tables 1 and 2). Proper levels of antimicrobials in processing water are necessary to prevent transfer of pathogens from contaminated leaves to uncontaminated leaves during washing.

Treatments with 30 ppm of peroxyacetic acid and mixed peracid reduced the population of *E. coli* O157:H7 on inoculated leaves by ≥ 1 log CFU per leaf piece more than did treatment with chlorine at 30 ppm with or without 10% organic load; however, only the 30-ppm mixed peracid treatment result was significantly different from that of chlorine (Figs. 1 and 2). In the postwash water containing 10% organic load, only peroxyacetic acid at 30 ppm, mixed peracid at 20 and 30 ppm, and chlorine at 50 ppm were

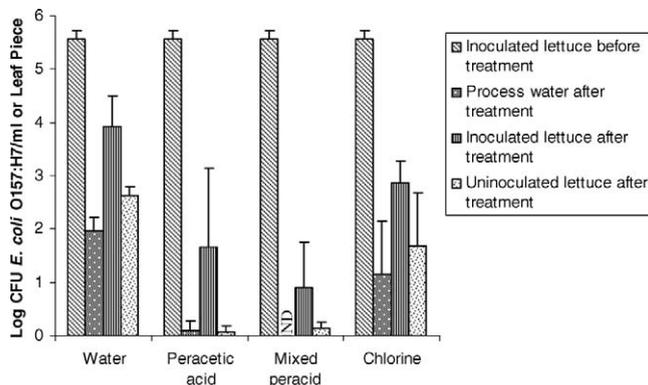


FIGURE 2. Comparison of antimicrobial agents at 30 ppm in processing water in the presence of 10% organic load for their effect on *E. coli* O157:H7 in processing water and on inoculated and uninoculated lettuce leaves. ND, not detected. The experiment was repeated three times. One sample was evaluated for inoculated lettuce before treatment, processing water after treatment, and inoculated lettuce after treatment in each replicate. Five samples were evaluated uninoculated lettuce after treatment in each replicate. Error bars represent the standard deviation.

significantly more effective than water for reducing *E. coli* O157:H7. In the presence of 10% organic load in processing water, peroxyacetic acid and mixed peracid at 30 ppm significantly reduced the contamination of uninoculated leaves by *E. coli* O157:H7 (ca. 0.1 log CFU per leaf piece), whereas chlorine at 30 ppm left 1.68 log CFU per leaf piece on uninoculated leaves (Tables 1 and 2). Results of this study revealed that mixed peracid at 30 ppm in the presence of organic load was more effective for inactivating *E. coli* O157:H7 in processing water and preventing contamination of uninoculated leaves than was chlorine at 30 ppm.

The organic load had a greater effect on the efficacy of chlorine than on that of peroxyacetic acid and mixed peracid. The 10% organic load in the processing water reduced the efficacy of chlorine at 30 ppm but had only minor effects on the mixed peracid and peroxyacetic acid treatments at 30 ppm. For example, *E. coli* O157:H7 counts in posttreatment water with 30 ppm of chlorine, peroxyacetic acid, or mixed peracid but without organic load were 0.49 log CFU/ml, not detected, and not detected, respectively, but with 10% organic load were 1.15 and 0.1 log CFU/ml and not detected, respectively (Tables 1 and 2). The organic load also negatively impacted the effectiveness of chlorine at 30 ppm but not the effectiveness of mixed peracid or peroxyacetic acid for preventing the transfer of *E. coli* O157:H7 to the uninoculated leaves. *E. coli* O157:H7 was not detected on uninoculated leaves after treatment with 30 ppm of peroxyacetic acid or mixed peracid without organic load, but the pathogen counts increased by approximately 0.1 log CFU per leaf piece in the presence of 10% organic load. In contrast, treatment with 30 ppm of chlorine resulted in an increase of *E. coli* O157:H7 on uninoculated leaves from 0.19 log CFU per leaf piece without organic load to 1.68 log CFU per leaf piece with 10% organic load (Tables 1 and 2). Thus, the reuse of processing water and subsequent buildup of organic matter both influence the effectiveness of antimicrobial treatments.

The results of this work revealed the potential impact of organic load on the effectiveness of antimicrobial treatment used to reduce the transfer of *E. coli* O157:H7 from contaminated leaves to the processing water and to uncontaminated leaves. Although this study did not replicate conditions that exist during processing, it illustrates the need to evaluate more than just the antimicrobial concentration when validating the effectiveness of produce processing controls. Factors such as organic load, fluid/produce ratio, antimicrobial type and concentration, and other variables during processing can have a profound effect on the potential for spreading contamination throughout a production lot. Additional research on the critical factors beyond antimicrobial type and concentration is needed to enhance pathogen control during produce processing.

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Web reference in support of 2010 CFP conference for issue:

Title: Antimicrobial Treatments for Washing Fruits and Vegetables

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- FDA 2008 Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlantProducts/ucm064458.htm> (Sections VIII.C.2.a and VIII.2.C.b)

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 036
Issue: 2010 III-006**

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

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Title:

4-501.19 Manual & Mechanical Warewashing Equipment, Wash solution Temp.

Issue you would like the Conference to consider:

Manual warewashing in retail food establishments has been dependent on a number of variables to assure effective cleaning. Temperature is but one variable that is dependent on the cleaning agent used, the type of manual washing processes, the volume of wares being washed as well as the type and where they originate (i.e., hot or cold environments). Additionally, the temperature variable has been a challenge in warewashing in refrigerated environments such as meat markets. To overcome this variable, food retailers have worked with their chemical suppliers to provide cleaning agents (detergents) that work in a variety of environments as well as in warm versus hot water with consistent results. Force applied 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. It is for this reason that 77% of the CFP 2006-2008 Criticality Committee recommended that this section be classified as a "Core ^C item." The 2009 Food Code classified this section as a "Priority Foundation ^{Pf} item." Due to the variables inherent in manual warewashing this section should be classified as "C" versus "Pf". In addition, water temperatures referenced within other areas of the 2009 Food Code allow for lower water temperatures used in conjunction with hand washing which suggests the water temperature can be lowered for all detergents, regardless of the cleaning task. The end result is not the temperature of wash water solution but the application of all the variables that apply to proper washing so that the items being cleaned are visually free of soil prior to the sanitization step.

Public Health Significance:

Retail food establishments have adjusted methodologies in manual warewashing processes to assure wares and utensils are properly cleaned prior to rinsing and sanitizing. Temperature is but one variable that can be compensated with proper scrubbing, water pressure spray devices, low temperature detergents among others. This is similar to FDA lowering the handwashing temperature requirements in the Food Code from 110°F to 100°F without increasing risk. If one reviews the definitions of Core ^C items and Priority Foundation ^{Pf} items, this section would fall under the general sanitation, operational controls, or Sanitation Standard Operating Procedures (SSOP) rather than those defined under Priority Foundation ^{Pf}. By requiring the wares/equipment being cleaned are visually

free of soil prior to sanitization makes the temperature but one variable that may need adjustment.

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 "P" 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.

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) a temperature to effectively remove visible soil. or the temperature specified on the cleaning agent manufacturer's label instructions.~~ ^{C Pf}

Further, the Annex 3 reference to Manual and Mechanical Warewashing Equipment, Wash solution Temperature be revised to address the importance of controlling the variables that help remove soils from the wares or utensils during washing and rinsing to assure effective sanitizing. An example change by replacement of the existing section is as follows:

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature is important for removing organic matter along with other variables. If the temperature is too low, 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 unless detergents are adjusted to work at lower water temperatures or other variables like power spraying, turbo washing, or heavy scrubbing are used. The manufacturer's label instruction should be consulted and followed for the correct application pertaining to cleaning agent. The items being washed should be visually cleaned by noting the absence of soil prior to sanitization.

~~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.~~

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 037
Issue: 2010 III-008**

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

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Title:

Establishment of Criteria for Presence and Use of General Purpose Cleaners

Issue you would like the Conference to consider:

Currently there are no formulation or label requirements defined in the Food Code or 21 CFR for General Purpose Cleaners and related products, despite the fact that these products are widely used in proximity to food, as well as on food contact surfaces. Common types of chemical cleaners used within food service establishments include: general purpose cleaners, floor and wall cleaners, scouring agents, carbon removers and degreasers for cooking surfaces and utensils. The Food Code currently addresses several types of chemical compounds in Section 7-2, including chemicals, lubricants, pesticides, medicines and first aid supplies. However, one of the products most commonly found in retail food establishments are general purpose cleaners. USDA/FSIS previously addressed these products (Categories A1, C1) which provided criteria for presence and use, in its "White Book" program which was terminated in 1999. The recommended solution below reflects USDA/FSIS criteria for cleaners in its White Book program, and despite the program's termination as part of an overall transition to HACCP, remains the best available minimum criteria for general purpose cleaners.

Public Health Significance:

The Food Code does not have detailed criteria for the presence and use of general purpose cleaners. The proliferation of new "green" cleaners and other new cleaning formulations presents possible new contamination risks. The Food Code should provide more detailed guidance on formulations and use of general purpose cleaners.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending the creation of a new section (7-204.15) to read as follows:

- Chemical cleaner formulations shall not contain intentionally added heavy metals such as lead, mercury, arsenic, antimony, or known human carcinogens. Fragrance components such as pine oil or d-limonene are not acceptable at detectable levels. Boric acid and salts thereof may be used in products only at concentrations up to 90 percent in association with strong acids, strong alkalis, soaps, or synthetic detergents. Products shall be labeled for use within food establishments. Instructions

specifying that use of chemical cleaners must be followed by a potable water rinse shall be included on the label, except for cleaners used in areas with subfreezing temperatures. Metal cleaners/polishes may only be used on non-food contact surfaces, and do not require a potable water rinse after use.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 045
Issue: 2010 III-014**

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

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Title:

Hand Sanitizer Use between Glove Changes

Issue you would like the Conference to consider:

According to current FDA Food Code requirements, hands must be washed between glove changes. The use of a Food Code-compliant hand sanitizer should be permitted in lieu of a full hand wash between glove changes. Enabling the use of effective hand sanitizer between glove changes when there is not visible soil present may enhance compliance with personal hygiene requirements and therefore reduce the risk of food borne disease. Specific procedures for glove removal should be provided and the requirement for hand washing between glove changes should remain when gloves have been torn or hands have become soiled.

Public Health Significance:

CDC reports the number of food borne illness outbreaks associated with hand contact, with or without gloves, from 1998-2002 (Lynch et al, 2006) (Table 1) See Attachment for all Tables referenced. Norovirus is the dominant etiology for both bare-hand and gloved-hand contact. This is why hand washing before donning gloves the first time is essential. However, after hands have been washed, bacterial agents are the concern because they may be naturally present on some foods or on humans. Additionally, gloves may serve as "incubators" and allow bacteria to multiply inside the glove. This is not true for viruses; therefore use of hand antiseptics known to be effective against bacteria should be sufficient when changing gloves. Many hand antiseptics provide a 4 to 5 log reduction for vegetative bacteria through in vitro tests.

Hand antiseptic effectiveness

There are several test methods available to evaluate the efficacy of a hand antiseptic. Laboratory (*in-vitro*) tests are most frequently used for Food Code compliant hand antiseptics because they provide greater flexibility and the test can be conducted on a number of pathogens to determine their relative susceptibility to the hand care product. Laboratory-based methods also reduce the variation that may be observed between individuals (e.g., the amount of product used, the size of the hand, the thoroughness or rubbing, etc.).

Human subject tests (*in-vivo*) can be done to study the impact of additional factors such as the mechanical removal of the test organism on the hands. However, because human

subjects are involved, generally a surrogate is used to represent pathogens and judgment is required to extrapolate the efficacy against a range of pathogens. The level of reduction observed through *in-vivo* testing is typically lower than that for *in-vitro* tests.

Table 2 provides an example of the variety of organisms that can be tested for a commercial Food Code compliant product, and lists the log reduction achieved using an *in vitro* test. Many of the organisms listed are not concerns for food borne illness. Results will vary by product, and potential by lab, strain, organism, and method used. For this study, 1 ml of culture was exposed to 10 ml of product for 15 sec then neutralized and plated for residual counts. (Swanson, 2009)

Alcohol is not the only active component that can provide an effective kill in a hand sanitizer. Table 3 provides an example of data for a hand antiseptic based on a quaternary ammonium compound. Because it is non-volatile, it may take longer for the product to evaporate than an alcohol based hand antiseptic, therefore the level of reduction for several periods of times is listed (Swanson, 2009).

References:

Lynch et al. 2006 Surveillance of food-borne disease outbreaks - United States, 1998-2002 MMWR 55(2210):1-34.

Swanson K 2009 Personal communication, December 17, 2009.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that § 2-301.16 be amended by adding ¶ (D) with the following language:

2-301.16 (D) Hand antiseptics may be used in lieu of hand washing between glove changes that occur with no intervening contamination of food preparation by hands provided that:

(1) Hands are washed prior to donning gloves;

(2) Gloves are removed using a wrist-down motion, a hand antiseptic is applied to hands and thoroughly rubbed into the hands prior to regloving; and

(3) Hands must be washed if gloves are torn or hands become soiled.

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Attachments:

- "Tables"

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Table 1. US reported hand-related outbreaks 1998-2002 (adapted from Lynch et al 2006)

Etiology	Bacterial	Bare-hand contact		Gloved-hand contact	
		37	40%* 94	4	35% 19
	<i>Salmonella</i>				
	<i>Staphylococcus aureus</i>	17		5	
	<i>Shigella</i>	12		3	
	<i>Escherichia coli</i>	12		1	
	<i>Clostridium perfringens</i>	8		2	
	<i>Campylobacter</i>	5		2	
	<i>Vibrio parahaemolyticus</i>	2		1	
	<i>Bacillus cereus</i>	1		1	
Viral & Parasitic	Norovirus	129	60% 143	30	65% 34
	Hepatitis A	13		4	
	<i>Giardia intestinalis</i>	1		-	
Multiple etiologies				2	1
Unknown etiology				526	132

Table 2. Log₁₀ reduction of microorganisms in 15 seconds using a "time kill" protocol (10 ml Food Code compliant, alcohol-based product, 1 ml culture)

Organism	Log reduction
<i>Acinetobacter baumannii</i>	>6.64
<i>Bacillus megaterium</i>	>5.78
<i>Citrobacter freundii</i>	>6.64
<i>Clostridium difficile</i>	5.03
<i>Corynebacterium diphtheriae</i>	>6.96
<i>Enterobacter aerogenes</i>	>6.59
<i>Enterococcus faecalis</i> MDR, VRE	>6.55
<i>Enterococcus faecium</i> MDR, VRE	>6.55
<i>Escherichia coli</i>	>5.97
<i>Escherichia coli</i> O157:H7	>5.70
<i>Klebsiella pneumoniae</i> subsp. <i>ozaenae</i>	>6.51
<i>Klebsiella pneumoniae</i> subsp. <i>pneumoniae</i>	>6.57
<i>Lactobacillus plantarum</i>	>5.80
<i>Listeria monocytogenes</i>	>6.74
<i>Proteus mirabilis</i>	>6.67
<i>Proteus vulgaris</i>	>6.70
<i>Pseudomonas aeruginosa</i>	>6.57
<i>Salmonella</i> Enteritidis	>6.92
<i>Salmonella</i> Typhimurium	>6.82
<i>Serratia marcescens</i>	>6.62
<i>Shigella dysenteriae</i>	>6.32
<i>Shigella sonnei</i>	>6.72
<i>Staphylococcus aureus</i> MRSA	>6.64
<i>Staphylococcus epidermidis</i>	>6.64

Table 3. Log₁₀ reduction of microorganisms using a "time kill" protocol (10 ml of Food Code compliant, quat-based product and 1 ml of culture)

Organism	Log reduction			
	15 sec	30 sec	60 sec	
<i>Enterobacter faecalis</i> VRE	>4.60		>4.60	>4.60
<i>Escherichia coli</i>	>5.00		>5.00	>5.00
<i>Escherichia coli</i> O157:H7	3.48		>5.00	>5.00
<i>Listeria monocytogenes</i>	4.70		5.00	>5.00
<i>Pseudomonas aeruginosa</i>	>5.00		>5.00	>5.00
<i>Salmonella choleraesuis</i>	>5.00		>5.00	>5.00
<i>Serratia marcescens</i>	>5.00		>5.00	>5.00
<i>Shigella flexneri</i>	>4.30		>4.30	>4.30
<i>Staphylococcus aureus</i>	>5.00		>5.00	>5.00
<i>Staphylococcus aureus</i> MRSA	>5.00		>5.00	>5.00
<i>Staphylococcus epidermidis</i>	4.70		>5.00	>5.00
<i>Streptococcus pyogenes</i>	>4.30		>4.30	>4.30
<i>Candida albicans</i>	>3.77		>3.77	>3.77

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 047
Issue: 2010 III-013**

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

All information above the line is for conference use only.

Title:

Bare Hand Contact for RTE Ingredients that are Fully Cooked After Handling

Issue you would like the Conference to consider:

Foods that may be ready to eat (RTE) but are not treated as RTE in their application should not be regarded RTE. RTE foods that are further fully cooked should be treated as raw foods and bare hand contact should be permitted. An example of this case is pizza toppings for commercial pizza operations. These items, e.g., cooked ground meat, cooked sausage and fresh uncooked vegetables, are RTE. However, they are ingredients placed on a pizza that is the baked in commercial ovens and served as a fully cooked pizza. Therefore, these items in this cooked pizza application are ingredients and should be able to be handled with properly cleaned bare hands.

Public Health Significance:

It is important that fully cooked foods meet the time and temperature requirements identified in the FDA Food Code. In this case, given that some of the RTE items on pizzas are animal products, the requirements for fully cooked status are Subparagraph 3-401.11 (A) (2) for comminuted, mechanically tenderized or injected meats, requiring 155 degrees F for 15 seconds; and Subparagraph 3-401.11 (A) (3) for poultry products, which requires cooking to internal temperature of 165 degrees F for 15 seconds. These temperatures and times, or their equivalents, are recognized as effective to destroy pathogenic bacteria in raw products that permit bare hand contact.

In order for ingredients to be handled with bare hands, they would not be considered RTE but instead as raw materials. The finished product for the consumer, in this case a pizza, is fully cooked to at least an internal temperature of 165 degrees F for 15 seconds. In addition, food establishments follow other Food Code requirements for personal hygiene and avoidance of cross-contamination to ensure that both ingredients and finished products are safe to consume and meet all FDA Food Code requirements.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that ¶ 3-301.11 (D) be amended by adding a new Subparagraph 3-301.11 (D) (1) with the following language:

3-301.11(D) (1) the ready-to-eat food is further fully cooked.

and renumbering ¶ (D) subparagraphs appropriately,

OR

that § 3-404.12 be added to the FDA Food Code to address RTE ingredients that are further fully cooked. The Section should include the following language:

Ingredients from containers that are used exclusively in food products which are subsequently fully cooked are not considered RTE and may be handled with bare hands.

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 054
Issue: 2010 III-011**

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Title:

Report - Hot Holding Committee

Issue you would like the Conference to consider:

Acknowledgment of the Hot Holding Committee's report to the CFP 2010 Biennial Meeting.

Public Health Significance:

Sharing and applying the latest science and food safety knowledge allows stakeholders to have a share in the endeavor to promote a safe national food supply and thereby reduce the incidence of food borne illness.

Recommended Solution: The Conference recommends...:

acknowledgement of the Committee's Final report to the 2010 Biennial Meeting and thanking the committee members for their work.

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Attachments:

- "2008-10 Hot Holding Committee Final Report"
- "2008-10 Hot Holding Committee Roster"
- "2008-10 Hot Holding Committee Survey Summary"
- "2008-10 Hot Holding Committee Quantitative Microbial Risk Assessment Data"
- "2008-10 Hot Holding Committee Original Survey Document"

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COMMITTEE NAME: Hot Holding Committee

COUNCIL (I, II, or III): III

DATE OF REPORT: January 8, 2010

SUBMITTED BY: Donna M. Garren and Roger E. Coffman, Co-Chairs

COMMITTEE CHARGE(s):

Study Change of Hot Holding Temperature from 135°F to 130°F. The 2008 Biennial Meeting recommended that a committee be formed under the direction of Council III to address the issues of hot holding temperatures and times, and any microbial risks that may be associated with different temperatures and times, as well as the accuracy and proper use of temperature measuring devices for this purpose and report back to Council III at the 2010 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The analysis of TCS (temperature control for safety) food hot holding temperature data available to the Committee from academic, regulatory, and industry sources around the country, combined with the results of the Hot Holding Committee survey that was conducted via e-mail distribution to retail food companies in June, 2009 (see attachments titled: *Original Survey Document* and *Summary of Completed Survey*), resulted in these answers:

- Regardless of the regulated TCS hot holding temperature requirements in various United States jurisdictions (130°F., 135°F., 140°F., 145°F., or 150°F.), the recorded TCS food temperature data assembled showed that a wide range of hot holding food temperatures are occurring (170°F. to 105°F.). TCS hot holding temperatures of 129°F. and below can allow organisms, such as *Clostridium perfringens*, to multiply in an un-controlled environment, increasing the risk of foodborne illness.
- It is reasonable to interpolate that in the majority of cases, **the commercially manufactured hot holding units are set up, and have the ability to hold TCS food at the current regulatory/industry temperature standard of 130/135°F. or above.**
- Food temperatures measured and reported at colder levels (from 130/135°F. down to 105°F.) indicate the food was affected by stratification in the hot holding unit. The colder temperatures for the top of food in hot holding units (steam tables) are due to many issues, including “evaporative cooling”, lack of stirring, and to a lesser degree, equipment malfunction.
- Metal stem thermometers/metal stem thermocouples were the usual method of choice for temperature measurement. Some use of infrared thermometers for surface

temperature measurement was reported. Infrared thermometers would be less effective in gathering necessary information, due to the inability to measure the “internal” temperature of the TCS food items in steam tables (temperatures closer to the hot holding thermal heat source). A study of calibration methods for infrared units may also be necessary.

- Evaporative cooling is a major cause of the TCS hot holding food temperatures being below 130/135°F. Data showing how much temperature loss is attributed to evaporative cooling, which foods are affected more by the temperature loss (thick, protein foods such as refried beans), the elapsed times that are involved (4 hours as an example), and corrective measures needed must be included in future analysis projects.
- One limiting factor to evaluating the occurrence of *Clostridium perfringens* growth is that illnesses due to *Clostridium perfringens* are not a “reportable illness”, so data collection on the public health affects of this organism is sporadic at best.
- The unknown value needed to calculate a safe TCS hot holding temperature is the evaporative cooling temperature loss that can be expected in hot holding units.

In conclusion, a scientifically reviewed value for what can be labeled as the “**evaporative cooling range**” must be determined. The “evaporative cooling range” would be the temperature loss that can occur in TCS food due to evaporative cooling in a hot holding unit over a set time period. The temperature that organisms begin to grow in TCS foods (129°F. or below for *Clostridium perfringens*) must then be taken into account.

The scientifically based “evaporative cooling range” temperature could then be added to the 129°F. growth limit to calculate a scientifically based higher “safe” TCS hot holding temperature.

Hot holding food data must continue to be assembled, processed, and analyzed for this study. Representatives from academia, industry and regulators can evaluate the collected information to reach an accurate recommendation for a hot holding temperature requirement, based on the risk to grow an organism such as *Clostridium perfringens* in TCS foods held in hot holding units. It is recommended that the charge issued to the Hot Holding Committee be re-issued, so that this study can be continued.

It is the recommendation of the Committee to re-create the Hot Holding Committee to continue the on-going studies of the science and data available on hot food holding, including:

- A study of calibration methods for infrared units.
- A study of evaporative cooling and temperature loss, elapsed time, and corrective action.
- A final recommendation for a hot holding temperature requirement based on risk.

REQUESTED ACTION

The Hot Holding Committee is submitting two Issues for Council III's consideration:

Issue 1 – Report - Hot Holding Committee

Issue 2 – Re-Create - Hot Holding Committee

The following attachments are submitted with this report:

- Original Survey Document
- Summary of Completed Survey
- Quantitative Microbial Risk Assessment (QMRA) for Hot Holding Survey
Charts and Graphs
- 2008-10 Hot Holding Committee Roster

Committee	Last Name	First Name	Position (Chair/Member)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
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III-Hot Holding	Bohm	Shirley	Member	Regulatory Federal	USFDA - CFSAN	5100 Paint Branch Parkway	College Park	MD	20740	301-436-2096	shirley.bohm@fda.hhs.gov
III-Hot Holding	Brickey	Matthew	Member	Industry - Food Service	National Restaurant Association		Washington	DC			MBrickey@restaurant.org
III-Hot Holding	Brown	Patrick J.	Member	Industry - Retail Food Stores	The Great Atlantic & Pacific Tea Company	2 Paragon Drive	Montvale	NJ	07645	(201) 571-8039	brownp@aptea.com
III-Hot Holding	Brown	Robert	Member	Industry - Retail Food Stores	Whole Foods Market	550 Bowie Street	Austin	TX	78703	(512) 542-3043	robert.brown@wholefoods.com
III-Hot Holding	Chen	Yuhuan	Member	Industry - Retail Food Stores	Grocery Manufacturers Association	1350 I St, NW, Suite 300	Washington	DC	20005	(202) 639-5974	ychen@gmaonline.org
III-Hot Holding	Coffman	Roger	Co-Chair	Regulatory - Local	Lake County Health Department	118 South Main Street	Wauconda	IL	60084-1859	(847) 984-5002	rcoffman@lakecountyil.gov
III-Hot Holding	Cutrufelli	Mark	Member	Regulatory - Federal	USDA-FSIS		Washington	DC		(301) 604-5924	Mark.Cutrufelli@fsis.usda.gov
III-Hot Holding	Fandrey	Mary	Member	Regulatory - State	Missouri Department of Health & Senior Services	930 Wildwood Drive, PO Box 570	Jefferson City	MO	65102		mary.fandrey@dhss.mo.gov
III-Hot Holding	Garren, Ph.D.	Donna M.	Co-Chair	Industry - Food Service	The Consumer Goods Forum	4306 Orkney Ct.	Woodbridge	VA	22192	(703) 583-3567	d.garren@theconsumergoodsforum.com
III-Hot Holding	Goode	Steven J.	Member	Regulatory - Local	Southern Nevada Health District	625 Shadow Lane, PO Box 3902	Las Vegas	NV	89127	(702) 759-0596	goode@snhdmail.org
III-Hot Holding	Gordon	Christopher	Member	Regulatory- State	Virginia Department of Health	109 Governor St.	Richmond	VA	23219	(804) 840-0114	Christopher.Gordon@vdh.virginia.gov
III-Hot Holding	Kunduru	Mahipal	Member	Industry - Retail Food Stores	Safeway Inc.	5918 Stoneridge Mall Rd.	Pleasanton	CA	94588	(925) 226-9393	mahipal.kunduru@safeway.com

III-Hot Holding	Lane	Janet	Member	Regulatory - Local	Harris County Public Health and Environmental Services	2223 West Loop South	Houston	TX	77027-5588	(713) 439-6267	jlane@hcphe.org
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III-Hot Holding	McMahan	Thomas	Member	Industry - Retail Food Stores	Albertsons, Inc.	250 E. Parkcenter Blvd.	Boise	ID	83706	(208) 395-3265	thomas.mcmahan@supervalu.com
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III-Hot Holding	Morris	Sheri L.	Member	Regulatory - State	Pennsylvania Dept. of Agriculture/Div. of Food Safety	2301 North Cameron Street	Harrisburg	PA	17110-9408	(717) 787-4315	shmorris@state.pa.us
III-Hot Holding	Pascall	Melvin	Member	Academia	Ohio State University	Food Science and Tech., OSU	Columbus	OH	43210	(614) 292-0287	pascall.1@osu.edu
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III-Hot Holding	Uhler	Paul	Alternate - Member	Regulatory - Federal	USDA		Washington	DC		202-205-0438	Paul.Uhler@fsis.usda.gov
III-Hot Holding	Westbrook	Tim	Member	Industry - Retail Food Stores	Publix Super Markets	1950 sandlake Rd	Orlando	FL	32809	407 702 8294	tim.westbrook@publix.com
III-Hot Holding	Wilson	Cheryl	Member	Regulatory - State	Texas Dept. of State Health Services	PO Box 149347	Austin	TX	78714-9347	(512) 834-6753	cheryl.wilson@dshs.state.tx.us
III-Hot Holding	Zorn	David	Member	Regulatory - Federal	USFDA	5100 Paint Branch Pkwy	College Park	MD	20740	(301) 436-1825	david.zorn@fda.hhs.gov

Question 1: What type of product temperature monitoring devices do you use in your operations? (Check all that apply.)

- 21 Question 1: Bi-metallic
 - 27 Question 1: Digital
 - 12 Question 1: Infra-red
 - 26 Question 1: Thermocouple
 - 0 Question 1: Other, please specify
-
-

Question 2: Do you have written product temperature monitoring standard operating procedures for hot holding?

Yes 39 of 41

Question 2: •If yes, would you be willing to share? Please send attachments of your procedures to Co-Chair, Donna Garren at donna_garren@comcast.net.

Question 3: Do you calibrate your product temperature monitoring devices?

Yes 35 of 41

Question 4: How often do you calibrate the product temperature monitoring device?

- 0 Question 4: Every hour
- 2 Question 4: Every 4 hours or mid shift
- 21 Question 4: Once per day
- 13 Question 4: Once per week
- 4 Question 4: Not at all
- 7 Question 4: Other, please specify

Most electric are calibrated.
or when dropped
When replacing the battery
When temp is questioned, after it has been dropped
and if dropped
Before each shift
As needed, if there is a question as to the accuracy

Question 5: What method do you use to calibrate?

- 34 Question 5: Ice point method
- 1 Question 5: Boiling point method
- 2 Question 5: Both
- 2 Question 5: Other, please specify

hot water against a calibrated thermocouple done t
Auditor verify against mercury

Question 6: What is your corrective action when you find that your product temperature monitoring device is out of calibration? (Check all that apply)

- 25 Question 6: Manually calibrated
- 18 Question 6: Change battery
- 14 Question 6: Send to the manufacturer
- 17 Question 6: Discard and replace
- 3 Question 6: Other, please specify

Send for re-calibration internally
Record variance on the unit temporarily
Refer to mfr. calibration procedures

Question 7: Do you measure product temperature for hot holding continuously or periodically?

- 4 Question 7: Continuous
- 37 Question 7: Periodic

Question 8: If product temperature measurement is periodic, how often do you take temperature measurement?

- 3 Question 8: Hourly
- 13 Question 8: Every 2 hours
- 11 Question 8: Every 4 hours
- 14 Question 8: Other, please specify

4 times per day about every 3 hours
each shift in hot wells - check water temp
As required by our HACCP program
Every 3-hours
every 3 hours
Every 3 hours
2 times daily

Once Per Shift

Before shift and as product is replaced, every 3 h
1st cooked, then 3 periodic times throughout the day

Once per shift 8 hour shift

temped as part of cooking process plus holding temp

3 hours

varies with product/procedures

Question 9: If product temperature measurement is continuous, how is the measurement recorded?

2 Question 9: Automatic system

8 Question 9: Manual system (hand written record)

2 Question 9: Other, please specify

Batch cooking recording method

N/A

Question 10: If product temperature measurement is continuous, how is the measurement captured?

8 Question 10: Internal

2 Question 10: Ambient

2 Question 10: Other, please specify

N/A

some roasts are probed too

Question 11: Do you stir the product before taking temperature?

Yes 26 of 41

Question 12: What is the location you take temperature in the product?

4 Question 12: On the surface

35 Question 12: In the center of the product

1 Question 12: Along the edge

5 Question 12: As far in as the probe reaches

Question 13: Is the location of the temperature measurement dependent on the food type?

Yes 25 of 41

Question 14: How far do you insert the product temperature device if you take temperature inside the product? Give approximate distance.

- 2 Question 14: < 1 inch
- 12 Question 14: 1 inch
- 17 Question 14: 2 inches
- 4 Question 14: 3 inches
- 10 Question 14: Other, please specify

it depends on the item. Typically in the middle
Into the center
depends upon the ingredient
Products thin. Will measure as far in as possible
center
geometric center
depends on the product (probe tip to the center)
Varies by food item
depends on product
depends on product

Question 15: If you insert the product temperature device <1 inch, what type of measuring device do you use?

- 5 Question 15: Bi-metallic
- 10 Question 15: Other, please specify

Question 16: Are there specific areas of hot holding equipment that you monitor product temperatures-i.e. corners of hot plates versus middle?

- 7 Question 16: Middle of warmer
- 7 Question 16: Perimeters of warmer
- 29 Question 16: Not applicable

Question 17: What corrective actions do you take when the temperature of the product is out of compliance with normal temperature limits?

- 26 Question 17: Discard

- 27 Question 17: Reheat
 10 Question 17: Increase steam table temperature (increase thermostat and/or add sterno)
 0 Question 17: No action
 7 Question 17: Other, please specify

Follow HACCP procedures for that product
 Evaluate warming unit, call service if necessary.
 hardly ever find this. Always much hotter than 135
 Discard if no time was documented
 depends on time/temperature parameters
 reheat 1X then discard if again
 Depends on time & temp. of food

Question 18: If you choose to reheat the product, how many times do you reheat?

- 29 Question 18: One time
 1 Question 18: Two times
 0 Question 18: Three times
 7 Question 18: Do not reheat
 0 Question 18: Other, please specify

Question 19: What is your procedure for reheating?

- 16 Question 19: Microwave
 16 Question 19: Convection oven
 3 Question 19: Fryer
 4 Question 19: Rotisserie oven
 4 Question 19: Not applicable
 10 Question 19: Other, please specify

boiling water bath
 Steamer
 original cooking method
 boil over open flame
 water bath
 Combi-Oven
 steamer or stove top
 Steamer
 Steamer or stove top
 APW Cooker

Question 20: Are the product temperatures recorded?

Yes 35 of 40

Question 21: If temperatures are recorded, how is it recorded?

- 32 Question 21: Manually
- 5 Question 21: Electronically
- 1 Question 21: Other, please specify

N/A

Question 22: Is the product stirred periodically if on steam table?

Yes 36 of 38

Question 23: What is the maximum shelf life for each product during hot holding?

- 1 Question 23: 1 hour
- 4 Question 23: 2 hour
- 2 Question 23: 3 hour
- 19 Question 23: 4 hour
- 4 Question 23: 6 hour
- 6 Question 23: 8 hour
- 12 Question 23: Other, please specify

can be as much as a day (12 hours)

5 hrs

30 minutes, 12 hours, depending on product.

Any longer than that, becomes Quality Issue

average, time is product sp. (related to quality)

Varies from 10 mins to 4 hours depending on item

1 day

Note: 2 hours is for quality purposes

roasts can be held overnight used next day

varies with product, never exceeds 4 hours

Not to exceed the shift.

Products range from 10 minutes to 4 hours.

Question 24: What is done with the product when the maximum shelf life for hot holding has been reached at the end of service period or shift?

- 35 Question 24: Discarded
 6 Question 24: Cooled and held for reheating
 7 Question 24: Other, please specify

Cooled for packaging or conversion
 cooled and re-worked later
 One time reheat only.
 Hardly ever see. use all the product
 some items are cooled for reheating
 Some product are blast chilled and packaged.
 not applicable

Question 25: How are products held during hot holding?

- 4 Question 25: In packaged form
 22 Question 25: In bulk hot display
 15 Question 25: Both
 4 Question 25: Other, please specify

Pre portioned
 holding drawers on cook line
 usually in serving pans (buffet concept)
 wrapped in ovenable cook-in-bag

Question 26: If packaged, what type of container is used for hot holding?

- 15 Question 26: Plastic
 8 Question 26: Metal
 9 Question 26: Card board/paper
 4 Question 26: Other, please specify

China
 foil bottom, plastic tops or cardboard boxes
 lexan
 N/A

**Question 27: What type(s) of equipment do you use for hot holding food?
 (Check all that apply)**

- 9 Question 27: Hot plates
- 31 Question 27: Steam tables
- 14 Question 27: Heat lamps
- 18 Question 27: Soup kettles
- 11 Question 27: Combination, heat lamps and hot plates
- 12 Question 27: Other, please specify

Hot Box

Steam drawer

Warming cabinets and drawers

drawer style units

Electric Chafing Dishes

Warming cabinet.

Hot water bath on stove tops

alto shaam

APW Cook Units

alto shams and winston cabinets

compartmentalized product holding units

Dry heat display cases

Question 28: Do you address the effect of evaporative cooling? For example, do you cover or maintain in a hot case until it is served?

Yes 25 of 39

Question 29: What is the hot-holding temperature in your jurisdiction(s) with which you must comply? (check all that apply if multiple jurisdictions)

- 5 Question 29: 130 F
- 24 Question 29: 135 F
- 24 Question 29: 140 F
- 4 Question 29: 145 F
- 2 Question 29: Other, please specify

Not sure, internal policy is 165F

company standard for North America min.140F

Question 30: Do you hold product exceeding the temperature requirements in jurisdictions?

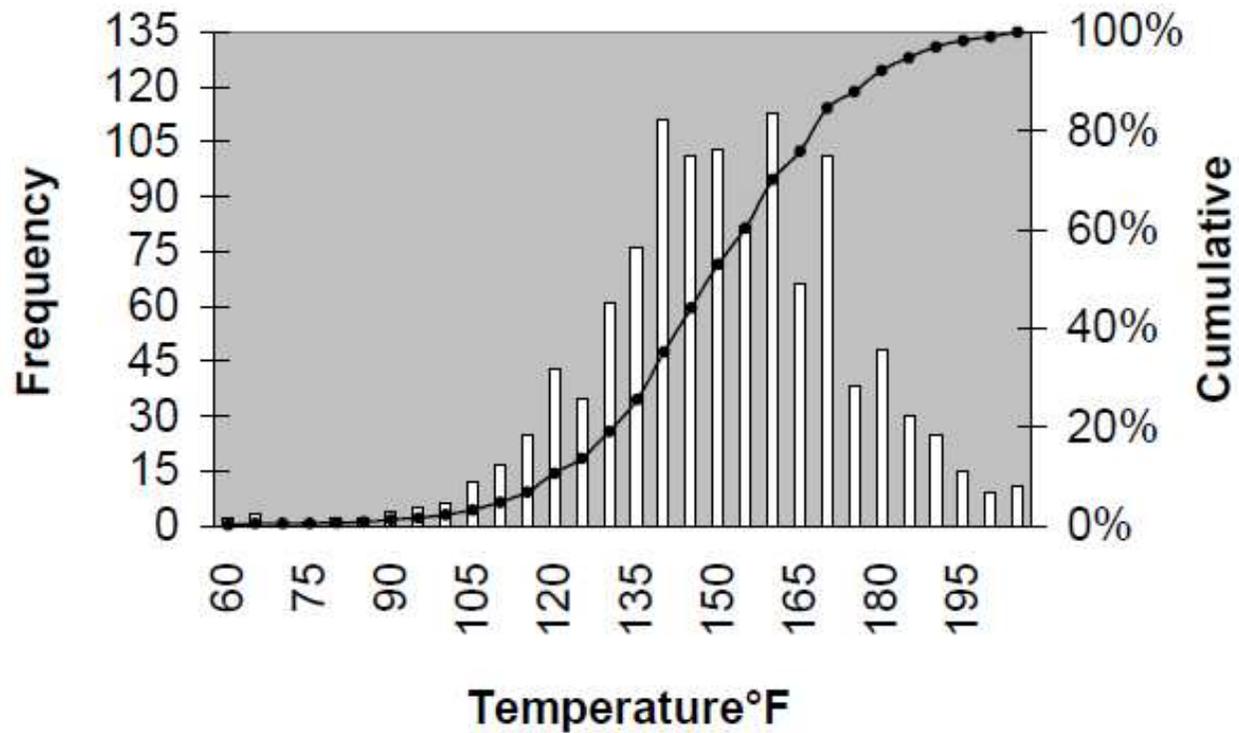
Yes 37 of 38

Simple preliminary QMRA for hot holding

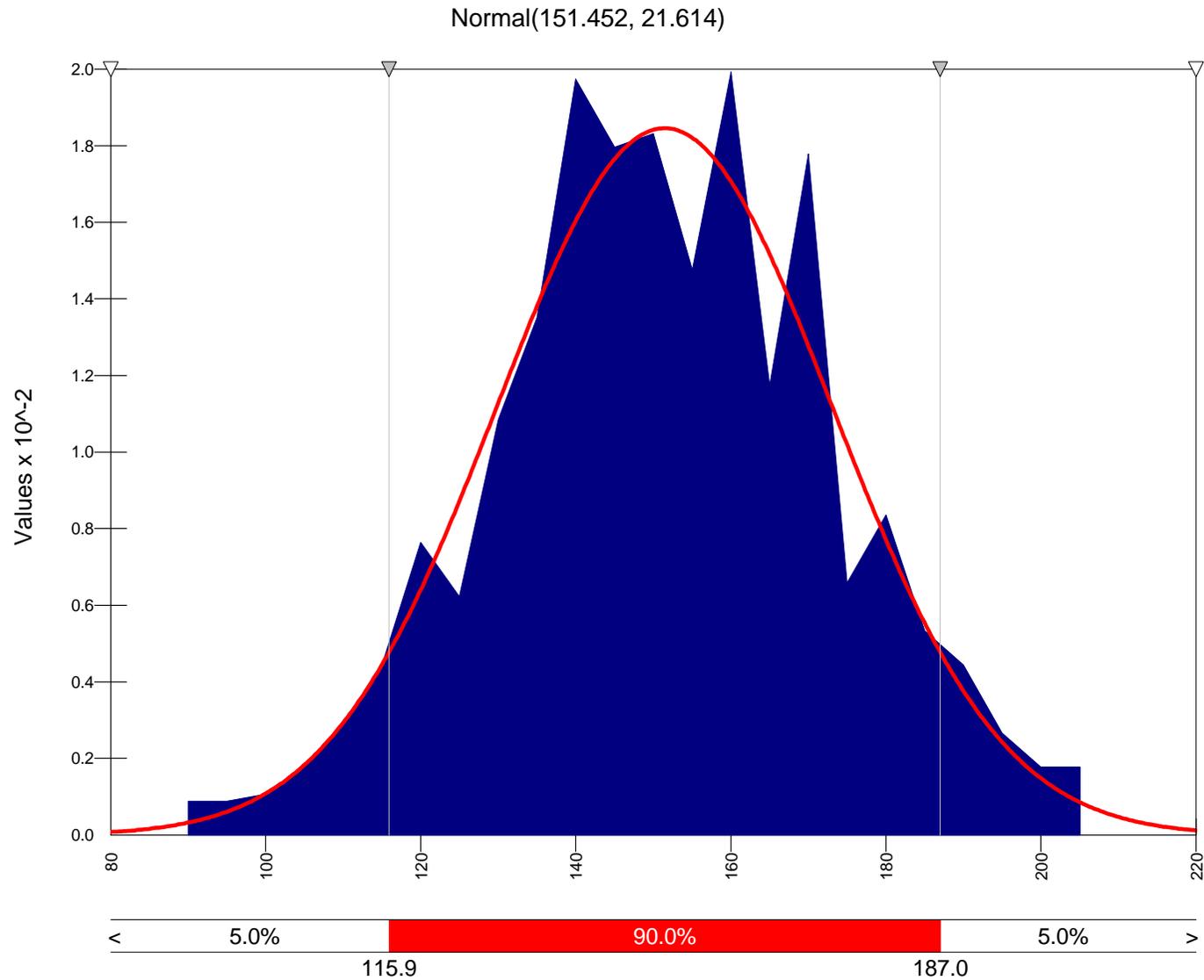
Don Schaffner

Temperature

Figure 1. Range and frequency distribution of hot holding temperatures in foods across food service and retail establishments in the U.S. (n=1147)



Normal distribution

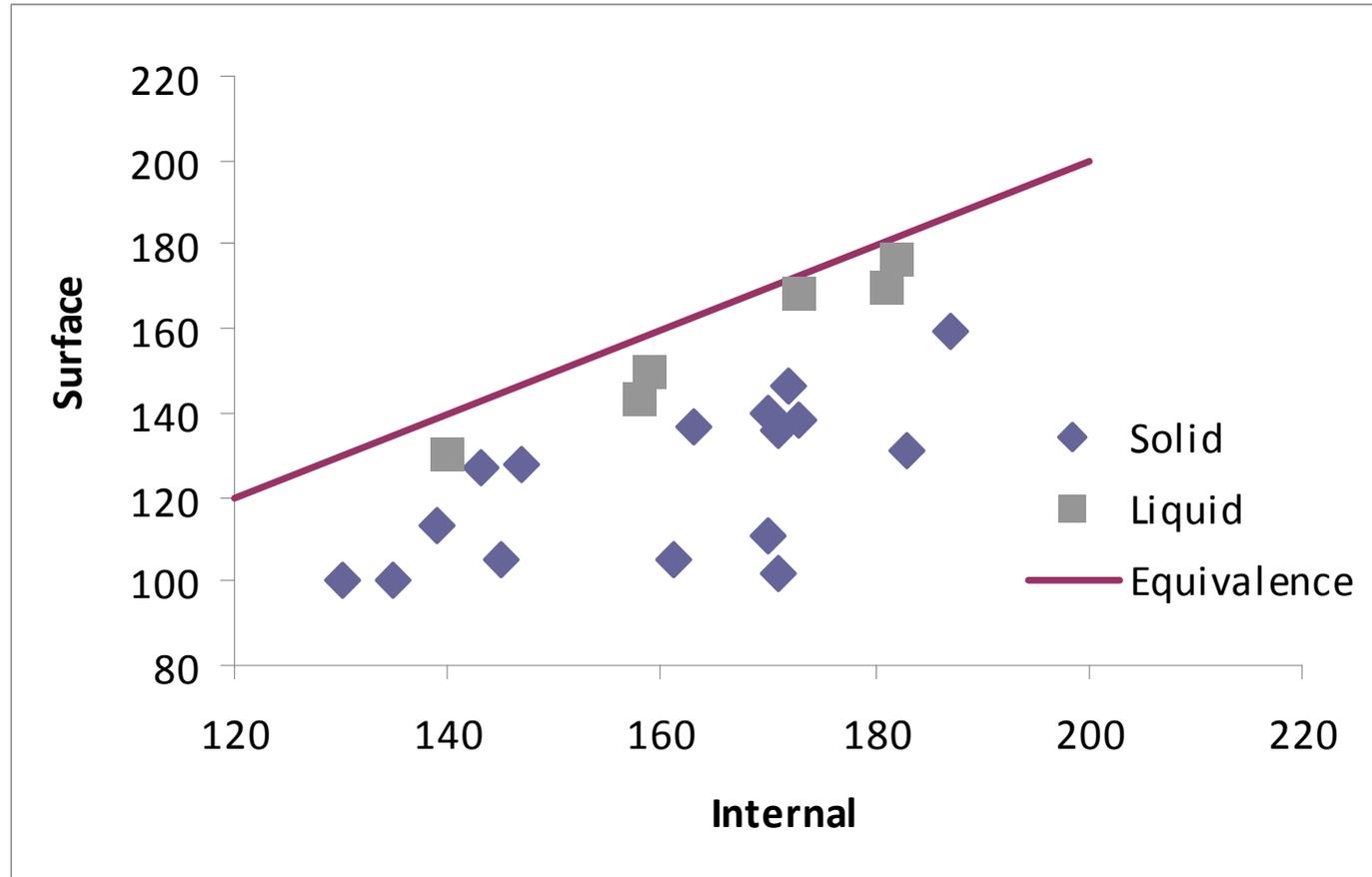


Evaporative cooling

Table 8. Temperature profiles (surface and interior) of hot held foods from four full service Maryland restaurants.

Product	Surface °F (std)	Interior °F (std)	Difference °F
Liquids:			
Gravy	150(3)	159(3)	9
Bean soup	170(4)	181(11)	11
Potato soup	168(7)	173(12)	5
Crab soup	176(5)	182(5)	6
White gravy	143(2)	158(2)	15
Clam chowder	130 (5)	140(6)	10
Solid or Semi-Solid			
Refried beans	105(7)	161(3)	56
Refried bean dip	105(6)	145(8)	40
Charro beans	136(7)	171(3)	35
Baked beans	131(4)	183(7)	52
Green beans	159(2)	187(4)	28
Mashed potatoes	127(5)	143(11)	16
Rice	137(3)	163(3)	16
Wild rice	146(14)	172(4)	26
Stuffing	138(5)	173(11)	35
Potatoes	140(8)	170(11)	30
Taco meat	111(12)	170(19)	59
Chicken	128(7)	147(15)	19
Beef	100(5)	130(4)	30
Turkey	113(5)	139(10)	26
Pork	98(4)	135(5)	37
Beef barbeque	102(6)	171(5)	69

Evaporative Cooling graph



Pathogens

Table 6. Effect of temperature on *Clostridium perfringens* growth parameters.

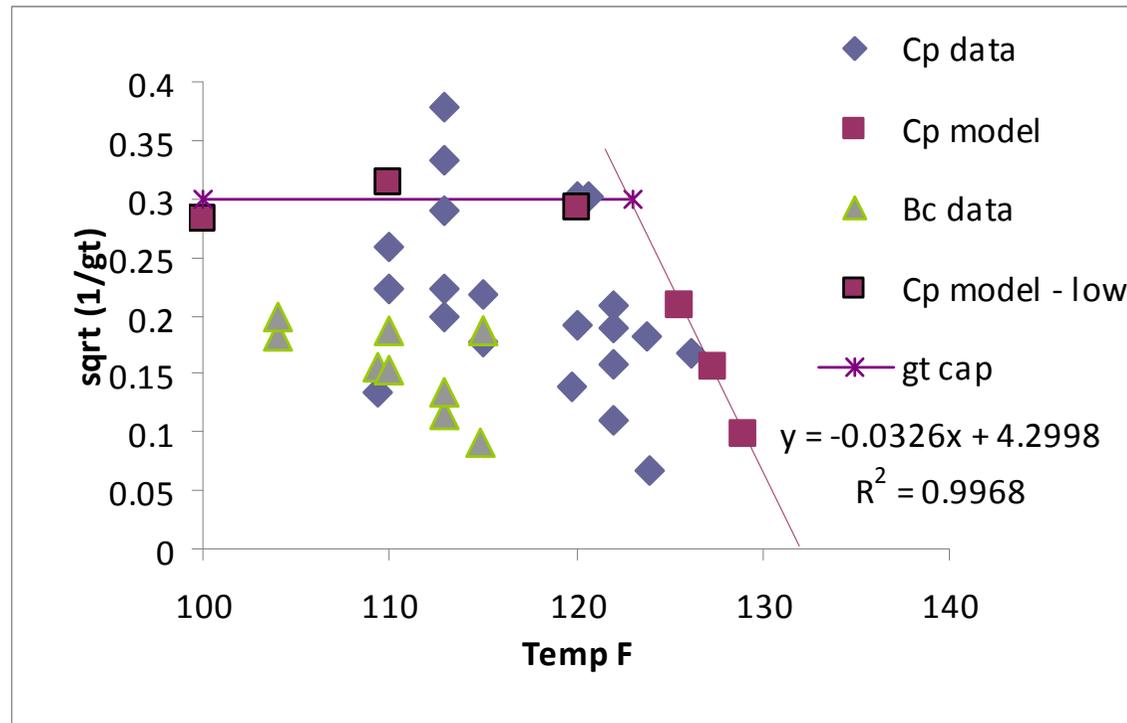
Temp °F	Temp °C	Food or substrate	Lag time (h) ^a	Generation time (min) ^a	pH	Bibliog.	
109.4	43	Cooked meat broth	0	58	-	6	
110	43.3	Chicken broth	1.08	20	6.4	7	
110	43.3	Cooked meat medium	0.73	15	6.8	7	
113	45	TG broth	0	20	-	17	
113	45	Cooked chicken thigh	0	12	-	7	
113	45	Autoclaved ground beef	1.5	7	6.1	21	
113							
113							
115	120.6	49.2	Autoclaved ground beef	ND	11	6.1	21
115	122	50	TG broth	0	23	7.2	17
119.8	122	50	Cooked roast beef	ND	84	-	4
120	122	50	Raw chicken breast	0	40	5.7	10
120	122	50	Raw chicken Leg	1	28	6.6	10
	123.8	51	Autoclaved ground beef	ND	30	6.1	21
	124	51.1	Cooked roast beef	ND	218	-	4
					36	7.0	25

Table 7. Effect of temperature parameters on *Bacillus cereus* growth.

Temp °F	Temp °C	Food or substrate	Lag time (h)	Generation time (min)	pH	Bibliog.
104	40	Skim milk	ND	30	6.6	18
104	40	TSB	ND	25	7	12
107.6	42	BHI	0	-	7.4	9
109.4	43	Rice	ND	41	-	19
110	43.3	Chicken broth	2.90	42	6.4	10
110	43.3	Cooked meat medium	2.10	29	6.8	10
113	45	TSB	ND	76	7.0	12
113	45	Rice + 10% beef extract	ND	55	7.0	12
114.8	46	BHI	ND	120	7.4	9
115	46.1	Chicken broth	4.50	29	6.4	10
115	46.1	Cooked meat medium	3.53	29	6.8	10
120	49.9	Chicken broth	NG	-	6.4	10
120	48.9	Cooked meat medium	NG	-	6.8	10
122	50	TSB	NG	-	7.0	12
122	50	BHI	NG	-	7.4	9
131	55	Rice + 10% beef extract	NG	-	7.0	12
131	55	TSB	NG	-	7.0	12
131	55	TSA	48	-	-	24

Generation times and lag phase duration reported in literature or estimated from graphs

Pathogens graphed

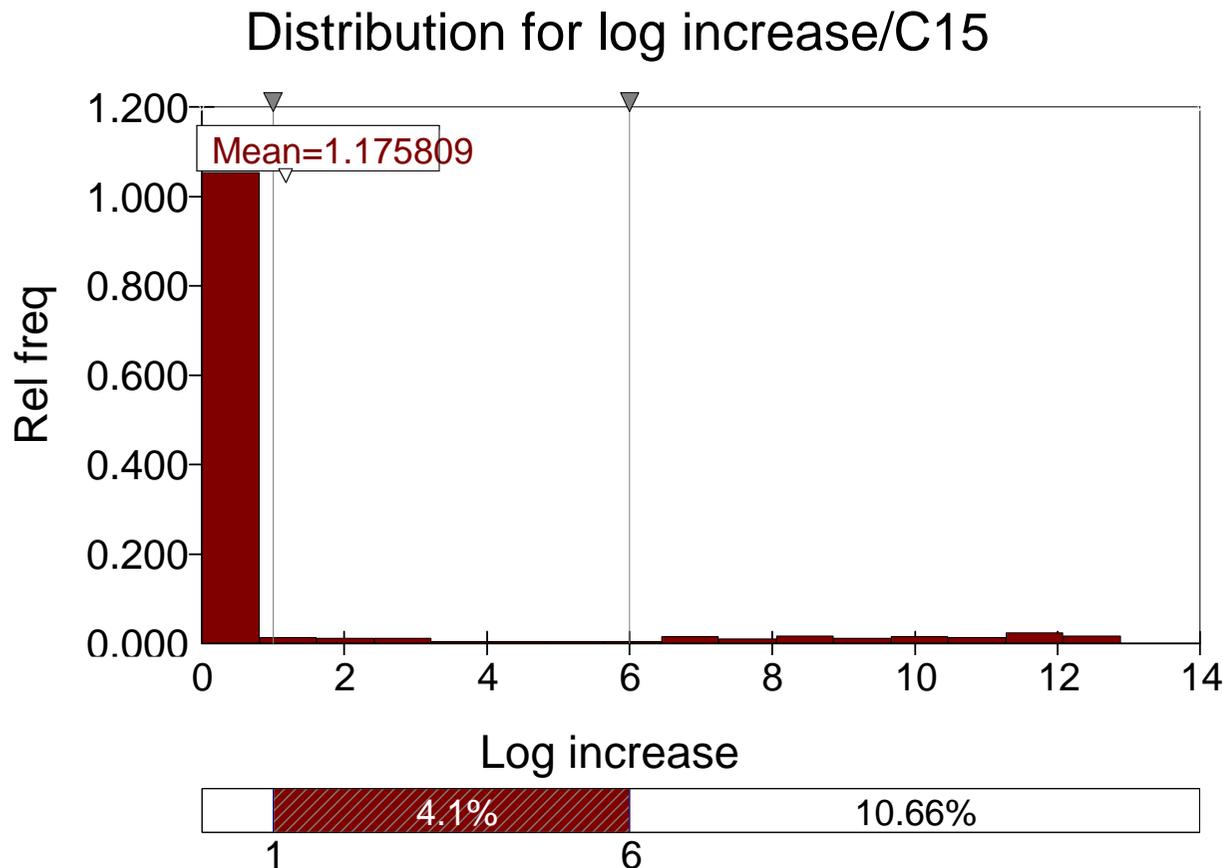


Model in @Risk, Excel

	A	B	C
1	Description	Source	Math
2	Temperature distribution	NACMCF - September 2001, pg 9	=RiskNormal(151.5, 21.6)
3	Magnitude of evaporative cooling	NACMCF - September 2001, pg 7	=RiskUniform(0,1)
4	Change due to EC	Assume varies uniformly from 100 F	=(C2-100)*C3
5	EC on or off, 1= on	Yes/no	0
6	Adjusted Temperature	Effect of EC	=C2-(C5*C4)
7	Error trap temp > 131.89	If temp > 131.89 no Cp growth	=IF(C6>131.89,131.89,C6)
8	sqrt 1/gt	NACMCF - September 2001, pg 4-5	=-0.0326*C7 + 4.2998
9	gen time (min)	calc from model	=1/(C8^2)
10	cap min gen time at 11 min	Cp can only grow so fast	=IF(C9<11,11,C9)
11	time (h)	assuming 4-8 hr	=RiskUniform(4,8)
12	time (min)	calc hr -> min	=C11*60
13	doublings Cp based on model	Calc	=C12/C10
14	CFU from 1	Calc	=2^C13
15	log increase	Calc	=RiskOutput("log increase") + LOG(C14)
16			
17			
18			

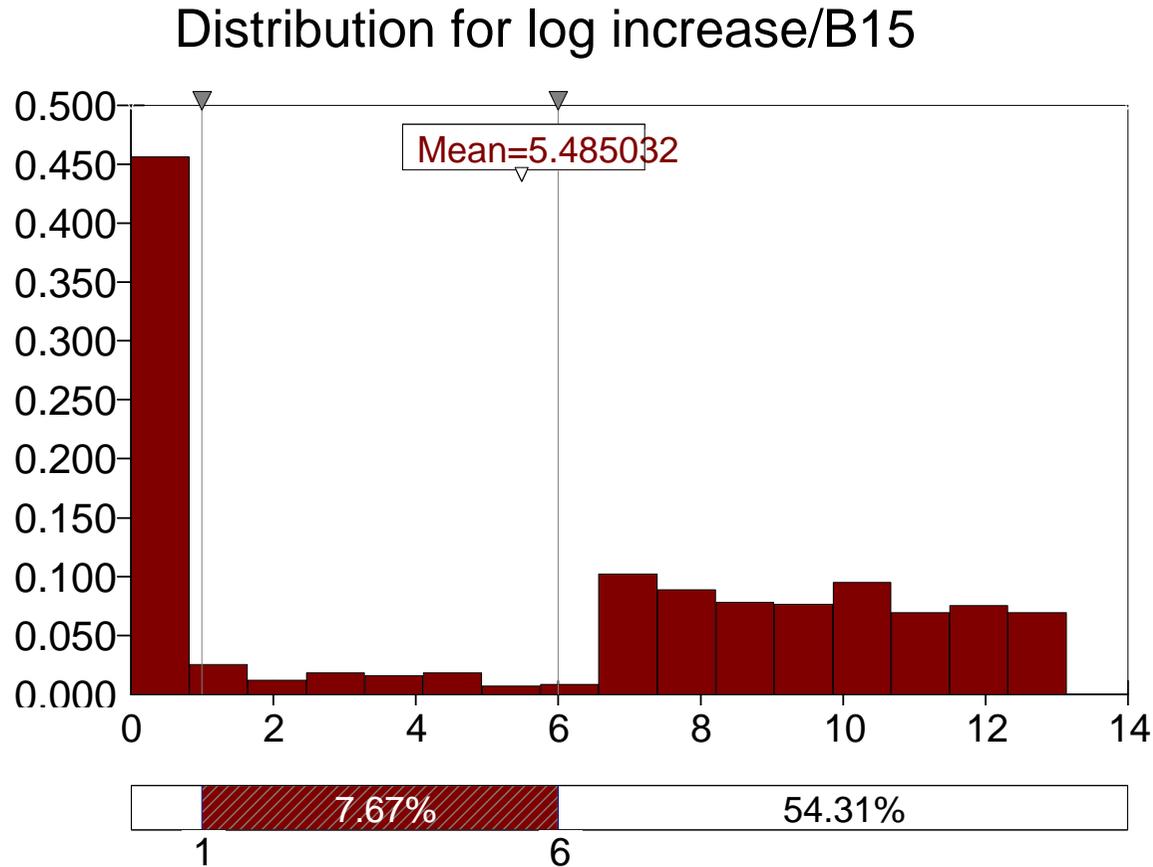
- Evaporative cooling effect is set on of off
- No good data on time, so time was assumed to vary from 4-8 hr

Simulation result, EC off



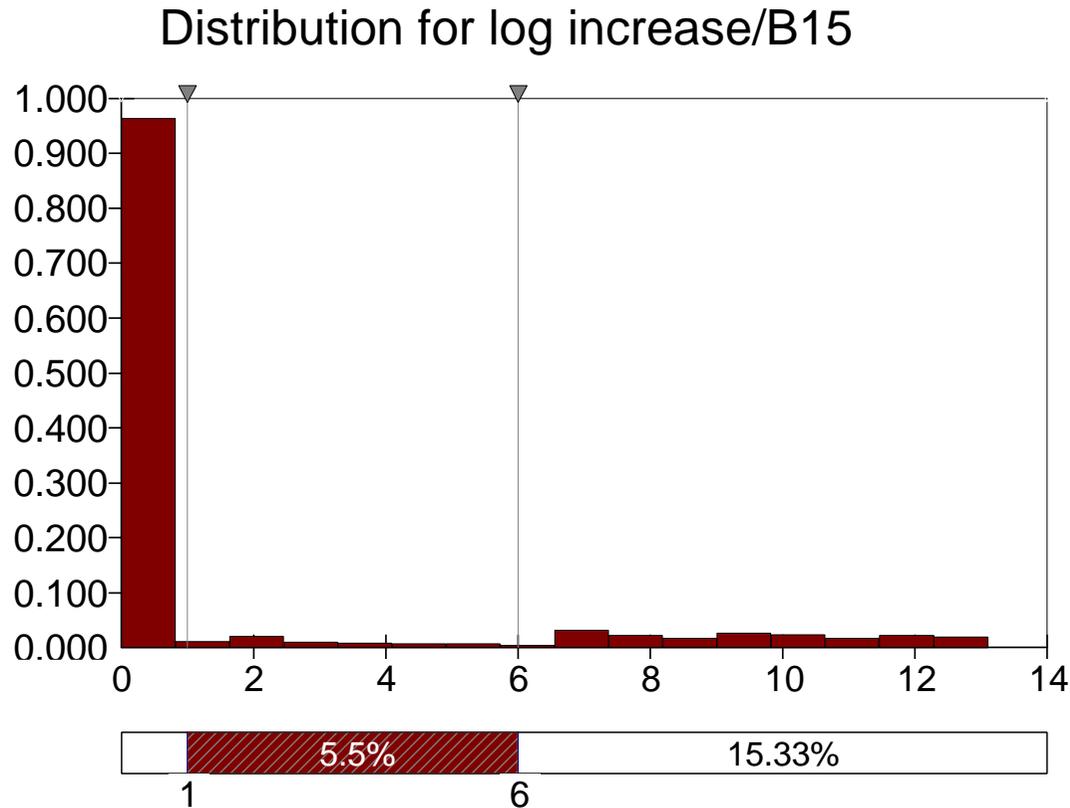
85% less than 1
log increase
10% very high
log increases
– Low
temperatures,
longer times

Simulation, EC on



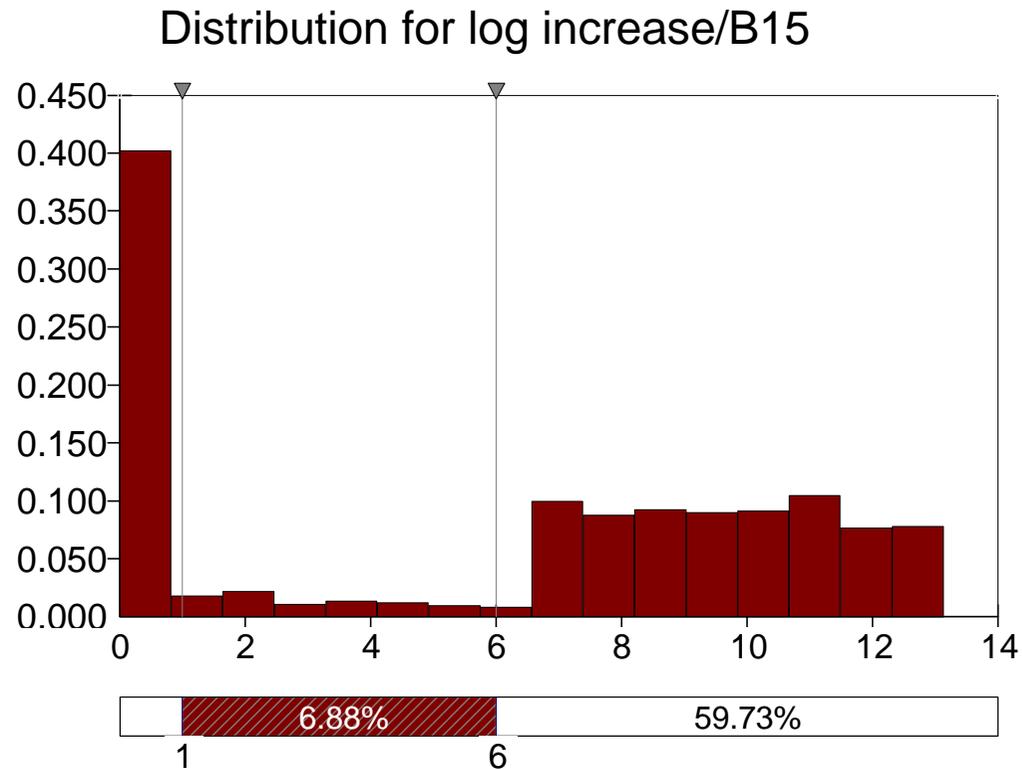
- ~38% less than 1 log increase
- 54% very high log increases

Simulation, EC off, Mean T↓5 F



- ~80% less than 1 log increase
- 15% very high log increases
- About a 5% increase in predictions of > 1 log CFU increase

Simulation, EC on, Mean T ↓ 5 F



- ~33% less than 1 log increase
- ~60% very high log increases

Simulation results

Fraction of the time the simulation predicts greater than a 1 log CFU increase during hot holding		
	Mean Temp 151.5	Mean Temp 146.5
No Evaporative Cooling	15%	21%
Evaporative Cooling assumed	62%	67%

More results, shorter times

- Mean 151.5, time = 0-4 hours, EC off
 - ~89% less than 1 log CFU
- Mean 146.5, time = 0-4 hours, EC off
 - ~85% less than 1 log CFU
- Mean 151.5, time = 0-4 hours, EC on
 - ~50% less than 1 log CFU
- Mean 146.5, time = 0-4 hours, EC on
 - ~45% less than 1 log CFU

Simplifications and assumptions

- Pathogens are always present
- Holding time varies uniformly, 0-4 or 4-8 h
- Lag time assumed to be zero
- All foods identical, all support growth
- Temperature constant throughout time period

Where to go from here?

- Remember a model is a like a map
 - It's only an abstract version of reality
 - Useful, not completely trustworthy
- Modify assumptions?
- Try different scenarios?
- Enhance and expand model?

Introduction: The Conference for Food Protection Hot Holding Committee is conducting a survey to gather data related to industry practices associated with hot holding food and product temperature measurements in retail and foodservice operations. All information collected in this survey is confidential. Any company information will be removed before a final report is shared with the Hot Holding Committee.

Directions: Please provide the response or responses that best describe your temperature monitoring and controls in your operations.

1. What type of product temperature monitoring devices do you use in your operations? (Check all that apply.)
 - Bi-metallic
 - Digital
 - Infra-red
 - Thermocouple
 - Other, please list:

2. Do you have written product temperature monitoring standard operating procedures for hot holding?
 - No
 - Yes.
 - If yes, would you be willing to share? Please attach your procedures to this survey.

3. Do you calibrate your product temperature monitoring devices?
 - No
 - Yes

4. How often do you calibrate the product temperature monitoring device?
 - Every hour
 - Every 4 hours or mid shift
 - Once per day
 - Once per week
 - Not at all
 - Other, please list:

5. What method do you use to calibrate?
 - Ice point method
 - Boiling point method
 - Both
 - Other method, please list:

6. What is your corrective action when you find that your product temperature monitoring device is out of calibration? (Check all that apply)
 - Manually calibrated
 - Change battery
 - Send to the manufacturer
 - Discard and replace
 - Other, please list:
7. Do you measure product temperature for hot holding continuously or periodically?
 - Continuous (go to question 9)
 - Periodic
8. If product temperature measurement is periodic, how often do you take temperature measurement?
 - Hourly
 - Every 2 hours
 - Every 4 hours
 - Other, please list:
9. If product temperature measurement is continuous, how is the measurement recorded?
 - Automatic system
 - Manual system (hand written record)
 - Other, please list:
10. If product temperature measurement is continuous, how is the measurement captured?
 - Internal
 - Ambient
 - Other, please list:
11. How and where do you measure product temperature? Answer following questions:
 - 11.1. Do you stir the product before taking temperature?
 - No
 - Yes
 - 11.2. What is the location you take temperature in the product?
 - On the surface
 - In the center of the product

- Along the edge
- As far in as the probe reaches

11.3. Is the location of the temperature measurement dependent on the food type?

- No
- Yes

11.4 How far do you insert the product temperature device if you take temperature inside the product? Give approximate distance.

- < 1 inch
- 1 inch
- 2 inches
- 3 inches
- Other, please list:

11.5 If you insert the product temperature device <1 inch, what type of measuring device do you use?

- Bi-metallic
- Other, please list:

11.6 Are there specific areas of hot holding equipment that you monitor product temperatures-i.e. corners of hot plates versus middle?

- Middle of warmer
- Perimeters of warmer
- Not applicable

11.7 What corrective actions do you take when the temperature of the product is out of compliance with normal temperature limits?

- Discard
- Reheat
- Increase steam table temperature (increase thermostat and/or add sterno)
- No action
- Other, please list:

11.8 If you choose to reheat the product, how many times do you reheat?

- One time
- Two times
- Three times
- Do not reheat
- Other, please list:

11.9 What is your procedure for reheating?

- Microwave
- Convection oven
- Fryer
- Rotisserie oven
- Not applicable
- Other, please list:

11.10 Are the product temperatures recorded?

- No
- Yes

11.11 If temperatures are recorded, how is it recorded?

- Manually
- Electronically
- Other, please list:

12. Is the product stirred periodically if on steam table?

- No
- Yes

13. What is the maximum shelf life for each product during hot holding?

- 1 hour
- 2 hour
- 3 hour
- 4 hour
- 6 hour
- 8 hour
- Other, please list:

14. What is done with the product when the maximum shelf life for hot holding has been reached at the end of service period or shift?

- Discarded
- Cooled and held for reheating

- Other, please list:
15. How are products held during hot holding?
- In packaged form
 - In bulk hot display
 - Both
 - Other, please list:
16. If packaged, what type of container is used for hot holding?
- Plastic
 - Metal
 - Card board/paper
 - Other, please list:
17. What type(s) of equipment do you use for hot holding food? (Check all that apply)
- Hot plates
 - Steam tables
 - Heat lamps
 - Soup kettles
 - Combination, heat lamps and hot plates
 - Other, please list:
18. Does your hot holding equipment have some type of certification, such as NSF or UL certification?
- No
 - Yes
19. Do you address the effect of evaporative cooling? For example, do you cover or maintain in a hot case until it is served?
- No
 - Yes
20. What is the hot-holding temperature in your jurisdiction(s) with which you must comply? (check all that apply if multiple jurisdictions)
- 130 F
 - 135 F
 - 140 F
 - 145 F
 - Other, please list:
21. Do you hold product exceeding the temperature requirements in jurisdictions?
- No
 - Yes

21. What are your hot holding requirements for products? (check all that apply)
 - 130 F
 - 135 F
 - 140 F
 - 145 F
 - Other, please list

22. Do you collect hot holding data in your operations?
 - No
 - Yes
 - If yes, would you be willing to share? Please attach your data to this survey.

23. Do you have 3rd party and/or internal audit reports on hot holding in your operations?
 - No
 - Yes
 - If yes, would you be willing to share? Please attach your data to this survey.

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 057
Issue: 2010 III-001**

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

All information above the line is for conference use only.

Title:

Report and Re-creation - Food Allergen Committee

Issue you would like the Conference to consider:

Acknowledgement of the Food Allergen Committee report and re-creation of the Committee to continue its work over the next two years.

Public Health Significance:

Nearly four percent of Americans (approximately 12 million) are affected by food allergies, including 3.7 percent of adults, and six percent of children younger than three years of age (Sicherer and Sampson 2006). Prevalence statistics vary according to methodology, including the assessment of food allergy via confirmed diagnosis, versus self-report (Rona, et al, 2007). Still, food allergy is a problem that pediatricians and scientists say is increasing among children (NIAID, 2006; Sicherer and Sampson, 2006). Additional research by FAAN (Food Allergy and Anaphylaxis Network) concludes that many food allergic reactions occur outside the home in restaurants and food service establishments.

Recommended Solution: The Conference recommends...:

acknowledgment of the Food Allergen Committee report and thanking the committee members for their work.

The Conference further recommends the 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.

Submitter Information:

Name: Tony Flood, Co-Chair
Organization: Food Allergen Committee
Address: International Food Information Council (IFIC)1100 Connecticut
Avenue, NW, Suite 430
City/State/Zip: Washington, DC 20036
Telephone: 202 296 4630 Fax: 202 296 6547
E-mail: flood@ific.org

Attachments:

- "Conference for Food Protection (CFP) Committee FINAL Report"
- "CFP Food Allergen 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 (CFP)
Committee FINAL Report**

COMMITTEE NAME: 2008 – 2010 Food Allergen Committee

COUNCIL (I, II, III): Council III

DATE OF REPORT: January 2010

SUBMITTED BY: Tony Flood and Gale Prince, co-chairs

COMMITTEE CHARGE(s):

1. Work directly with FDA pertaining to the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (continuation charge of 2004 biennial meeting)
2. Work with industry and deliver food allergen information to state / local regulatory officials; food managers; health professionals; and food employees through appropriate marketing / outreach channels.
3. The Conference further recommends that the Food Allergen Committee work with the FDA to develop an appropriate educational component regarding food allergen awareness.

**COMMITTEE ACTIVITIES (Progress Report)
SPECIFIC RECOMMENDATIONS**

Progress Report – Charge #1

Work directly with FDA pertaining to the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (continuation charge of 2004 biennial meeting)

- The CFP Food Allergen Committee is currently working with FDA to provide input and review of several resource and educational documents. These documents will help increase awareness about food allergy for the respective audiences as well as provide information and education for state / local regulatory officials; food managers; and food employees. The proposed projects for review include the following:
 - Provide input and review of the DRAFT allergen guidance document developed and written by FDA staff. The overall purpose of this “guide” is to serve as a resource for identifying and managing potential allergens that are present in foods at the food service level. It is also designed to complement the current food safety strategies that are already in place. We expect awareness will increase among users of this “guide”.
 - Timeline for completion – TBD

their respective audiences. We will seek to better understand how we might be helpful in crafting new allergy resources or repackaging existing resource materials that are useful to the target audiences. By identifying what is currently available in regards to food allergy resources and educational materials, we understand and ultimately are able to identify specific gaps in food allergy resources. By participating in this exercise, we will be better equipped to develop or recommend the development of a tangible product that would address the very essence of the committee charge.

- This activity will also provide an opportunity for the Committee to better understand and identify possible marketing and outreach strategies for the project. The Committee also discussed ideas to extend the outreach of the project and to engage stakeholders such as National Environmental Health Association (NEHA), Food Marketing Institute (FMI), National Restaurant Association (NRA), International Food Information Council (IFIC), Institute of Food Technologists (IFT Extension, the Food Allergy and Anaphylaxis Network (FAAN) and others as identified by the committee as possible venues for marketing and outreach strategies.
- We recommend this outreach to be “spearheaded” by groups like FAAN or IFIC – these organizations have established relationships with several health professional organizations such as the American Academy of Allergy, Asthma and Immunology (AAAAI), the American Academy of Pediatrics (AAP) and the American Medical Association (AMA) to name a few. The Committee would continue to provide input and perspective on any future outreach activities.
- Along with the development of an allergen resource page, the International Food Information Council Foundation is collaborating with the NRA, FAAN and AAAAI to revise its current food allergy poster for restaurant staff. The poster will be available for a nominal fee or in some instances free to all food allergy stakeholders via various networks including web sites. The poster will be made available in English and Spanish and will be available for the 2010 CFP Biennial Meeting. Members of the CFP Allergen Committee will have an opportunity to provide input. An issue will be submitted to the 2010 Biennial Meeting seeking FDA and CFP “endorsement” of the poster.

Progress Report: Charge #3

The Conference further recommends that the Food Allergen Committee work with the FDA to develop an appropriate educational component regarding food allergen awareness.

- The Committee discussed options to address the charge. As discussed, the Committee identified “regulators and industry that is regulated” as the target audience in this charge. We feel it is important for this Committee to increase its awareness of the current FDA food allergen activities as outlined in the Food Allergen Labeling and Food Protection Act (FALCPA). We will continue to reach out to our FDA representatives and identify opportunities to broaden the FDA engagement to better align ourselves with the current thinking, communication and education strategies regarding food allergy overall.
- To address this particular charge, the CFP Food Allergen Committee will provide a brief update during the 2010 Biennial meeting.
 - The focus of this proposed session is hoped to increase awareness about food allergy control efforts for retail / food service industry and regulatory officials.

Additional discussions:

- The Committee felt it necessary to reach out to the Food Allergy and Anaphylaxis Network (FAAN) a resource organization in the event we have issues or questions or needed clarification regarding consumer-related / advocacy issues. The Committee co-chair Tony Flood met with the new leadership of FAAN in early 2009.
 - Julia Bradsher, President and CEO of FAAN is very interested in being engaged with the CFP Allergen Committee and in December, provided an update to the CFP committee via web cast.

SPECIFIC RECOMMENDATIONS

The CFP Food Allergen Committee recommends re-creation of the Allergen Committee. We also recommend the Committee be charged with the following:

- Identify appropriate strategies to develop an FDA “endorsed” Allergen Management Course, including the review of course curriculum.
- Review the pending publication of FDA materials 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.

COMMITTEE MEMBERSHIP

- Members of the CFP Food Allergen Committee were selected by categories. The categories include: regulatory / federal; regulatory / state; regulatory / local; restaurant; retail; retail / convenience; industry / manufacturing; academic; expert / advisory resource. A detailed list of committee members is attached along with contact information. We would like to thank the Committee members for their support and participation in the 2008 – 2010 CFP Food Allergen Committee.

This final report and the committee member roster is respectfully submitted by Tony Flood and Gale Prince, co-chairs of the 2008 – 2010 CFP Food Allergen Committee.

Committee Name: Allergen Committee

Last Name	First Name	Position (Ch	Constituency	Employer	Address	City	State	Zip	Telephone
Flood	Anthony	co-chair	Other - Consumer	International Food Information Council	1100 Connecticut Ave. NW	Washington	DC	20036	202-296-6540
Prince	Gale	co-chair	Other - Consultant	Food Safety Consultant	7875 Woodstone Drive	Cincinnati	OH	45244	513-236-6264
Abel	Greg	member	Regulatory / Federal	USDA, FSIS, OPPD, LPDD	1400 Independence Ave, SW Room 2925 South Building				(202) 205-0145
Canavan	Jeffrey W.	member	Regulatory / Federal	Virginia Department of Agriculture & Consumer Services	4677 Brookside Road	Washington	DC	20250-3700	
Anderson	Bud	member	Regulatory / State			Roanoke	VA	24014	(540) 248-1579
Bombet	Carolyn	member	Regulatory / State	Louisiana Department of Health and Hospitals	628 N. 14th Street Box 10	Baton Rouge	LA	70802	(225) 342-7779
Miles	Pamela	member	Regulatory / State	Virginia Department of Agriculture & Consumer Services	102 Governor Street Room 349	Richmond	VA	23219	(804) 786-0412
Moris	Steven	member	Regulatory / State	Kansas Department of Agriculture	109 SW 9th Street	Topeka	KS	66612-1215	(785) 296-3511
Galindo	Teresa	member	Regulatory / Local	San Antonio Metro Health Department	332 W. Commerce	San Antonio	TX	78205	(210) 207-8853
Hirsch	Brian	member	Regulatory / Local	Summit County General Health District	1100 Graham Road Circle	Stow	OH	44224	(330) 926-5653
Jue	Robert	member	Regulatory / Local	Central District Health Department	707 N. Armstrong Place	Boise	ID	22202-4801	(208) 327-8523
Mitchell-Baker	Cassandra	member	Regulatory / Local	Fairfax County Health Department	10777 Main Street Suite 111	Fairfax	VA	22030	(703) 246-8438
Sommers	Maggie	member	Restaurants	National Restaurant Association	1200 17th Street NW	Washington	DC	20036-3097	202 331 5985
Foegle	Tom	member	Restaurants	Brinker International	6700 LBJ Freeway Suite 3105	Dallas	TX	75240	(972) 770-1745
Brooks	Scott	member	Restaurants	Yum! Brands	669 Long Meadow Spring	Branch	TX	78070	(502) 874-2501
Jackson	Keith	member	Restaurants	Potbelly Sandwich Works	222 Merchandise Mart, 24th Floor	Chicago	IL	60654	(312) 475-3854
Kohl	Larry	member	Retail	Food Marketing Institute	2345 Crystal Drive, Suite 800	Arlington	VA	22202-4801	(202) 220-0659
Tryba	Cas	member	Retail	Big Y Foods	2145 Roosevelt Ave	Springfield	MA	01102-7840	(413) 504-4450
Rossow	Todd	member	Retail	Publix Super Markets, Inc.	P.O. Box 32034	Lakeland	FL	33802	(863) 688-1188
McGuffey	Charles	member	Retail / Convenience	7-Eleven, Inc.	1626 S Greenstone Lane	Duncanville	TX	75137	(972) 828-6844
Grottenthaler	Robert	member	Industry / Manufacturing	Titteringtons Baking Company	48 Cummings Park	Woburn	MA	01801	(781) 938-7600
Wallace	Susan	member	Academic	Johnson & Wales Univ	265 Harborside Avenue	Providence	RI	2905	(401) 598-1706
Swanson	Katherine	member	Expert / Advisory Members	Ecolab	655 Lone Oak Drive	Eagon	MN	55121	(651) 795-5943
Bardsher	Julia		Expert / Advisory Members	FAAN	11781 Lee Jackson Highway	Fairfax	VA	22033	703 563 3053

Committee Name: Allergen Committee

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 058
Issue: 2010 III-021**

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

All information above the line is for conference use only.

Title:

Packaged Ice Manufacturing at Retail

Issue you would like the Conference to consider:

Currently, the Food Code references Ice in Section 3-202.16. It is defined as a food or a cooling medium made from drinking water. However, the Food Code does not appear to reference the manufacture and distribution of packaged ice at the retail level. The International Packaged Ice Association recommends that CFP support recognition in the Food Code of packaged ice manufacturing sold for human consumption.

The International Packaged Ice Association (IPIA) represents more than 400 packaged ice manufacturers and distributors. The IPIA mandates as a prerequisite to association membership that member producers demonstrate compliance with PIQCS (Packaged Ice Quality Control Standards). PIQCS was developed over ten years ago and is based on Good Manufacturing Practices specific to packaged ice and HACCP (Hazard Analysis Critical Control Point). The PIQCS standards are available at:

<http://www.packagedice.com/downloads/PIQCSManualFINAL.pdf>.

However, an estimated 40% of the packaged ice sold at retail for human consumption is produced at the retail level without specific guidance or inspection.

Public Health Significance:

Ice is widely used in retail food establishments, and is sold as packaged ice from a large number of retail food establishments. Ice receives little attention as a possible source of food borne illness. Packaged Ice is a manufactured food and as such is subject to the Good Manufacturing Practices Regulations for Foods contained in the Code of Federal Regulations, Title 21, Chapter 1, Part 110 [21CFR; Part 110]. Both Congress and the FDA acknowledged this in the "Fiscal Year 2010 Department of Agriculture Appropriations Bill" (the annual legislation that has the authority to fund the Food and Drug Administration). It contained the following language on packaged ice: *"Packaged Ice Manufacturing: The Committee recognizes that ice is a food product produced in the United States for both interstate and intrastate commerce, and has been made aware of concerns regarding individual retail outlets that manufacture and bag ice. The Committee directs FDA to work to educate manufacturers regarding safe production of ice, including the issuance of a Food Facts sheet informing the public about existing FDA regulations that apply to ice manufacturers. Further, the Committee directs FDA to consider whether or not formal*

regulations regarding the safe handling, processing, and packaging of packaged ice sold for human consumption would be an appropriate measure."

The processing of bottled water is subject to the product specific Code of Federal Regulations, Title 21, Chapter 1, Part 165 [21CFR; Part 165]. Many states have adopted and currently enforce these regulations which contain provisions pertinent to ice. However, there are no specific packaged ice processing regulations at the Federal level, and only two states, Florida and Montana, implement such requirements for packaged ice production at the retail and wholesale level, similar to those they enforce for bottled water. The Florida and Montana regulations are attached. Packaged ice plants range in size from the smaller retail packaged ice manufacturing operation to the large commercial wholesale manufacturer. They also include the self service mobile ice vending units.

The list of possible contaminants that could be present in packaged ice by not following proper GMP's is comprised of well known microorganisms and enteric viruses. Source water contamination, contaminated food contact surfaces, with the most common being mold, mildew and slime in the ice machine and unsanitized ice scoops, and cross contamination in the handling process can occur. The manual nature of the bagging process by smaller retail packaged ice manufacturers (an estimated 40% of packaged ice manufactured and sold to the public) speaks to this last possibility of ice contamination from improper personnel hygienic practices, including pathogen transmission by sneezing, coughing, and open sores with bare hand contact. Potential contaminants include chemical, viral, bacteriological and parasitic pathogens.

The number of documented cases of contaminated ice when GMP's were not followed is small in comparison to higher profile foods. The number may be small for two reasons. First, there is a popular misconception that ice is a preservative for other foods and the freezing process kills microorganisms. Second, ice is not one of the first food products looked at if at all when a food borne illness incident occurs. The CDC indicates that over 50,000 cases per year of reported food borne illness are of unknown origin and ice is widely used in retail food establishments.

Annex 2 of the Food Code references two reports on ice contamination:

1. Cliver, D.O., 1988. Virus transmission via foods; A scientific status summary by the Institute of Food Technologists' Expert Panel on Food Safety and Nutrition. Food Technol. 42(10):241-248.
2. Jackson, G.L., 1990. Parasitic protozoa and worms relevant to the U.S. Food Technol. 44(5):106-112.

Other supporting reports:

1. 2002 article from NACS (National Association of Convenience Stores): *" In the past 25 years, over 475,000 cases of waterborne disease outbreaks have been recorded. To bring this closer to home: "A survey of convenience store, on-premise ice machines indicated that 36 percent of packaged ice produced came from water that did not meet EPA drinking water standards," according to Dr. Debra Huffman of the University of South Florida. She continues to say, "Regardless of the type of microorganism such as E.coli, hepatitis, or protozoa, the results are the same, lack -- of water treatment and/or poor ice processing conditions result in people becoming ill."*

2. Example from January, 2007, Houlihans restaurant in Indiana

Health officials are particularly concerned with those patrons who consumed drinks with ice. *"Restaurant patrons may have been exposed to hepatitis A "*

3. Example attached Anderson Cooper 360, 2008
4. Example attached ABC News Science Fair project
5. AFDO guidelines attached for handling and manufacturing packaged ice

In conclusion, the public is at increased risk of being exposed to contaminated or adulterated ice because there are currently no specific government health and safety standards for the manufacturing of Packaged Ice at the wholesale or retail levels.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting modification of the Food Code,

- Add to Section 1-201.10 Statement of Application and Listing of Terms:

"Packaged Ice" means food intended for human consumption that is formed from drinking water, spring water or purified water by freezing to a solid state that is sealed in packages and offered for sale for human consumption.

- Modify Section 3-202.16, to read:

3-202.16 Ice, including packaged ice.

Ice, including packaged ice, for use as a food or a cooling medium shall be made from drinking water

- Modify Annex 3, Public Health Reasons/Administrative Guidelines to read:

3-202.16 Ice, including packaged 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.

- Modify Guide 3-B Instructions for Marking the Food Establishment Report-page 19 to read:

29. Water and ice, including packaged ice from approved source. Packaged ice meets 21 CFR (Code of Federal Regulations) 101 labeling requirements.

Submitter Information:

Name: Jane McEwen, Executive Director
Organization: International Packaged Ice Association
Address: P.O. Box 1199
City/State/Zip: Tampa, FL 33601
Telephone: 800-742-0627 Fax: 813-251-2783
E-mail: jane@packagedice.com

Attachments:

- "State of Florida regulations for packaged ice"
- "State of Montana Ice Regulations"
- "ABC News Science Fair Project"
- "Anderson Cooper 360"
- "AFDO Guidelines for Handling and Manufacturing Packaged Ice"

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.

5K-4.023 Packaged Ice.

(1) In addition to the requirements in the general food products statute, Chapter 500, F.S., and all applicable rules in Chapter 5K-4, F.A.C., packaged ice plant operators and packaged ice dealers shall comply with the following rules.

(2) DEFINITIONS:

(a) ICE means food intended for human consumption that is formed from drinking water by freezing to a solid state.

(b) IMPORTED means manufactured, processed, packaged, stored or distributed from a point outside of the state of Florida.

(c) MAXIMUM CONTAMINANT LEVEL (MCL) means the maximum permissible level of a contaminant as set forth in Chapter 403, F.S., and Chapter 64E-8, F.A.C. (1/93), titled "Drinking Water Systems", and Chapter 62-550, F.A.C. (5/94), titled "Drinking Water Standards, Monitoring and Reporting".

(3) REQUIREMENTS:

(a) Each person or public body that establishes, maintains, or operates a packaged ice plant must obtain a Packaged Ice Plant Operating/Food Permit from the department each year. Each packaged ice plant location must have a permit.

(b) Each packaged ice dealer must obtain a Packaged Ice Dealer/Food Permit from the department each year. Ice transported into the state and packaged either before or after importation into the state must meet all of the requirements of this section and must be packaged, labeled, handled, and otherwise processed and sold according to the provisions of this section.

(c) Any packaged ice plant operator who is also a packaged ice dealer shall be issued a combined Packaged Ice Plant Operating-Dealer/Food Permit by the department. Such permit shall be issued each year upon compliance with all statutory and rule requirements for the issuance of a Packaged Ice Plant Operating Permit and a Packaged Ice Dealer Permit. Each location must have a permit.

(d) Each packaged ice plant operator or packaged ice dealer who is engaged in the sale or distribution of any other food product and whose operation qualifies as a food establishment under Chapter 500, F.S., shall be issued a combined Food/Packaged Ice Permit by the department. Such permit shall be issued each year upon compliance with all statutory and rule requirements for the issuance of a Food Permit, a Packaged Ice Plant Operating Permit, a Packaged Ice Dealer Permit, or a combination thereof. Each location must have a permit as per Section 500.12(1)(a), F.S. and subsection 5K-4.020(2), F.A.C.

(e) All permits shall expire on December 31 of each year.

(f) Application for permits must be made in writing to the department on form IN-63, an Annual Food Permit Application, (Revised 10/94).

(4) PERMIT FEES:

(a) Each packaged ice plant operator must pay the department an annual non-refundable fee of \$250.00 for each permit.

(b) Each packaged ice dealer must pay the department an annual non-refundable fee of \$100.00 for each permit.

(c) Each packaged ice plant operator who is also a packaged ice dealer must pay the department an annual, non-refundable fee for each permit. Such fee shall be the greater of the Packaged Ice Plant Operating or the Packaged Ice Dealer permit fee required in this subsection.

(d) Each packaged ice plant operator or packaged ice dealer who is engaged in the sale or distribution of any other food product and whose operation qualifies as a food establishment under Chapter 500, F.S., must pay the department an annual, non-refundable fee for each permit. Such fee shall be the greater of the Food Permit fee required by Rule 5K-4.020, F.A.C., or the applicable permit fee required by this subsection.

(e) Fees charged to applicants for new permits shall be prorated with the applicant paying 1/12th of the applicable fee for each month remaining in the calendar year, including the month of application.

(5) SOURCE WATER AND FINISHED PRODUCT QUALITY:

(a) All water used for the manufacture of ice intended for human consumption and in preparation of brine solutions must be from an approved drinking water supply as described in Chapter 64E-8 or 62-550, F.A.C.

(b) Imported packaged ice product must be manufactured from source water that has been approved as a drinking water supply by the agency with jurisdiction in the state where the ice is manufactured and packaged.

(c) Packaged ice dealers importing product must submit to the department a copy of the current source certification or a letter from the agency with jurisdiction for approval of drinking water supplies. This information must be submitted to the department with each annual permit application.

(d) Packaged ice must be in conformance with maximum contaminant levels that have been established for drinking water supplies in Chapters 64E-8 and 62-550, F.A.C.

(e) All packaged ice plants shall submit to an approved laboratory, once every three months, a sample of each type of finished product for microbiological analysis. A copy of the quarterly analytical results shall be forwarded to the department by out-of-state packaged ice dealers. In-state packaged ice plants shall maintain these records as required by Section 500.509, F.S., and make them available to the department upon request.

(f) The quarterly laboratory analysis must include testing for fecal and total coliform organisms and Heterotrophic Plate Count (HPC). Total coliforms shall not be greater than 2.2 organisms/100 ml. using the Most Probable Number (MPN) method or not greater than 1 organism/100 ml. using the Membrane Filtration (MF) method. The HPC shall not exceed 500 colonies/ml. Packaged ice shall have no fecal coliform-positive samples.

(g) Should finished product samples exceed the standards outlined in paragraph (f) of this subsection, the plant shall submit samples to an approved laboratory, on a weekly basis, until two (2) consecutive acceptable samples are obtained. Copies of weekly sample analyses shall be submitted to the department upon receipt by the packaged ice plant or packaged ice dealer.

(h) The department shall collect and analyze samples of source water and finished product when necessary to determine if the source water and/or finished product meet quality standards established in this rule. When indicated by reason of complaint or illness, the department may obtain and analyze or require the ice plant to obtain and have analyzed, by an approved laboratory, samples of source water and/or finished product.

(i) All records of sampling and analyses of source water and finished product shall be maintained by the plant for a period of not less than 2 years and shall be made available to the department upon request.

(6) PROCESSING AND PACKAGING:

(a) Ice shall be processed and packaged using methods that preclude contamination of the product.

(b) Air used for water agitation shall be filtered or otherwise treated to render it free of oil, dust, dirt, insects and extraneous material.

(c) Manual packaging of product shall be performed in a manner that will preclude contamination of the packaging material and the product.

(d) Any spillage created during manufacture, packaging, transportation or storage shall be disposed of and shall not be packaged or re-packaged for sale for human consumption.

(e) Ice packaging material shall be of foodgrade quality and closures shall be designed to adequately protect its contents. Only pin holes or a butterfly vent that does not exceed 1/4 inch in diameter shall be used in ice packaging material. Pin holes or butterfly vents must be located in the upper 1/3 portion of the bag.

(f) Packaging material shall be protected from contamination during storage and handling.

(7) STORAGE AND TRANSPORTATION:

(a) Packaged ice plants producing product that is not to be used for human consumption shall store this product in a designated area that is clearly identified and separated from other packaged ice products.

(b) Packaged ice shall be stored above the floor protected from splash and shall not be located in areas susceptible to overhead dripping.

(c) Wooden platforms or pallets shall not be used for the purpose of transporting ice or storing ice above the floor unless platforms or pallets have been designed or covered with surfaces that protect the product from splintering. Such surfaces shall be easily cleaned and sanitized or shall be replaced between uses.

(d) Product shall be transported in an enclosed facility designed and equipped to protect the product from contamination and shall be maintained in a clean condition.

(e) Packaged ice shall be handled in such a manner to preclude contamination during transportation and delivery. At no time during transport or delivery shall the packaged ice product come into contact with the floor or ground.

(8) LABELING: Packaged ice plants producing product that is not to be sold for human consumption shall designate "NOT FOR HUMAN CONSUMPTION" on the package. This designation shall be clearly visible to the consumer.

(9) NOTIFICATION TO THE DEPARTMENT: The operator or manager of a packaged ice plant or dealer who knows or should know that a primary maximum contaminant level has been exceeded or believes or has reason to believe that circumstances exist such as source contamination, spills, accidents, natural disasters, breakdowns in the sanitary processing of ice or other similar problems that may adversely affect the safety of the packaged ice, shall immediately notify the department of the incident.

(10) PRODUCT RECALL PROCEDURES:

(a) If the department determines, based upon results of representative sample tests and risk analysis that an immediate hazard to

the health, safety and welfare of the public is present in any packaged ice product, the department shall order the packaged ice plant or dealer to initiate a product recall to effectively avoid or significantly minimize the threat to the public's health and if appropriate, issue a notification to customers. The plant or dealer shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

(b) When a laboratory report reveals a maximum contaminant level (MCL) has been exceeded, but when investigation indicates that the condition causing the MCL to be exceeded was promptly corrected and that previously distributed product will not cause illness nor present any significant health hazard, a company recall and media notification shall not be necessary. In circumstances where a recall or media notification is not necessary but consumer complaints indicate problems regarding product taste or odor, the department shall order the plant to communicate the exceedence of the MCL and the implementation of corrective measures by direct mailings to affected customers.

(11) DEPARTMENT RESPONSIBILITIES AND DUTIES: Packaged ice plant operators and packaged ice dealers shall allow the department to examine records pertaining to the operation and maintenance of the plant or source water.

(12) FORMS: Form IN-63, an Annual Food Permit Application (Revised 10/94), is hereby incorporated by reference. Copies may be obtained from the Florida Department of Agriculture and Consumer Services, 3125 Conner Boulevard, Room 294, Tallahassee, Florida 32399-1650.

Specific Authority 500.509, 500.12(1)(d), 570.07(23) FS. Law Implemented 500.453, 500.509 FS. History—New 1-19-95, Formerly 5E-6.023, Amended 8-8-95.

DEPARTMENT OF PUBLIC HEALTH
AND HUMAN SERVICES

CHAPTER 110

FOOD AND DRUG STANDARDS

Subchapter 8

Drinking Water and Ice

37.110.801 DRINKING WATER (1) Any person engaged in the production, packaging, manufacturing or processing of drinking water, culinary bottled water, or water otherwise processed and packaged for human consumption, is subject to the licensing requirements of 50-50-201, MCA, for food manufacturing establishments. Any manufacturing or bottling plant located in a state, territory, or nation other than Montana that prepares water in bottles or other containers for drinking or culinary purposes for sale in Montana must also be licensed by the department.

(2) Each food manufacturing establishment in Montana where water is prepared for sale in bottles or other containers for human consumption and the sources of all such water must be inspected at least once each year by the local health officer, sanitarian or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction. A copy of each inspection must be submitted to the department within 30 days after the inspection occurs.

(3) Each food manufacturing establishment in Montana where water is prepared for sale in bottles or other containers for human consumption must:

(a) obtain its water from a community public water system approved by the water quality division of the department of environmental quality, or, if water is obtained from a separate or independent system, that system must comply with the statutes governing public water supplies, 75-6-101 et seq., MCA, the rules governing public water supplies, ARM 17.38.201 et seq., and the rule governing plans for public water supplies or wastewater systems, ARM 17.38.101.

(b) maintain sampling records demonstrating compliance with the bacteriologic, chemical and radiologic sampling requirements specified in (6)(b) of this rule for at least 12 months after the date of sampling.

(4) The operation of all food manufacturing establishments involved in producing, packaging, manufacturing, or processing drinking or bottled water and the products marketed must comply with these rules and with the Montana Food, Drug and Cosmetic Act, 50-31-101 et seq., MCA; the food manufacturing establishment rules, ARM 37.110.301 et seq.; the federal standards regarding food labeling, 21 CFR 101; the federal quality standards for foods with no identity standards, 21 CFR 103; the federal standards for processing and bottling of bottled drinking water, 21 CFR 129; and the Fair Packaging and Labeling Act, 15 USC 1451 et seq.

(5) Every food manufacturing establishment desiring to sell, market or distribute bottled water in Montana, whether located in Montana or not, must apply for a license on a form provided by the department, which must be signed by the owner or the owner's legal representative, and must submit the fee required by 50-50-206, MCA. Such fee must be payable to the department and the application must be postmarked no later than midnight on December 31 of each year. Submission of a renewal application and fee after this time will require the food manufacturing establishment to submit the late fee required by 50-50-206, MCA. The license year is January 1 through December 31.

(6) In addition to the fee, the late fee, if applicable, and the application form identified in (5) above, the food manufacturing establishment must submit the following to the department for review:

(a) A certification affidavit from the state or local health officer, sanitarian or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, affirming that the establishment meets the requirements of 21 CFR 103 and 129;

(b) If the source water is not mineral water, copies of the most recent inorganic, volatile organic, organic chemical and radiological analyses of the establishments water showing compliance of the source water with the maximum contaminant levels for regulated water systems as required by 40 CFR 141; or a certification affidavit from the state or local health officer, sanitarian, or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, affirming that the water source complies with these standards;

(c) Test results for pesticides and synthetic organic chemicals, if the department determines such tests are necessary or if random testing has shown there is or may be contaminants present at levels which may adversely affect public health;

(d) A copy, photocopy, or printer's proof of each label for each product to be marketed and for each size to be marketed;

(e) A description of the source of the water, water treatment used, all substances added to the water, and any other documentation required by the department to verify that labels and terminology used on the labeling conform with applicable law; and

(f) For products labeled "mineral water" or for a label containing the term "mineral water", copies of the results of laboratory testing of mineral content and total dissolved solids (TDS) of the product, obtained during the 12 months preceding the license year from an agency approved to test drinking water by the department or another public health agency.

(7)(a) The department hereby adopts by reference:

(i) ARM 37.110.301 et seq., setting standards for food manufacturing establishments;

(ii) ARM 37.110.201 et seq., setting standards for public water supplies;

(iii) ARM 17.38.101, governing plans for public water supplies;

(iv) 21 CFR 101, setting food labeling standards;

(v) 21 CFR 103, setting quality standards for foods with no identity standards;

(vi) 21 CFR 129, setting standards for processing and bottling bottled drinking water;

(vii) 40 CFR 141, containing maximum contaminant levels for drinking water, and

(viii) 15 USC 1451 et seq., containing federal law on packaging and labeling.

(b) Copies of these statutes and rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; IMP, Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; AMD, 1995 MAR p. 368, Eff. 3/17/95; TRANS, from DHES, 2001 MAR p. 2423.)

37.110.802 ICE (1) This rule applies only to ice that is intended for human consumption and is sold in packaged form or in bulk form for food, drink or culinary purposes. This rule does not apply to persons, hotels, restaurants, inns, caterers, food service contractors, or theaters that manufacture or furnish ice solely to or for their customers in a manner that is incidental to the production, sale or dispensing of other goods and services.

(2) Natural ice that is cut from water on a stream, creek, river, lake, pond, or other body of surface water may not be used as ice for human consumption.

(3) Except as provided in (1) above, any person who manufactures, transports, distributes, sells or provides ice, with or without charge, to the public must obtain a food manufacturing license and must comply with these rules and with the statutes governing food manufacturing establishments, 50-50-101 et seq., MCA; the rules governing food manufacturing establishments, ARM 37.110.301, et seq.; and the rules governing public water systems, ARM 17.38.201 et seq.

(4) Ice plants must be operated in a clean and sanitary manner. The room in which ice production occurs may not be used for any purposes other than ice or food production and the storage and refrigeration of ice or food.

(5) Ice production facilities shall meet the provisions of 21 CFR 110, which provides standards for current good manufacturing practice in manufacturing, packing, or holding human food.

(6) Ice produced and packaged for sale to the public must be labeled in accordance with the Montana Food, Drug and Cosmetic Act, Title 50, chapter 31, MCA, and in accordance with 21 CFR 101, which establishes federal food labeling standards, and must display legible labeling including, but not limited to, the identity of the product, the net weight or contents of the package, and the name and place of business of the manufacturer, packer, distributor, seller, or provider.

(7) Packaged ice transportation, hauling vehicles, and bulk containers, including display or storage freezers, are regarded as a part of the licensed premises and are subject to review or inspection by the department or the local health officer, sanitarian, or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, prior to issuance or renewal of its license or on a regular annual inspection.

(8) The food manufacturing establishment must sample and have analyzed its manufactured ice products, and the waters from which the ice is made, at least once a month for compliance with the maximum microbiological contaminant levels contained in ARM 17.38.207, and send the results to the department. The food manufacturing establishment is also required to comply with the bacteriological quality sampling provisions of ARM 17.38.215 (3) through (7) for transient non-community water systems. The department may increase the required sampling frequency based upon sampling results or other conditions which indicate an increased risk to the health of the users of the product. The department may decrease the required sampling frequency to quarterly or biannually based on a showing that the source consistently does not contain the contaminant, is either a community water system or a groundwater source not under direct influence of surface water, and that the samples consistently meet the required sanitary standards, rendering the source and operation generally not vulnerable to microbiological contamination.

(9) The delivery of ice to the customer must be done under sanitary conditions. Ice must be packaged in durable freezable containers labeled in conformance with the labeling requirements as described in (6) above. Boxes or containers intended for non-food use or for use in packaging another food are not acceptable transport containers. All boxes, containers, cases or contact surfaces within bins or transport vehicles must be constructed of food grade materials.

(10) Natural or manufactured ice that does not conform to standards set forth in this rule must be conspicuously identified or labeled as unsafe or inedible and may not be sold or distributed for human consumption. Such ice may be used for cooling or refrigeration purposes only if such use does not permit it to come in direct contact with food or drink meant for human consumption. If such ice is sold or distributed for refrigeration purposes, the seller or distributor must notify the buyer or consumer that it is not safe for human consumption.

(11) The department hereby adopts by reference ARM 37.110.301 et seq., setting standards for food manufacturing establishments; ARM 17.38.201, et seq., setting standards for public water supply systems; 21 CFR 110, setting standards for packing, manufacturing, or holding human food; and 21 CFR 101, setting food labeling standards. Copies of these rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; IMP, Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; TRANS, from DHES, 2001 MAR p. 2423.)

Rules 03 and 04 reserved

37.110.805 COMMON CARRIERS (1) Water and ice provided by common carriers for drinking or culinary purposes in railway trains, buses, or other public transportation conveyances and in all railway stations in Montana must be taken from supplies which conform to standards for drinking water contained in 40 CFR 141 and 40 CFR 142.

(2) The department hereby adopts by reference 40 CFR 141, setting maximum contaminant levels and other standards for drinking water, and 40 CFR 142, establishing procedures for implementing and enforcing drinking water standards. Copies of these rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-50-103, MCA; IMP, Sec. 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; TRANS, from DHES, 2001 MAR p. 2423.)

Rules 06 through 09 reserved

37.110.810 MINIMUM PERFORMANCE REQUIREMENTS FOR LOCAL HEALTH AUTHORITIES (1) To qualify for reimbursement under 50-50-305, MCA, for regulation of sources of drinking water and ice, a local board of health must either enter into a written, signed cooperative agreement with the department that establishes the duties and responsibilities of the local board of health and the department consistent with this subchapter, or ensure that the following are done by the local health officer, sanitarian, or sanitarian-in-training:

(a) Ensure that, at least once per year, each plant or establishment within the jurisdiction of the local board of health where water is prepared for sale in bottles or other containers or artificial ice is manufactured, and the sources of all such water, are inspected, either by the foregoing individuals or by another government agency and, at the same time, that a sample of the water is submitted to a DEQ-approved laboratory for analysis for contaminants.

(b) Submit quarterly inspection reports to the department within 10 days following the close of each quarter of the fiscal year (1st quarter--September 30; 2nd quarter--December 31; 3rd quarter--March 31; 4th quarter--June 30) on forms approved by the department.

(c) Retain for 5 years all documentation of enforcement of this subchapter, including but not limited to inspection reports, consumer complaints, illness investigations, plans of correction, and enforcement actions, and, upon request, submit copies of the documentation to the department or otherwise make it available to the department.

(2) A failure by the local board of health to meet all of its responsibilities under the cooperative agreement or under (1)(a) through (d) above shall result in the withholding of funds from the local board reimbursement fund in an amount to be determined by the department. (History: Sec. 50-50-305, MCA; IMP, Sec. 50-50-305, MCA; NEW, 1994 MAR p. 2941, Eff. 11/11/94; AMD, 1995 MAR p. 26, Eff. 11/11/94; TRANS, from DHES, 2001 MAR p. 2423.)

[ABCNews.com](#) > [GMA](#) > [Healthy Living](#) > [GMA OnCall](#)

Fast-Food Ice Dirtier Than Toilet Water

Seventh-Grader's Science Project Turns Up Some Disturbing Results

Feb. 20, 2006



Jasmine Roberts never expected her award-winning middle school science project to get so much attention. But the project produced some disturbing results: 70 percent of the time, ice from fast food restaurants was dirtier than toilet water.

The 12-year-old collected ice samples from five restaurants in South Florida -- from both self-serve machines inside the restaurant and from drive-thru windows. She then collected toilet water samples from the same restaurants and tested all of them for bacteria at the University of South Florida.

In several cases, the ice tested positive for E. coli bacteria, which comes from human waste and has been linked to several illness outbreaks across the country.

"These [bacteria] don't belong there," said Dr. David Katz, medical contributor to "Good Morning America." "It's not cause for panic, although it is alarming because what she found is nothing new. You're not more likely to get sick now. But she's done us a favor by sounding the alarm."

Both Roberts and Katz said that the ice is likely dirtier because machines aren't cleaned and people use unwashed hands to scoop ice. Toilet water is also surprisingly bacteria-free, because it comes from sanitized city water supplies.

Support from Big Brother

Roberts got interested in the project after reading a newspaper article about bacteria in airplane water and decided to do something similar. Plus, she said, all of her friends chew on ice, and it drives her crazy.

"I just picked the not-obvious choice," the seventh-grader said of her project. Her 18-year-old brother, Justus, is also an award-winning science fair veteran who said he has encouraged his little sister's interest in science.

Anderson Cooper 360
Tuesday, June 21, 2005
7:00 – 8:00 p.m.
Transcript

HEIDI COLLINS, CNN CORRESPONDENT: It's cold, refreshing and oh- so-good on a hot summer day, but did you ever think about what's in your ice?

JENNIFER BERG, NEW YORK UNIVERSITY: Fecal matter in ice is a serious problem.

COLLINS: Jennifer Berg is the head of the graduate department at the Food Science and Nutrition program at New York University. She says ice can hold bacteria that makes you just as sick as anything else you eat.

BERG: Tainted ice is usually a result of having e.coli, fecal matter inside the ice.

COLLINS (on camera): How worried should people be about something like this?

BERG: You know, we don't want to make the American public completely neurotic and so scared of our food supply, when in reality we have a safer food supply than most countries, but we do need to be careful.

COLLINS (voice-over): Ice can become contaminated in many ways, like microorganisms in the water supply. But according to the experts CNN consulted, the most common causes of ice contamination are poor handling and storage.

Take Denton, Texas, 1999. Fifty-eight members of a high school drill team were infected with various levels of gastrointestinal illnesses at a camp. The ice got contaminated with e.coli after campers used their bare hands to scoop ice out of the machine. And recently, a British government study surveyed clubs, bars and pubs in London, and found half the ice they used was full of bugs and bacteria that can make people sick.

(on camera): So that got us thinking, what would we find if we bought ice just like you would on any given day at any given restaurant across the country?

(voice-over): We took our ice samples in Chicago, Dallas, Atlanta, New York and Los Angeles, at a combination of fast food chains and local establishments in each town, a total of 23 samples. In each location, we walked in and ordered our drinks with our ice on the side, and then carefully, without touching the ice, poured it into sterile bags, and then set the samples off to a certified food laboratory, Microbac Laboratories in Warrendale, Pennsylvania.

(on camera): Now, our study didn't follow all EPA protocol. That would mean we would have had to have gone to each restaurant four or five times, tested the city water, and then made sure that our sample ice touched nothing before it went into our sample bags. But

our results were tested against the most basic EPA standards, and what we found was disturbing.

(voice-over): In every city but one, there was a restaurant that failed those EPA standards.

This McDonalds in Atlanta failed. This Dunkin Donuts in Chicago failed. This 7-Eleven in Dallas failed, and so did this Burger King in Los Angeles.

On the day we tested, according to Microbac Laboratories, each ice sample from these four establishments was contaminated with fecal matter.

(on camera): That's disgusting.

BERG: It's so easy to spread. It's very easy to prevent, very easy to prevent. It's a matter of washing in very warm water, really washing not just the hands but up until, you know, through the forearm, with soap, very hot water, drying it off, training employees to all do that.

COLLINS (voice-over): And the one city that got a clean bill of ice? Well, that surprised even us.

(on camera): When you think of New York, you think horribly dirty city, but yet when we did our little ice samples, not a single place failed. Why?

BERG: New York City has much more stringent laws and regulations in place inspecting food. The other thing is, in a city like New York, and if you're talking about the fast food places that you've looked at, they have very high volume. By the end of the evening, that ice machine has emptied out. They've completely depleted their supply.

COLLINS (voice-over): We then contacted the establishments that failed our single tests. In every case, after hearing the results of our test, the owner/operator said they shut down their ice machines and cleaned them thoroughly, and also retrained their employees.

All four restaurants said they retested their ice after cleaning the machines and found no trace of bacteria.

7-Eleven sent us this: "The safety of 7-11 customers is of the utmost importance to us." And from Dunkin Donuts: "Dunkin Donuts strives to endure adherence to food safety standards." McDonald's issued this statement from the franchise owner: "My restaurant has an excellent track record with our local health department. My last inspection score was 99 out of 100." Burger King responded by telling us: "The particular restaurant has consistently achieved high health and safety results from both our internal and external audits, as well as those of the local health department."

However, health departments in Atlanta and in Los Angeles told us they do not test water

in ice machines during health inspections.

To be fair, none of the other locations of these establishments failed our tests in other cities, and we only tested the failed establishments once. But clearly, there is contaminated ice out there. So, will it make you sick?

BERG: You personally, Heidi, probably not, but chances are people did. Young children, older people, anybody who was sick to begin with.

COLLINS: Most common complaints: Nausea, vomiting and diarrhea.

So what can you do to protect yourself? If you are lucky enough to live in one of the handful of states that have food safety officers, look for the sign telling you that one is on duty. Otherwise, if you see the server filling your cup, make sure they are wearing gloves, and they don't touch the ice.

Or you could do what Jennifer Berg does.

(on camera): Do you get ice in any of your drinks when you're out to eat?

BERG: I just decided it's OK to just have beverages room temperature.

(END VIDEOTAPE)

COLLINS: So whether you drink your drink with or without ice, you should know dirty hands in the ice bin is only half the problem. The other culprit for the contaminated ice is the ice machine itself. These dispensers need to be cleaned on a daily basis to prevent that buildup of water and bacteria in the very bottom of the bin and in the water lines.

COOPER: So are there any actual numbers on how many people get sick from ice?

COLLINS: Not really. There are not exact numbers. In fact, the CDC has been tracking the outbreaks of illnesses since about 1968 caused by contaminated ice, but they don't have precise figures, because people usually think they're getting sick from the food they eat, and hardly anybody really thinks of ice as a food.

COOPER: All right. Heidi Collins, thanks.

AFDO* GUIDELINES
FOR THE INSPECTION AND ENFORCEMENT
OF GMP REGULATIONS
FOR HANDLING AND MANUFACTURING PACKAGED ICE

INTRODUCTION

This nation has established very comprehensive standards governing the sanitary processing of food and the safety of food. Ice is a food and is subject to these same standards. It makes sense to prepare beverages under strict sanitary and safety standards and to pour these beverages over ice subjected to the same standards.

Ice is a manufactured food and as such is subject to the Good Manufacturing Practices Regulations for Foods contained in the Code of Federal Regulations, Title 21, Chapter 1, Part 110. Additionally, many states have passed the model Food and Drug Act which contains the same language as the federal statute. Therefore, ice is also defined as a food under most state laws and regulations.

PURPOSE

These guidelines provide information to uniformly apply the Good Manufacturing Regulations to packaged ice manufacturing and handling operations. This information should be used as guidance during inspections of packaged ice manufacturing and handling operations and should be taken into consideration when violations of Good Manufacturing Practices are evaluated for regulatory follow-up.

These guidelines have been prepared as an adjunct to the GMP Regulations and do not replace or supersede them. In addition, the Packaged Ice Association has developed specific guidance for ice manufacturing and handling operations which, if followed, will result in general compliance with the GMP regulations and these guidelines.

Many inspections are being conducted by state and local governments which cover convenience stores and other types of establishments that also house a small ice manufacturing operation. These inspections should evaluate the packaged ice manufacturing and handling processes for compliance with the GMP Regulations and these guidelines.

Inspections of large ice manufacturing plants must be inspected using these same standards to evaluate compliance.

PERSONNEL-MANAGEMENT

Evaluate the cleanliness of employee's clothing. If it is heavily soiled, immediate correction is required. Clothing that contains grease, oil, dirt, or other material must not be permitted for an employee who handles ice or food contact surfaces.

*Association of Food & Drug Officials, P.O. Box 3425, York, PA 17402 (717) 757-2888

Employees must wash and sanitize hands after handling objects that are not clean or sanitized. Frequent handling of unsanitized objects and returning to handling ice or food contact surfaces represents a serious violation of GMP Regulations.

PACKAGED ICE GUIDELINES

Where ice is manufactured in facilities housing more than one operation and employees are engaged in both operations assessments must be made about the potential for cross-contamination of the ice. Therefore, it may be necessary for health officials to prohibit the housing of two operations in the same area. For example, housing ice manufacturing operations in garages and gas stations is unacceptable unless very carefully controlled conditions are met.

Employees must not be allowed to consume food, drink beverages, smoke, etc. in the ice manufacturing area. Also, employees must wear hair restraints.

Management is responsible for a sanitation training program that promotes continual awareness and adherence to high sanitary standards. This can be evaluated through and observation of employee's personal cleanliness and practices. When good sanitary practices are violated, management must take appropriate action to correct them.

When good sanitary practices are violated, discuss them with the owner and recommend changes that will solve the problems. Serious deficiencies in good sanitary practices cannot be solved without management's commitment.

ICE PLANT ENVIRONMENT

The area surrounding the ice manufacturing area must be free of debris that will harbor rodents, insects, and other pests. Thus, the inspection should evaluate the environment. Old equipment must be removed, tall grass and weeds must be cut frequently, and pools of water in the yard area must be eliminated.

The sewer system must function properly and never constitute a problem with back-ups or overflows that have the potential of contaminating equipment or ice.

Generally, plant environments can be easily controlled, and there should be no reason for harborage to exist. These violations may become more significant when the ice plant is infested with rodents, insects, or other pests. When this occurs, health officials must insist that the plant environment be improved as part of the plant clean up process. Live infestations by pests require that the plant be closed until the animals and insects are removed.

PLANT CONSTRUCTION AND DESIGN

There are several ice manufacturing systems sandwiched into other operations which are not compatible with food manufacturing processes. When this situation occurs, health officials have a responsibility to require that the ice processing area be separated by an enclosure within these buildings or other suitable separation to prevent the potential for contamination.

The enclosed area must be large enough to permit employees to work within the enclosure and to perform all the manufacturing and packaging steps within the enclosure. The enclosure must be well constructed, clean, and prevent potential for contamination.

Health officials must insist that holes in walls be repaired, that ill fitting doors, windows, and screens be repaired, and that the construction itself permit easy cleaning of the walls, floors, and equipment.

SANITARY OPERATION AND CONTROLS

Equipment must be cleaned on a schedule of frequency that prevents accumulation of mold, fungus, and bacteria. A formal cleaning program and schedule which includes the use of sanitizers to eliminate micro-organisms must be developed and used. Inspections must include an evaluation of the cleaning schedules and an evaluation of the status of all equipment and the plant environment.

Health officials must insist that cleaning of the plant and equipment be frequent enough to prevent contamination. At the least, equipment must be cleaned and sanitized before the beginning of operations when the operation or plant has been shut down. Other cleaning schedules will be based on the needs of individual plants and must cover cleaning following processing interruptions.

Ice cannot be packaged on platforms open to the environment; nor can it be processed in a truck, unless the truck is specifically dedicated to the packaging of ice and meets the same standards set forth in these guidelines.

Live animals and birds must not be permitted in the plant. Infestations by live animals and bird require immediate correction. Therefore, the facility must be closed until these pests are eliminated.

Single service supplies, such as bags and other containers, must not be reused. Single service containers must be stored in an area free from potential contamination with non food items such as toxic substances, and dirt. These containers must be free from potential contamination from pests such as insects, rodents, and animals.

WATER

Water used in the entire plant must be potable water unless the health authority authorizes the use of non-potable water for certain operations. Water from an approved city water supply is considered potable water and needs no testing for quality.

A plant may use a private water supply provided the following conditions are met:

--The water must be tested under worst case environmental conditions to establish a water quality profile. This research should demonstrate that worst case environmental conditions have no adverse impact on water quality or reveal those conditions which do impact on quality.

--Plans must be established to suspend use of private water supplies under those conditions which have been shown to adversely affect the quality of the water without regard to further testing before suspension of use. Water tests must be conducted before the private supply is again used.

For example, private well water must be assessed following periods of heavy rainfall producing heavy rainfall run off. These assessments will produce a profile that establishes the impact of such events. This data provides guidance to control the quality of water without conducting laboratory analysis to establish water quality following these events.

It is not enough to simply test water from private wells randomly according to an arbitrary schedule. Rather, evaluations must be performed in relationship to events that may adversely affect water quality as mentioned above.

Water quality is one of the highest priorities in an ice plant. Health officials must carefully evaluate water quality control programs during every inspection.

Private well water must be tested monthly in addition to the tests specified above. This will detect changes in water quality which are not triggered by environmental events. Pesticide and chemical contamination should be part of any periodic test program.

ENFORCEMENT GUIDELINES

Public health officials must insist on high standards and compliance with the Good Manufacturing Practices for Food Regulations.

1. When employees are dressed in clothing that is heavily soiled with grease, dirt, or other debris, immediate correction must be made. This can be corrected by the pant owner providing clean outerwear when these employees handle ice, or other suitable alternatives. It is a serious violation of GMPs when employees clad in filthy garments handle ice or food contact surfaces. Failure to correct these conditions should result in suspension of operating permits or closure until corrections are made.

2. It is a serious violation of GMPs to manufacture or process ice in a building infested with rodents, insects, or wild or domestic animals. Plants so infested must be closed until a permanent correction has been made.
3. Water from private wells must be tested under worst case environmental conditions. Failure to develop appropriate profiles for private wells represents a serious public health problem. Public health officials should help develop a plan to test private wells and to develop an acceptable overall water control program. Once a plan is developed, it must be implemented immediately. Failure to implement and adhere to this plan should result in closure until correction is made.
4. Ice must be tested periodically for the presence of bacteria. This should be done each 90 to 120 days. These tests must be more frequent when internal conditions do not conform to Good Manufacturing Practices Guidelines. Failure to perform this key step should result in immediate sampling by the health authority. Also, licenses should be suspended until an appropriate product testing program is implemented or other action appropriate to local standards may be taken. Under no circumstances should the public be expected to consume ice that has not been subjected to an effective quality control program, and periodic testing is a cornerstone of all public health and Good Manufacturing Practices programs.
5. The ice manufacturing area must be in a facility housing a food plant providing barriers to a potential contamination of the ice, be in a facility dedicated to the manufacture of ice, or be within an enclosure in another facility. Failure to follow these guidelines should result in closure and license suspension until permanent correction is made.
6. Cross connections between potable water and non-potable water lines are cause for immediate closure until the plumbing has been corrected. This requires permanent correction before ice can be manufactured.

#

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 059
Issue: 2010 III-012**

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

All information above the line is for conference use only.

Title:

Re-create - Hot Holding Committee

Issue you would like the Conference to consider:

The 2008-10 Hot Holding Committee has evaluated the information available on the TCS hot holding temperature requirement of 135°F., has determined that more information is needed, and recommends that the committee be re-created to continue the work of the committee through 2012.

One specific area of study would be the "evaporative cooling range" -- the temperature loss that can occur in TCS food due to evaporative cooling in a hot holding unit over a set time period. The purpose of the study would be to determine a scientifically based "evaporative cooling range" temperature that could then be added to the 129°F. growth limit (for *Clostridium perfringens*) to calculate a scientifically based "safe" TCS hot holding temperature.

Public Health Significance:

The Public's health will continue to be served by further enhancing the latest science and food safety knowledge to promote a safe national food supply and thereby reduce the incidence of food borne illness.

Recommended Solution: The Conference recommends...:

that the Hot Holding Committee be re-created under the direction of Council III to address:

- a study of calibration methods for infrared units.
- the issues of evaporative cooling and its relationship to hot holding temperatures, including temperature loss, elapsed time, and corrective action.
- a final recommendation for a hot holding temperature requirement based on risk.

This scientifically based "evaporative cooling range" temperature could then be added to the 129°F. growth limit (for *Clostridium perfringens*) to calculate a scientifically based "safe" TCS hot holding temperature, and report back to Council III at the 2012 Biennial Meeting.

Submitter Information:

Name: Roger E. Coffman, Co-Chair
Organization: Hot Holding Committee

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Attachments:

- "2008-10 Hot Holding Committee Final Report"

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

COMMITTEE NAME: Hot Holding Committee

COUNCIL (I, II, or III): III

DATE OF REPORT: January 8, 2010

SUBMITTED BY: Donna M. Garren and Roger E. Coffman, Co-Chairs

COMMITTEE CHARGE(s):

Study Change of Hot Holding Temperature from 135°F to 130°F. The 2008 Biennial Meeting recommended that a committee be formed under the direction of Council III to address the issues of hot holding temperatures and times, and any microbial risks that may be associated with different temperatures and times, as well as the accuracy and proper use of temperature measuring devices for this purpose and report back to Council III at the 2010 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The analysis of TCS (temperature control for safety) food hot holding temperature data available to the Committee from academic, regulatory, and industry sources around the country, combined with the results of the Hot Holding Committee survey that was conducted via e-mail distribution to retail food companies in June, 2009 (see attachments titled: *Original Survey Document* and *Summary of Completed Survey*), resulted in these answers:

- Regardless of the regulated TCS hot holding temperature requirements in various United States jurisdictions (130°F., 135°F., 140°F., 145°F., or 150°F.), the recorded TCS food temperature data assembled showed that a wide range of hot holding food temperatures are occurring (170°F. to 105°F.). TCS hot holding temperatures of 129°F. and below can allow organisms, such as *Clostridium perfringens*, to multiply in an un-controlled environment, increasing the risk of foodborne illness.
- It is reasonable to interpolate that in the majority of cases, **the commercially manufactured hot holding units are set up, and have the ability to hold TCS food at the current regulatory/industry temperature standard of 130/135°F. or above.**
- Food temperatures measured and reported at colder levels (from 130/135°F. down to 105°F.) indicate the food was affected by stratification in the hot holding unit. The colder temperatures for the top of food in hot holding units (steam tables) are due to many issues, including “evaporative cooling”, lack of stirring, and to a lesser degree, equipment malfunction.
- Metal stem thermometers/metal stem thermocouples were the usual method of choice for temperature measurement. Some use of infrared thermometers for surface

temperature measurement was reported. Infrared thermometers would be less effective in gathering necessary information, due to the inability to measure the “internal” temperature of the TCS food items in steam tables (temperatures closer to the hot holding thermal heat source). A study of calibration methods for infrared units may also be necessary.

- Evaporative cooling is a major cause of the TCS hot holding food temperatures being below 130/135°F. Data showing how much temperature loss is attributed to evaporative cooling, which foods are affected more by the temperature loss (thick, protein foods such as refried beans), the elapsed times that are involved (4 hours as an example), and corrective measures needed must be included in future analysis projects.
- One limiting factor to evaluating the occurrence of *Clostridium perfringens* growth is that illnesses due to *Clostridium perfringens* are not a “reportable illness”, so data collection on the public health affects of this organism is sporadic at best.
- The unknown value needed to calculate a safe TCS hot holding temperature is the evaporative cooling temperature loss that can be expected in hot holding units.

In conclusion, a scientifically reviewed value for what can be labeled as the “**evaporative cooling range**” must be determined. The “evaporative cooling range” would be the temperature loss that can occur in TCS food due to evaporative cooling in a hot holding unit over a set time period. The temperature that organisms begin to grow in TCS foods (129°F. or below for *Clostridium perfringens*) must then be taken into account.

The scientifically based “evaporative cooling range” temperature could then be added to the 129°F. growth limit to calculate a scientifically based higher “safe” TCS hot holding temperature.

Hot holding food data must continue to be assembled, processed, and analyzed for this study. Representatives from academia, industry and regulators can evaluate the collected information to reach an accurate recommendation for a hot holding temperature requirement, based on the risk to grow an organism such as *Clostridium perfringens* in TCS foods held in hot holding units. It is recommended that the charge issued to the Hot Holding Committee be re-issued, so that this study can be continued.

It is the recommendation of the Committee to re-create the Hot Holding Committee to continue the on-going studies of the science and data available on hot food holding, including:

- A study of calibration methods for infrared units.
- A study of evaporative cooling and temperature loss, elapsed time, and corrective action.
- A final recommendation for a hot holding temperature requirement based on risk.

REQUESTED ACTION

The Hot Holding Committee is submitting two Issues for Council III's consideration:

Issue 1 – Report - Hot Holding Committee

Issue 2 – Re-Create - Hot Holding Committee

The following attachments are submitted with this report:

- Original Survey Document
- Summary of Completed Survey
- Quantitative Microbial Risk Assessment (QMRA) for Hot Holding Survey
Charts and Graphs
- 2008-10 Hot Holding Committee Roster

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 060
Issue: 2010 III-015**

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

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Title:

Temperature of Water for Handwashing Sinks

Issue you would like the Conference to consider:

To make the language in section 5-202.12 requiring handwashing sinks to be equipped to provide water at least at 38°C (100°F), consistent with that of 2-301.12 where "warm water" is required for handwashing.

Public Health Significance:

Handwashing is a vital step in providing food safety and successful handwashing requires several steps to be effective. The mechanical action of washing one's hands, use of soap, length of time hands are washed, rinsing, hand drying and proper handwash training, have all been noted as important factors in accomplishing proper hand washing. Sighting a specific threshold temperature of the water being supplied to the handwashing sink does not predicate successful handwashing, which can be accomplished at various water temperatures. Food Code 2-301.12 recommends to use "warm water" rather than water at a specific temperature. This is supported by work of Michaels et al (2002) which concluded that there was no statistical difference between log reductions in both resident or transient bacteria based on water temperature. This paper also suggested that use of higher water temperatures contributed to drying of skin, which may result in a disincentive for hand washing. Personal water temperature preferences may also encourage food handlers to wash their hands more frequent, for a longer time.

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 at least 38°C (100°F)~~ through a mixing valve or combination faucet. ^{Pf}

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Attachments:

- "Michaels et al 2002. Water temperature as a factor in handwashing efficacy"

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

Water temperature as a factor in handwashing efficacy

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Abstract

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Keywords:

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

For many years, sanitarians have specified that the hands of food service workers should be washed and rinsed in warm or hot water to reduce the risk of cross-contamination and disease transmission. In the food service environment, it has been suggested that handwashing with water at higher temperatures contributes to skin damage when frequent handwashing is necessitated, and that insistence on hot water usage is a deterrent to handwashing compliance. Separate handwashing studies involving different water temperatures and soap types (antibacterial versus non-antibacterial) were performed. The 'glove-juice' technique was employed for microbial recovery from hands in both studies. Initial work evaluated antimicrobial efficacy based on water temperature during normal handwashing with bland soap. Uninoculated, sterile menstrua (tryptic soy broth or hamburger meat) was used to study the effects of treatment temperatures (4.4°C, 12.8°C, 21.1°C, 35°C or 48.9°C) on the reduction of resident microflora, while *Serratia marcescens*-inoculated menstrua was used to evaluate treatment effects on the reduction of transient contamination. Results of this first study indicated that water temperature exhibits no effect on transient or resident bacterial reduction during normal handwashing with bland soap. The follow-up study examined the efficacy and skin irritation potential involving water temperatures with antimicrobial soaps. Hands of participants were contaminated with *Escherichia coli* inoculated ground beef, washed at one of two water temperatures (29°C or 43°C) using one of four highly active (USDA E2 equivalency) antibacterial soaps having different active ingredients (PCMX, Iodophor, Quat or Triclosan). Skin condition was recorded visually and with specialized instrumentation before and after repeated washing (12 times daily), measuring total moisture content, transepidermal water loss and erythema. Overall, the four soap products produced similar efficacy results. Although there were slight increases in Log₁₀ reductions, visual skin irritation, loss of skin moisture content and transepidermal water loss at higher temperatures, results were not statistically significant for any parameter.

Introduction

A critical and thorough evaluation of simple handwashing procedures reveals numerous variables to be considered by food service managers in order to achieve maximum or appropriate de-germing of the hands and fingernail regions. Numerous studies have explored issues such as type of soap (i.e. antibacterial versus plain, liquid versus bar), amount of soap, nailbrush

use, drying technique (i.e. cloth versus paper towels, paper towels versus air-drying), and application of instant hand sanitizers (postwash liquids). Previous studies indicate that these variables are crucial in achieving effective removal of transient bacteria from the hands under controlled testing conditions. Rarely mentioned in the scientific literature is testing to determine specific guidelines for water temperatures and flow rates. Many of the currently employed hand-

washing practices are based on untested traditions that could possibly result in compromised skin health. It is expected that warm or hot water would be beneficial in reducing bacterial counts from hands during handwashing, as heat provides energy for the increased solubility and melting of fats, oils and other soils which may serve as vehicles for bacterial transfer from hands. Warm/hot water, combined with the detergents present in soap, should theoretically provide greater emulsification of contaminating soils on the skin, resulting in a more efficient lifting of these soils for rinsing away.

Some food safety experts strongly recommend the use of antimicrobial soaps for food service workers, while others are now focusing on handwashing frequency. With the rise of antibiotic resistance, increased concern has been expressed with respect to antimicrobial soap usage. The reasoning has been that when warm/hot water is combined with antimicrobial soap, the temperature of activation is approached, accelerating chemical reactions and improving kill rates. Soil emulsification should allow for greater exposure of microorganisms in the contaminating soil to the antimicrobial active agents. Thus, bacterial population numbers may be reduced two ways: through soil emulsification and lifting/rinsing away, and inactivation provided by the antimicrobial agent(s) with higher temperatures doing a significantly better job. The infected food worker is the focus of improved hygiene measures, and food safety managers and regulators would be remiss to not try to optimize effectiveness. Asymptomatic food handlers have been identified as being responsible for approximately one-third of outbreaks traced back to the infected worker. Poor personal hygiene has been cited as a contributory factor in an average of 30% of foodborne illness outbreaks occurring in the U.S. between the years of 1973 and 1997 (Bean & Griffin 1990; Bean *et al.* 1996; Olsen *et al.* 2000). The vast majority of foodborne illness outbreak cases attributed to the infected food handler occurs in the food service environment (Michaels *et al.* 2002).

The main initiative in hand hygiene is the reduction of potentially pathogenic microorganisms from contaminated skin surfaces. Optimization of all variables involved in this task must not only provide sufficient removal and/or kill of potential pathogens, but must also refrain from damaging the skin, as this can affect handwashing compliance (Boyce and Pittet 2001) and seriously compromise food service safety. Skin damage associated with work from routine and frequent handwashing has also been seen to result in colonization of workers hands with potential pathogens.

With so many variables involved in such a 'simple procedure', it would make sense to explore and maxi-

mize all possible aspects of the process while minimizing negative collateral. This is especially important due to the many observations of food service workers revealing what is considered to be poor habits in handwashing techniques. Studies indicate that handwashing compliance drops considerably without supervision and monitoring, or in situations where skin damage occurs. This further amplifies the need to strengthen knowledge of all variables that might improve or weaken daily handwashing practices throughout the food processing and service industry.

As described by Price, two types of flora exist on the hands, transient and resident species (Price 1938). The transient flora is generally removed fairly easily. They do not have adhesion characteristics that hold them to the skins' surface and are somewhat suppressed by secretions and competitive exclusion by the resident flora (Dunsmore 1972). Resident flora is removed more slowly. Because of coevolution, resident flora have adapted to conditions on the skins' surface that cause rapid die-off of most transients. Invaginations such as the nail fold, hair follicles and sebum-producing sebaceous glands support a rich resident flora. Transient flora may consist of pathogens, spoilage bacteria or harmless environmental species. Under certain conditions, transient flora can change status and become permanent residents. Resident flora, as a rule, are not pathogenic types. Although colonization with coagulase-positive staphylococcus is fairly common (Noble & Pitcher 1978). Frequent or prolonged exposure of the skin to microbial contamination in soils, skin damage or fissures provide portals of entry to deeper tissue, and may result in many pathogenic bacteria found among the resident species (Price 1938; Kaul & Jewett 1981). Food workers in a number of different food industry segments (including catering and bakery) have been found colonized by varying numbers of potential pathogens (Seligman & Rosenbluth 1975).

The effective water temperature used for washing and rinsing hands was a topic of intense discussion at the U.S. Year 2000 Conference for Food Protection. This biannual conference assembles federal and state regulators, food safety academicians, food service industry scientists and safety managers to establish and recommend guidelines to the United States Food and Drug Administration (FDA) for inclusion into the FDA Model Food Code. This code, as adopted by individual US states, forms the basis for food safety regulation and enforcement activities to the food service industry. Several submitters of issues, brought before science and technology council (Council III), expressed their concern regarding the use of higher water temperatures as recommended of the food service/processing industry (Table 1). The United States Food and Drug

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

Submitter	Issue	Reason
L. Wisniewski (Select Concepts – Consulting)	‘Warm Water’	1. Hand Discomfort Decreases Frequency
M. Scarborough (Georgia Department of Human Resources, Division of Public Health)	37.7°C (100°F)	1. No Science (43°C vs. 37.8°C) 2. Plumbing Code @ 100°F Max. (Safety Concerns)
J. Budd (Healthminder/Sloan Valve Company)	35°C (95°F)	1. No Scientific Basis 2. Max Soap Efficacy at 35°C 3. Hand Comfort 4. Hot Water Discourages Hand Washing
E. Rabotoski (Wisconsin Conference Food Protection)	‘Tempered’ 29.5°C (85°F) to 43°C (110°F)	1. Hand Discomfort 2. Possible Scalding
B. Adler (Minnesota Department of Health)	Impose Temp. Range 43°C 110°F To 54.4°C (130°F)	1. Need upper limit or subject to OSHA 2. Food workers Don’t Wash 25 Sec. So Cannot Scald.
Reimers (H.E.B. Grocery Company)	‘Tempered’ To Warm	1. No Science . 2. Max Soap Efficacy 3. 43°C Risks Injury 4. Waste Water as Wait for Temp. at 43°C

Administration (FDA) Food Code provides recommendations for the food service industry to follow regarding food handling practices, application of HACCP principles and personal hygiene implementation (US Public Health Service 1999; US Public Health Service 2001). The main goal of the FDA has been the creation of uniform practices throughout all of the United States. The 1999 FDA Food Code requires sinks used for handwashing to be equipped so as to be ‘capable of providing water of at least 43°C (110°F), accomplished through use of a mixing valve or a combination faucet’ [tap] (US Public Health Service 1999).

All but one of the submitters requested temperature decreases with the intent of improving hand comfort, as the discomfort associated with higher temperatures results in decreases in hand washing frequency or compliance. Several submitters note a lack of scientific information on the subject. There is concern that a minimum handwashing temperature of 43°C (110°F), in addition to causing discomfort, will result in injury or scalding and may even be in conflict with local plumbing codes. Two submitters point out that soaps currently available target maximum effectiveness at around 35°C (95°F). Two submitters requested that the minimum temperature of 110°F (43°C) be changed to warm water or that it be tempered to a range of 85°F (29.5°C) to 110°F (43°C). and finally, one submission sought to place an upper temperature limit of 130°F (54.4°C), for fear that these regulations would be subject to Occupational Safety and Health Administration (OSHA) scrutiny and criticism without a limit.

Interestingly, it was noted in this submission, through reference to the Consumer Product Safety Commission, that second or third-degree burns have been shown to occur in the elderly at temperatures not much over 43°C (110°F). Council I and the General assembly of voting delegates passed a recommendation to lower the regulatory water temperature minimum to 29.5°C (85°F). In recognition of concern expressed by a number of stakeholders with regards to the issue of handwashing water temperature, the initial results of the work described in this report and the will of state voting delegates, the 2001 Food Code lowered the required handwash water temperature to 37.8°C (100°F) (US Public Health Service 2001).

The universe of food handling situations requiring effective personal hygiene spans from temporary hand-wash stations set up in produce fields and county fairs to advanced state of the art clean room style kitchens used to produce extended shelf life ready-to-eat foods sold at retail. In quick service restaurants, workers frequently switch between food and money handling. Due to the potential for money to carry potential pathogens, as described by Michaels, hands may require washing from up to 40 times or more in an 8-h shift (Michaels 2002). In many of these situations, it is difficult to provide water meeting strict temperature ranges. With regard to international settings, it is doubtful that underdeveloped parts of the world will easily be able to tap into warm/hot water supplies, much less into clean water sources at all. Water temperature shortcomings have been a common point of criticism by

food safety experts when reviewing handwashing procedures in the developing world as part of HACCP activities. Further, no matter where the location, it is difficult to manage and monitor food handlers to insure that minimum temperature levels are maintained during all handwashing activities. When subject to regulatory inspections, in the U.S., violations are given to food industry entities based on Food Code specifications. In some cases, based on accumulation of violations with water temperature being one of them, mandatory 48 h closure can result. This appears to be both costly and unnecessary based on the results of the studies described here.

In an extensive literature review of the effect of water temperature on hygienic efficiency, only two existing experimental studies shed light on this issue. Both of these involved hand sampling studies, in which the objective was to remove, identify and enumerate as many bacteria on the hands as possible, either as normal or transient flora. In hand scrubbing experiments, Price found that at temperatures from 24°C (75.2°F) to 56°C (132.8°F) there was no difference in de-germing rate (Price 1938). Since he scrubbed hands with a brush for a specific period of time, each in turn in a series of sterile wash basins, he might have been capable of seeing differences upon counting the flora in each basin. After conducting over 80 experiments in a 9-year period, Price concluded that the largest variable in determining the rate of removal of bacteria from the hands was the vigorousness of scrubbing. Other factors such as soap used or water temperature were less important. In later hand sampling experiments by Larson and others (implementing the glove juice method for recovery of microorganisms), no differences in isolation rates were seen at either 6°C (42.8°F) or 23°C (73.4°F) (Larson *et al.* 1980). While this information is inconclusive and does not answer questions concerning bacterial loads suspended in a confounding soil, they tend to indicate that there may not be a noticeable difference in efficacy over a range of temperatures from 6°C (42.8°F) to 56°C (132.8°F).

Various menstria have been used for handwashing efficacy studies. For studies involving transient flora, the most often used soil is tryptic soy broth (TSB). Microorganisms exhibit good survivability, with even distribution of contaminating microorganisms into skin cracks, creases and invaginations being possible. Ground beef probably represents the most appropriate menstria because of concern for risks of *E. coli* O157:H7 infection, but is only occasionally used (Sheena & Stiles 1982; Stiles & Sheena 1985). Meade and others have shown numerous sporadic cases of foodborne illness have been tied to poor personal

hygiene after ground beef preparation (Meade *et al.* 1997). In addition, due to its viscosity, thixotropic properties and level of organic soil, it would appear to be a good surrogate for fecal material.

A review of pertinent literature was also undertaken to determine if, independent of efficacy, facts on skin damage support a lowering of the temperature. The Consumer Product Safety Commission (CPSC) has noted that residential water heater thermostat settings should be set at 49°C (120°F) to reduce the risk of the majority of tap water scald injuries. Although the majority of scalding attributed to the home occur in children under the age of five and the elderly, third-degree burns are known to result in a two second exposure to 66°C (150°F), six-seconds at 60°C (140°F) and 30 s at 54.4°C (130°F) (US Consumer Product Safety Commission 2000). As we age, our skin becomes thinner, losing suppleness. This fact is important as many seniors are now actively involved in the food service industry. Due particularly to the elder risk, some have recommended that water be delivered from the tap at even lower temperatures of less than 43°C (110°F) (Stone *et al.* 2000).

The activity of soaps, friction and rinsing become crucial since the temperatures recommended in handwashing water alone would not provide thermal destruction of pathogenic microorganisms. Relevant to the discomfort issue associated with hot water is a previously conducted study by Horn and Briedigkeit involving dishwashing soaps (Horn & Briedigkeit 1967). In that study, participants were only able to withstand water temperatures at 43°C, 45°C, and 49°C (110°F, 113°F and 120°F), with tolerance levels due to discomfort peaking at one-minute (Horn & Briedigkeit 1967). Even though considerably longer than the 10–25 second exposure period that would result from handwashing, it is indicative of the fact that temperatures from 43°C and upwards (110°F and upwards) are at or near the human discomfort threshold.

Friction has been described as a key element in removing microbial contaminants from hands (Price 1938; Kaul & Jewett 1981). Friction applied during hand drying is instrumental in finishing the process (Madeline & Tournade 1980; Knights *et al.* 1993; Michaels *et al.* 2002). Removal of transient flora appears to be even more friction dependent than removing resident flora. Surfactant and antimicrobial compounds in soap are responsible for lifting soil and killing microorganisms suspended in the soil. When using bland soap to wash hands, handwashing efficacy appears to be dependent on the effects of surfactant action of the soap along with friction applied during the washing and rinsing process. Rinsing also provides the necessary removal by dilution. To facilitate appro-

appropriate rinsing of the hands, some personal hygiene consultants have suggested the practice of using thicker, higher viscosity soaps in larger doses, which would require a longer, more vigorous rinsing routine.

Price, upon noticing that in his scrubbing experiments that water temperature had little effect at degreasing of the skin, commented that water applied to the skin at a given temperature quickly reaches equilibrium with normal skin surface temperature unless hands are totally immersed (Price 1938).

Skin oils derived from sebum are liquid in the sebaceous gland and solidify on the skin surface. Beef tallow has a melting point range between 35°C and 40°C (95°F and 104°F), while lard or butterfat are liquefied at around 30°C (86°F) (Lide 1990). If handwashing efficacy for both resident and transient floras embedded in both natural and artificially applied fats depended on thermal melting, then 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, uninoculated TSB and irradiated ground hamburger were used as confounding soils in testing for the reduction of the resident flora. Following hand contamination, baseline microbial counts were acquired using the 'glove-juice' method on one hand. Hands were moistened and washed/lathered for 15 seconds with 3 mL bland (nonantibacterial) soap, rinsed for 10 seconds (water flow rate of 7 L/minute) at the assigned water temperature (also used for the prelather moistening), and the opposing hand was then sampled using the same glove-juice technique. No drying of hands was performed, which would have had the effect of diminishing differences between experimental groups. Baseline and postwash readings were then compared to obtain bacterial reduction values. For this study, no skin condition assessments were performed.

The first study was performed using a non-antibacterial soap and examined temperature effects on bacterial reductions based on the solubility of greasy soils. It did not address the increased temperature effect on antimicrobial activation or possible skin damage. Therefore, the second study was undertaken, which not only involved a comparison of the microbial reduction effects of four antibacterial soaps at two different temperatures, but also evaluated skin conditions on the hands of participants throughout the study. The potential of each soap to cause negative skin changes at each water temperature combination was assessed by measuring the skin moisture content, rate of water loss from the skin, skin scaliness by computerized analysis of a digitized skin image, and by visual assessment of the dryness and erythema. This study was performed at BioScience Laboratories, employing eight subjects and using four different antimicrobial soaps, each having a different antimicrobial active ingredient. The soaps had antimicrobial activity equivalent to USDA E2 ratings (50-p.p.m. chlorine equivalency). The active ingredients in these products were Quaternary Ammonium (3% dual Quat formulation), Triclosan (1%), Parachlorometaxyleneol (PCMX-3%), and Iodophor (7.5% PVP-I). Participants consisting of paid volunteers performed multiple handwashes during two five-day test periods (weeks one and two) seven days apart using *Escherichia coli* (ATCC #11229) contaminated gamma irradiated ground beef. On days one through five of weeks one and two, the skin condition was evaluated visually, for moisture content using the Corneometer[®] 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). Log₁₀ reduction data was determined with the first wash of days one, three and five under each water temperature condition. After handling the contaminated ground beef in a way to uniformly contaminate hands, one hand was sampled immediately (again, using the ‘glove-juice’ technique) for a baseline reading. The subjects’ then washed both hands at the specific water temperature (85° ± 2°F for week one and 110° ± 2°F for week two) with their randomly assigned product with their opposing hand being sampled to establish microbial counts. Each subject then washed 11 consecutive times with their assigned test product each day drying hands between washes, then hands were evaluated visually and digitally 30 minutes fol-

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

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

*Griffith *et al.* 1969.

lowing the last wash. In all washing cases, lathering was performed for 15 seconds and rinsing for 10 seconds with three mL of the assigned test product.

Results and discussion

After extensive statistical analysis of the results from the first set of experiments, it was determined that there was no significant difference in bacterial log₁₀ 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 log₁₀ 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 log₁₀ 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.

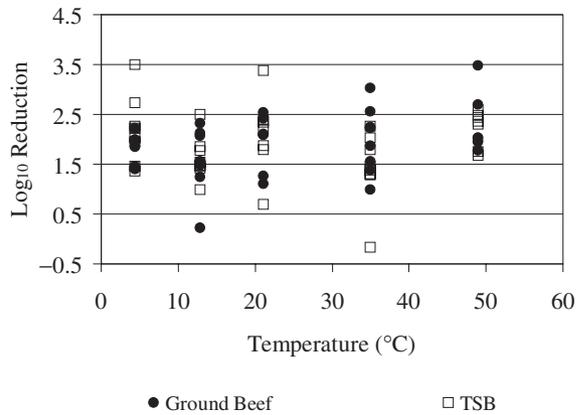


Figure 1 Handwashing efficacy (Log₁₀ reduction) for transient flora (*S. marcescens*) in ground beef and TSB at selected water washing and rinsing temperatures.

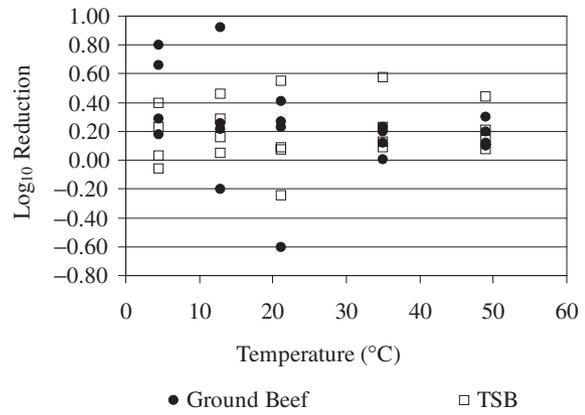


Figure 2 Handwashing efficacy (Log₁₀ reduction) for resident flora in ground beef and TSB at selected water washing and rinsing temperatures.

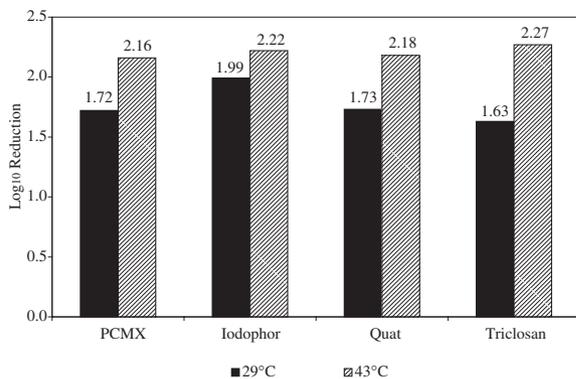


Figure 3 Average Log₁₀ reduction of transient flora (*E. coli*) in ground beef using selected antimicrobial soaps.

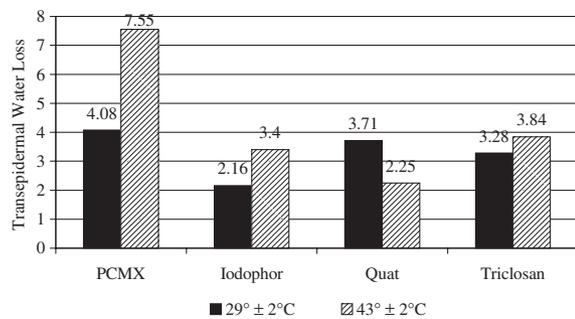


Figure 4 Average Tewameter® readings selected antimicrobial soaps at 2 different water temperatures.

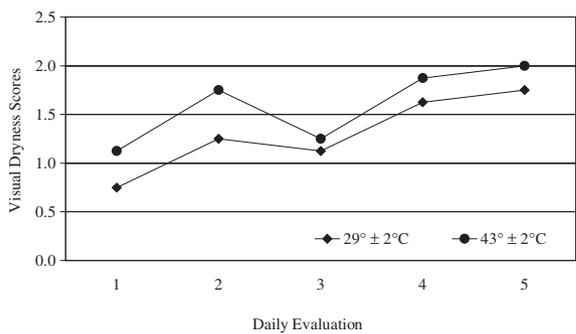


Figure 5 Average baseline-adjusted visual dryness scores (8 subjects) resulting from washing hands with 4 different E2 antimicrobial soaps for 5 days (12 x/day).

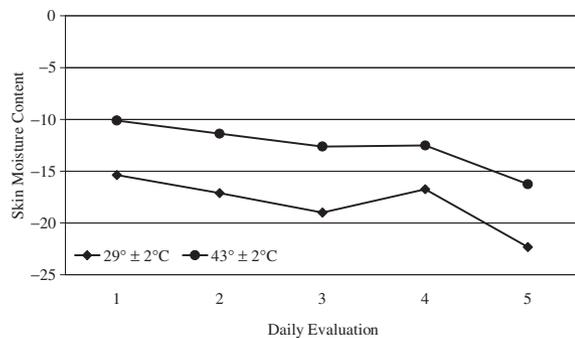


Figure 6 Baseline-adjusted Corneometer® readings (8 subjects) resulting from washing hands with 4 different antimicrobial soaps for 5 days (12 x/day) at two different handwashing temperatures.

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

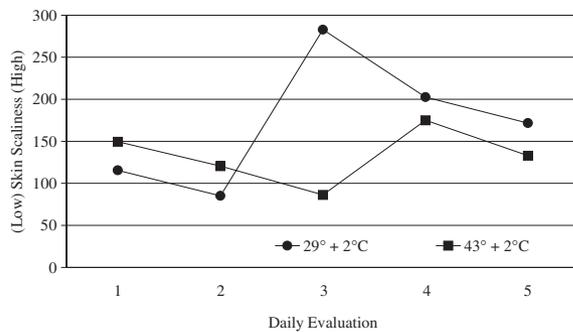


Figure 7 Average baseline-adjusted skin scaliness (8 subjects) resulting from washing hands with 4 different antimicrobial temperatures as measured using Visiometer®.

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 from hands. There in fact was a virtual absence of data to back up the various positions on the subject. Sanitarians and food safety experts have specified water temperatures varying from room temperature (running water) up to 'as hot as you can stand', the latter of which is probably in the range of from 49°C (120°F) to 55°C (131°F). Regulations in the US and elsewhere tend to focus on temperatures between 43°C (110°F) and 49°C (120°F). Concern that these temperatures could be detrimental to skin health without documented efficacy led to the experiments described here. Hands were contaminated with soils similar to those encountered in the food service environment. These soils contained marker bacteria allowing handwashing efficacy to be determined at specified water temperatures against both transient flora and resident flora simultaneously.

The initial experiment involved testing with bland non-antimicrobial soap at 5 temperatures from 4.4°C (40°F) to 49°C (120°F). Independent of soil or bacterial type (resident or transient) there was no significant difference in efficacy attributed to water temperature. In the second experiment antimicrobial soaps (4) were used having different antimicrobial active ingredients, at each of two water temperatures, 29.5°C (85°F) and 43°C (110°F). Skin condition was monitored with frequent handwashes (12 ×/day) for the second set of water washing temperature experiments. In this experiment, even though slightly higher efficacy with was seen with antimicrobial soaps at higher temperatures, overall, there was no statistical difference in efficacy as measured in Log₁₀ reduction at the two water temperatures (regardless of soil or microflora types). Concomitant to the increase in efficacy at higher temperatures was a consistent trend for increases in measures of skin damage, such as skin moisture content, transepidermal water loss and erythema. This was also found not to be statistically significant.

Both the trend for higher efficacy of soaps with attendant skin damage at higher temperatures are grounded in theory. Under the conditions of these experiments neither was shown to be proven for practical application. Since efficacy is not markedly improved at higher temperatures but rather the real danger exists of skin damage, requirements for specific handwashing water temperature should be relaxed to improve acceptance of frequent handwashing by food workers at appropriate times to reduce foodborne illness potential.

Water temperature should be in a comfortable range, perhaps tempered.

As has been shown by many previous researchers, overall handwashing effectiveness is more dependent on the 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
2010 Issue Form**

**Internal Number: 067
Issue: 2010 III-017**

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

All information above the line is for conference use only.

Title:

Elimination of Open, Refillable Soap Dispensers

Issue you would like the Conference to consider:

The Food Code emphasizes the critical role of hygiene in prevention of foodborne illness. Numerous sections of the 2009 Food Code address specifications and requirements for water quality, air supply, surface and utility cleanliness, and cleaning materials. Similarly, various Code Sections, including 2-102.11(C)(8), 2-301.11-16, 5-202.12, 5-203.11, 5-204.11 and 5-205.11, delineate sink and faucet parameters, handwashing procedures, and other aspects for proper handwashing in food handling operations. However, the Code lacks specification for the types of soap dispensing systems suitable for handwashing products in food handling settings. This important gap creates the potential for increased microbiological contamination due to the use of open, refillable reservoir-type dispensing systems. It has been known for decades that contaminated soap can lead to disease transfer. Following a number of infectious disease outbreaks, the use of open, refillable soap systems in Healthcare facilities was essentially eliminated in the 1990's and codified in the 2002 CDC/HICPAC Guidelines for Hand Hygiene in Health-Care Settings. Very recent guidance from Health Canada (issued December 2009) requires professional food handler antiseptic products to be labeled "Do not refill container", essentially banning bulk dispensing systems for food environments in Canada.

Recent research by the University of Arizona demonstrates that high level bacterial contamination of open, refillable soap dispensing systems is widespread, including retail Foodservice settings. Additional studies at the University of Montana show that on-going recontamination of fresh soap in refillable dispensers is due to biofilm formation and nearly impossible to eliminate despite aggressive cleaning procedures. Further, these studies show that biofilm contamination of open, refillable dispensers occurs regardless of design or materials of construction. Even more recent studies by GOJO Industries demonstrate that soap contamination transfers from the dispensed soap to the hands during washing and subsequently to surfaces (fomites).

Solutions to this contamination problem are readily available. A plethora of sealed, non refillable dispensing systems are virtually universally available. While some of these systems are proprietary, many are essentially commodity products in the same way that open systems are today, providing a facility with a broad choice of products and suppliers.

Public Health Significance:

High level contamination (approaching pure bacterial cultures) of open, refillable and non hygienic soap dispensers with coliforms and other pathogenic organisms represents an unnecessary risk of infection to foodservice workers and patrons.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA requesting the following change to the Model Food Code:
5-202.11

(C) A dispensing system for hand soap and/or hand antiseptic shall be of a sealed-refill design and not have a product reservoir susceptible to refilling from a secondary container, "topping off", or dilution with water or other materials. If used, individual bottles of hand soap or hand disinfectant shall be disposed of after use of the initial contents and not refilled.

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Attachments:

- "Bacterial Contamination of Soap from Open, Refillable Bulk Dispensers"
- "Evaluation of Contaminated Bulk Soap Dispensers for Biofilm Bacteria"
- "Handwashing with Contaminated Soap Results in Hand Contamination"
- "Opportunistic Pathogens From Contaminated Bulk Soap on the Hands"
- "Open Refillable Bulk Soap Dispensers in Public Restrooms"
- "Guidance Document: Human-Use Antiseptic Drugs"

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.

How Safe is Your Soap?

**Bacterial Contamination
of Soap from Open
Refillable Bulk Dispensers**

Charles P. Gerba, PhD

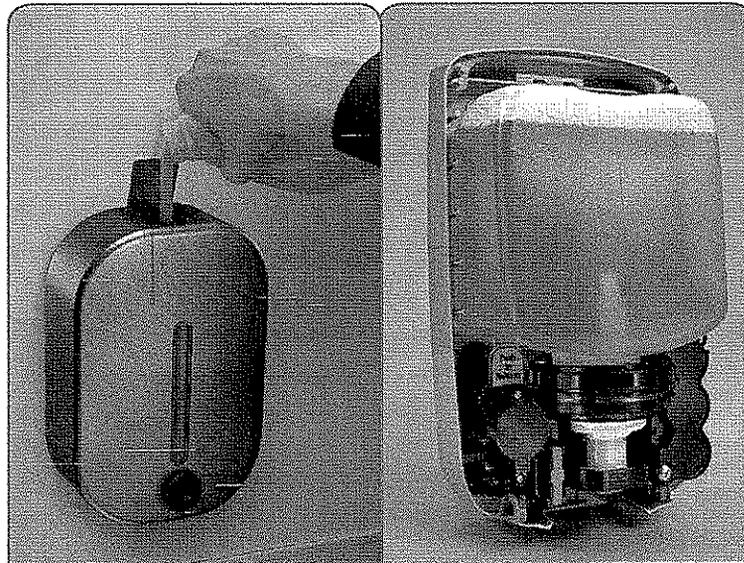
Marisa B. Chattman

Sheri L. Maxwell

An overview and summary of research studies conducted by
The University of Arizona, Tucson, AZ, and presented to:

- The American Society for Microbiology 107th General Meeting
Toronto, ON, Canada; May 21-25, 2007
- The National Environmental Health Association 71st Annual
Educational Conference & Exhibition
Atlantic City, NJ; June 18-21, 2007

Do you know the difference?



**Open Refillable
Bulk Soap Dispenser**

**Sealed Soap
Dispensing System**

Design	<ul style="list-style-type: none"> • Open to the environment • Permanent nozzle is reused 	<ul style="list-style-type: none"> • Factory sealed • New nozzle with each refill
Refilling Method	<ul style="list-style-type: none"> • Pour soap into dispenser from bottle 	<ul style="list-style-type: none"> • Snap new cartridge into dispenser
Maintenance	<ul style="list-style-type: none"> • Labor intensive • Extensive cleaning and sanitizing required 	<ul style="list-style-type: none"> • Labor-free • No need for cleaning and sanitizing
Contamination	<ul style="list-style-type: none"> • Prone to contamination 	<ul style="list-style-type: none"> • Safe from contamination

Bacterial Contamination of Soap from Open Refillable Bulk Dispensers

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Bulk Soap Contamination Research Study Summary

Background

Several studies conducted during the last 25 years have demonstrated that liquid soaps can become contaminated with microorganisms and multiple instances of infections and nosocomial outbreaks associated with such contamination have been reported (1-4). Contamination often occurs after the product reaches the user (extrinsic contamination) (1;3;5) and has been observed in both nonmedicated (1) and antimicrobial products including those with the active ingredients Chloroxylenol (PCMX) (3), Benzalkonium chloride (5;6), Triclosan (4), and Chlorhexidine gluconate (2;5;7-10). All types of liquid soap, regardless of the active ingredient or preservative system, are susceptible to contamination when exposed to adverse circumstances. Soap dispensers with sealed disposable refills are an alternative to this contamination challenge. By contrast, open refillable ("bulk") soap dispensers continue to present significant risk of contamination during use. Because the addition of soap

to a partially empty dispenser ("topping off") can lead to bacterial contamination in healthcare settings, the CDC recommends the use of soap dispensed from disposable containers or containers that are thoroughly washed and dried prior to refilling (11;12).

Recent studies conducted at the University of Arizona by prominent microbiologist, Dr. Charles P. Gerba, revealed that liquid hand soap collected from open refillable dispensers are a public health risk. Dr. Gerba determined the levels of bacteria in soap sampled from various types of dispensers. He found unsafe levels of bacterial contamination in soap from open refillable dispensers, whereas no bacterial contamination was found in soap from dispensers with sealed disposable refills. This research has been presented at two recent scientific conferences (13;14).

National Environmental Health Association 71st Annual Educational Conference & Exhibition

Atlantic City, NJ; June 18-21, 2007

Title: Bacterial Contamination of Liquid Hand Soaps Used in Public Restrooms

Authors: C. P. Gerba and S. Maxwell; University of Arizona, Tucson, AZ

Abstract

The objective of this study was to determine the occurrence of heterotrophic and coliform bacteria in liquid hand soaps collected from public restrooms across the United States. Sample locations included public restrooms in restaurants, health clubs, office buildings and retail stores. The liquid soap samples collected were from refillable dispensers (also referred to as "open systems" or "bulk soap" systems). Of 541 samples, 133 (25%) had bacterial numbers greater than 500 CFU/mL and 87 samples (16%) contained coliform bacteria. Approximately 65% of the bacteria isolated from the soap belonged to the coliform group.

The average number of bacteria detected in the soap was 3.02×10^6 CFU/mL with a range of 590 to 5.3×10^7 CFU/mL. The average number of coliform bacteria was 3.94×10^6 CFU/mL with a range of <10 to 6.5×10^7 CFU/mL. Opportunistic pathogens identified in the liquid soap samples included *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Serratia marcescens*, *Pseudomonas aeruginosa* and *Enterobacter sakazakii*. No bacteria were detected in dispensers that required sealed soap replacements. All of the organisms detected in the soap samples were Gram-negative bacteria. This is most likely because of the presence of sodium lauryl sulfate in the soap, which inhibits the growth of Gram-positive bacteria. The results suggest that some liquid soap dispensers become colonized by Gram-negative bacteria over time, possibly because of the degradation of preservatives in the liquid soap.

American Society for Microbiology 107th General Meeting

Toronto, ON, Canada; May 21-25, 2007

Title: Bacterial Contamination of Liquid Hand Soaps

Authors: M. Chattman, S. Maxwell and C. P. Gerba; University of Arizona, Tucson, AZ

Abstract

The occurrence of heterotrophic bacteria (HPC) and coliform bacteria in liquid hand soap from 130 refillable unsealed (a.k.a. open or bulk) dispensers collected from employee break rooms, airplane restrooms, kitchens and public restrooms was determined. The percentage of samples that contained HPC numbers above 500 CFU/mL was 23%, averaging 4.5×10^6 CFU/mL. Total coliform bacteria were detected in 22% of the samples, averaging 2.2×10^6 CFU/mL. Bacterial species most frequently identified included *Serratia marcescens*, *Enterobacter aerogenes*, and *Klebsiella pneumoniae*. One of the soap dispensers containing contaminated soap was monitored over a three month period. Various levels and types of bacterial contamination were observed. When bacteria were added to uncontaminated, factory-sealed, liquid hand soap the bacteria quickly died. Liquid hand soap from a public restroom, that contained large numbers of bacteria was pasteurized

and inoculated with *K. pneumoniae*. Growth was observed, indicating that degradation of preservatives must occur in the soap dispenser over time, allowing for the growth of bacteria. These results demonstrate that bacteria growing in soap dispensers are not resistant to the preservatives and that preservative degradation takes place, likely after introduction of the soap in the dispensers.

Contaminated Bulk Soap is a Public Health Risk

Dr. Gerba's studies demonstrate that soap from open refillable dispensers in public restrooms in the US are routinely contaminated with opportunistic pathogens. Soap users are exposed to an average of over 1,000,000 of these bacteria approximately 1 in 4 times they wash with soap from an open refillable soap dispenser. This level of contamination is 1000 times greater than upper limit recommended by cosmetic industry standards (15) and presents a potential health risk to the soap users as well as to others they may have contact with. Hands are known to be a common transmission vector and it has been shown that bacteria remain on the hands after using contaminated soap (1). The risk of acquiring an infection is greatest for anyone who has a defect in their body's normal defense mechanisms. Up to 20% of the US general public have impaired immune function and this percentage is growing due to advances in medicine which are prolonging life as well as the increase in the proportion of elderly in the population (16-18). The immunocompromised population includes a diverse group with a wide variety of conditions ranging from the severely immunocompromised (HIV/AIDS, cancer, organ or bone marrow transplant recipients) to pregnant women, young children and the elderly which exhibit non-specific general reduced immune function (19;20). The fetus, neonate

and young children have reduced immune function for the first few years of life until their immune systems mature (19). Over 12% of the US population is over the age of 65 and are at a greater risk of acquiring infections due to their age-related diminished immunity (16;21). In addition, many common chronic conditions weaken the immune system including diabetes (18), cirrhosis/alcoholism, chemical dependency, nutritional deficiencies, and any defects resulting in skin barrier function loss (burns, ulcers, or dermatitis) (17;20).

Illnesses Caused by the Contaminating Bacteria

In the recent study by Dr. Gerba, several of the bacterial species isolated from the contaminated soap (e.g. *Klebsiella*, *Enterobacter*, *Citrobacter*, *Serratia*, and *Pseudomonas*) are medically important opportunistic pathogens. These organisms cause a variety of illnesses including respiratory tract infections, pneumonia, urinary tract infections, bloodstream infections, surgical site infections, meningitis, skin ulcers, gastroenteritis as well as wound and soft tissue infections (22-24). *Klebsiella pneumoniae*, for example, is responsible for 1-5% of community-acquired pneumonia (25). *Enterobacter sakazakii* causes neonatal meningitis (26). *Citrobacter* causes sepsis, meningitis and central nervous system abscesses in neonates and young infants (27) and there has been one report of *Citrobacter koseri* causing a central nervous system infection in a healthy person with a fully functional immune system (28). *Citrobacter freundii* was also implicated as a potential cause of an outbreak of diarrheal disease (24). *Pseudomonas aeruginosa* is a common nosocomial pathogen causing urinary tract infections, sinusitis, wound infections, and pneumonia. Occasionally it has been known to cause a rare form

of community-acquired pneumonia with a 33% mortality rate that can affect persons with healthy immune systems (29). *Serratia* has been implicated in multiple outbreaks due to contaminated soaps in healthcare facilities (1;3;4). *Pañtoea* is a rare pathogen that was reported to be responsible for 7 infant deaths in a neonatal outbreak (30). The frequent presence of such high numbers of organisms known to be medically significant both in the community and in healthcare settings is quite alarming.

Reducing the Risks of Bulk Soap Contamination

Unsafe levels of contamination were found in 23% - 25% of soap samples collected from open refillable dispensers. In contrast, no contamination was found in soap samples collected from dispensers containing sealed disposable refills. It is recommended that all open refillable dispensers should be switched to dispensers with sealed disposable refills, which are a safer alternative and avoid unnecessary health risk.

Bacterial Contamination of Liquid Hand Soaps

Introduction

Liquid hand soap is used daily by millions of people worldwide. Hand washing, with soap and water, is a universally accepted method to reduce the microbial load on the hands. People encounter situations in which they are exposed to a variety of bacteria that have the ability to cause infection. In response to these situations, many people wash their hands with soap and water. Society recognizes that good hygiene can reduce the risk of bacterial infection. Some public facilities have soap dispensers that require sealed bags or cartridges while others have dispensers that are refillable by using stock soap solutions that are often diluted with tap water. Bulk open refillable liquid soap dispensers in many public restrooms and restaurants, offer a suitable environment for the growth of potentially disease causing microorganisms.

Materials and Methods

Soap was collected into sterile 50mL centrifuge tubes through the dispenser mechanism. One mL of Dey-Enger (DE) neutralizing broth (Remel, Lenexa, KS) was added to each sample tube and shaken for 30 seconds. Heterotrophic plate counts (HPC) were obtained by spread plating 0.1mL onto duplicate petri dishes containing R2A media (Difco, Sparks, MD) and incubated at 30°C for 5 days.

Coliform enumeration was performed by spread plating on mEndo agar plates (Difco, Sparks, MD) and incubating at 37°C for 24 hours. Representatives of each colony type were streaked for isolation on petri dishes containing Tryptic Soy Agar (TSA) (Difco, Sparks, MD). Identification of bacteria was performed by using API20E strips (BioMerieux, Marcy-l'Etoile, France).

Results

Table 1: Occurrence of Bacteria in Liquid Hand Soap from Refillable Dispensers

Type of soap dispenser	Total number of liquid soap samples tested	Number >500 CFU/mL	Coliform bacteria	Average number HPC CFU/mL	Average number coliform bacteria CFU/mL
Refillable	132	30	29	4.5×10^6	2.2×10^6
Disposable bag	20	0	0	0	0

Figure 1: Frequency of Detection of Various Bacteria in Soap Samples

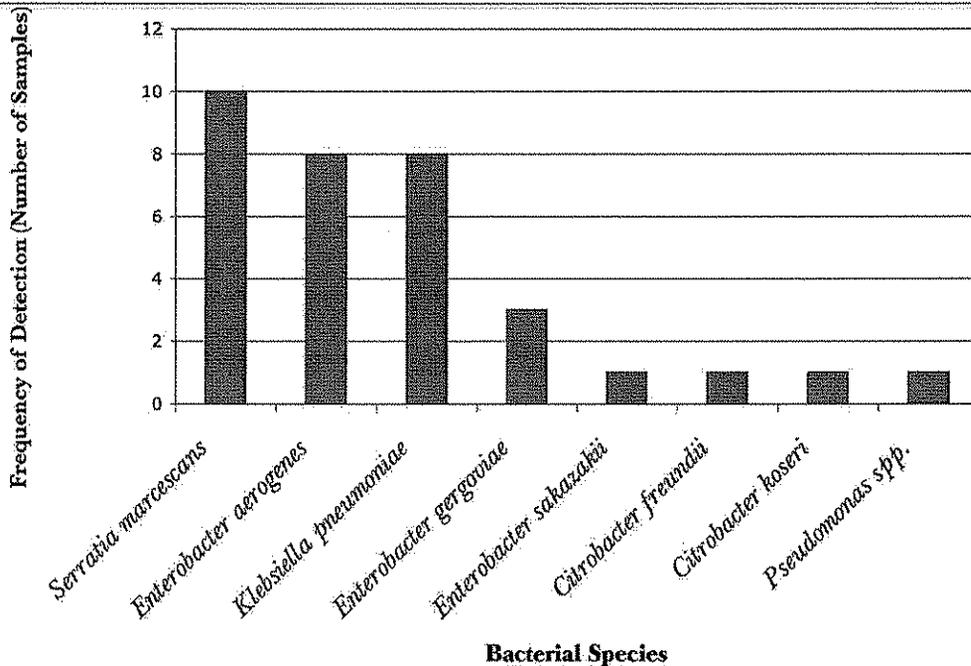


Table 2: Occurrence of HPC and Coliform Bacteria Over Time in a Restaurant Soap Dispenser

Date	HPC (CFU/mL)	Coliform bacteria (CFU/mL)
5/29	4.3×10^7	2.0×10^7
6/21	9.3×10^3	<1
7/17	1.9×10^7	8.2×10^6
7/31	9.5×10^6	7.3×10^6
8/14	1.2×10^7	9.0×10^6
8/28	<1	<1
9/12	3.2×10^7	2.6×10^7

Table 3: Growth of *Klebsiella pneumoniae* in Pasteurized Contaminated Soap (CFU/mL)

Sample	Time (Days)			
	0	1	4	8
9/12	6.3×10^2	3.4×10^4	5.9×10^5	2.5×10^6
Negative Control*	<1	<1	<1	<1

* Undiluted, pasteurized soap inoculated with same amount of bacteria as sample. Number of *Klebsiella pneumoniae* added to each soap sample was 5.6×10^3 (9.3×10^2 CFU/mL).

Table 4: Minimum Inhibitory Concentration of a Liquid Soap against *Klebsiella pneumoniae* (CFU/mL)

Dilution	0	Time (Days)			
		60 min	1	5	10
No Dilution	50	<1	<1	<1	<1
1:1	330	<1	<1	<1	<1
1:2	490	<1	<1	<1	<1
1:4	480	160	<1	<1	<1
1:10	410	320	<1	<1	<1
1:100	350	580	240	<1	<1
1:1000	410	550	240	1.5×10^4	1.5×10^5
Negative Control*	500	520	150	1.5×10^3	2.3×10^3

* No soap added.

Conclusions

- 22.7% of samples taken from refillable bulk dispensers contained >500 CFU/mL HPC, and 22% contained coliform bacteria, averaging 10^6 CFU/mL.
- Bacterial species identified were all opportunistic pathogens.
- No bacteria were found in sealed system soap dispensers.
- A soap dispenser monitored over a three-month period, demonstrated that bacterial contamination was prolonged although the levels and types of bacteria varied.
- Eight types of uncontaminated, factory-sealed, liquid hand soaps were inoculated with various species of bacteria. All of the bacteria quickly died in the soaps after addition, even when the soap was diluted.
- The minimum inhibitory concentration of a specific brand of soap used at a restaurant that had bacterial contamination in the soap indicated that it contained sufficient concentrations of preservatives to inhibit bacterial growth.
- Liquid soap from a public restroom, that contained large numbers of bacteria was pasteurized and inoculated with *Klebsiella pneumoniae*. Growth was observed, thus it appears that degradation of preservatives must occur in the soap dispenser, allowing for the growth of bacteria.
- Bacteria growing in the soap dispensers are not resistant to the preservatives and that preservative degradation takes place, likely after introduction of the soap into the dispensers.

Bacterial Contamination of Liquid Hand Soaps Used in Public Restrooms

Introduction

Washing hands with soap and water is a universally accepted method to reduce the microbial load on the hands and is used daily by millions of people worldwide. However, the majority of public facilities have soap dispensers that are refillable using a stock soap solution. The CDC recognized in 1975 that the use of these types of dispensers can result in a suitable environment for the growth of potentially disease causing microorganisms. Current health-care hand hygiene guidelines do not recommend the use of open refillable dispensers. The liquid soap used in these dispensers can become contaminated regardless of the preservative used when the microbial population exceeds the preservatives defenses. When product contamination has been reported, contamination was more likely to have occurred extrinsically (after product had been used) than intrinsically (during manufacturing). The likelihood of extrinsic contamination is greatest when the product is open to repeated exposure to bacteria from the user or the environment, hence, the packaging and the dispensing method plays a significant role in product safety.

Materials and Methods

Liquid soap samples were collected from public restrooms in five cities [Boston, MA (107), Atlanta, GA (120), Columbus, OH (109), Los Angeles, CA (94), and Dallas, TX (111)]. Samples were organized into 5 categories: office, health clubs, food service, retail locations and other (education, leisure, etc.). The total number of liquid soap samples analyzed in this report were 541, consisting of 428 soap samples from the sink area and 113 soap samples from the shower area at health clubs, 65 from men's showers and 48 from women's showers. A total of 428 liquid soap samples from the sink area, 226 from men's restroom sink areas and

202 from women's restroom sink areas, were analyzed for this report. Samples with <500 CFU/mL were not considered since industry standards allow for this amount of bacteria in liquid soap. All samples were confirmed to be from open refillable systems.

The samples were collected in sterile 50 mL conical tubes and shipped to the laboratory on ice. 1 mL of DE neutralizing broth (Remel, Lenexa, KS) was added to each sample tube and shaken vigorously for 60 seconds. Heterotrophic plate counts (HPC) were obtained by the spread plate method on R2A media (Difco, Sparks, MD). Plates were incubated at 30°C for 5 days. Any sample showing bacterial content was reexamined for Coliform bacteria.

Coliform analysis and enumeration was performed using the spread plate method on mEndo agar (Difco, Sparks, MD) and incubated at 35°C for 24 hours. Bacterial colonies were counted and recorded, representatives of all colony types were subcultured to TSA plates (Difco, Sparks, MD) for oxidase tests and identification. TSA plates were incubated at 35°C for 24 hours. Identification of bacteria was obtained using API20E strips (BioMerieux, Marcy-l'Étoile, France). *S. aureus* analysis was performed by using the spread plate method on TSA amended with 5% Sheep Blood (BA) (Hardy Diagnostics, Phoenix, AZ) to check for hemolysis. Plates were incubated for 24-48 hours at 35°C. Beta hemolytic isolates were enumerated and streaked onto a TSA plate and incubated for 24 hours at 35°C. Isolated colonies underwent further confirmation testing utilizing catalase production, microscopic morphology, coagulase production (tube and slide tests) and antibiotic (polymyxin) sensitivity.

Results

Figure 1: Locations Containing HCP and Percent of HCPs that were Coliforms

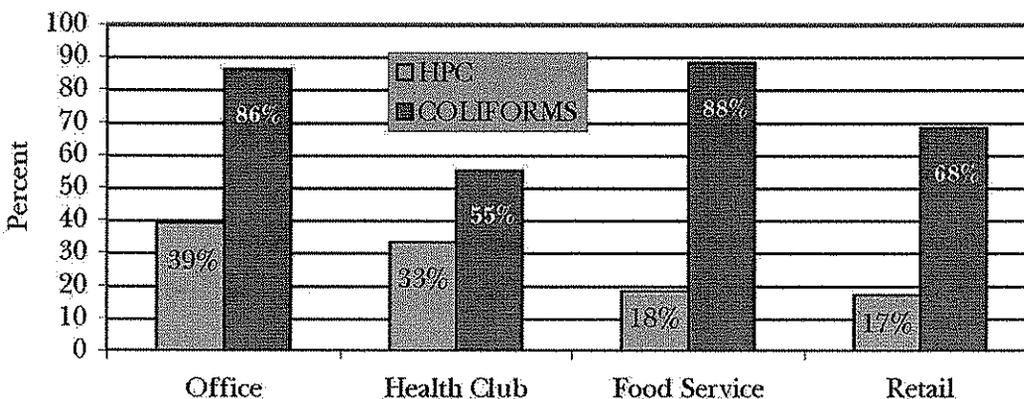


Figure 2: Frequency of Bacterial Species Isolated from Refillable Liquid Soap Dispensers

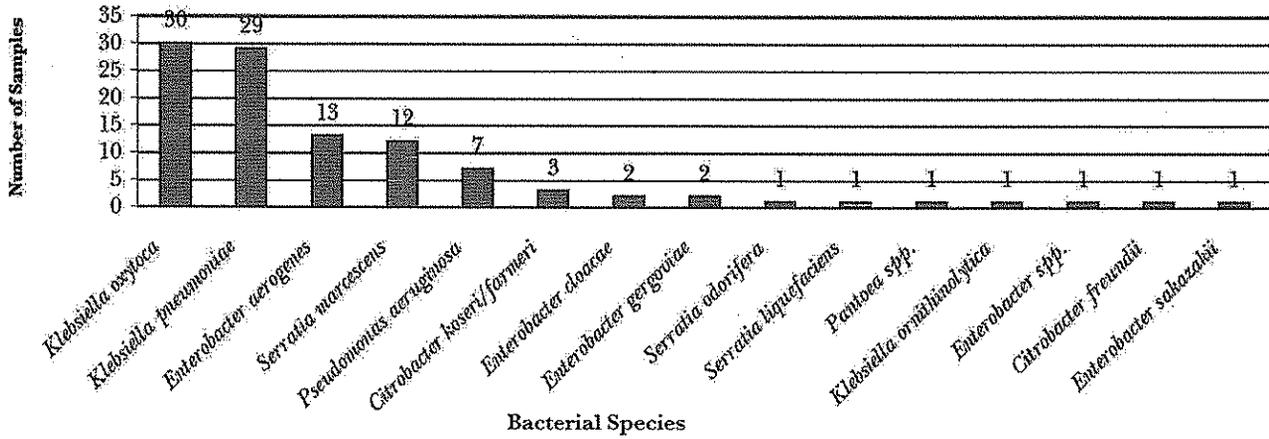
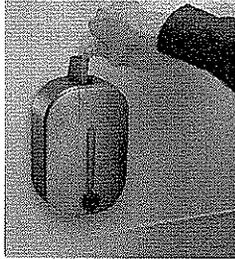


Figure 3:



Sealed System
0% Contaminated



Open Refillable Bulk
Soap Dispenser
Being Refilled
25% Contaminated

Table 1:

Total number of open refillable soap samples	Number of samples with bacteria	Number of samples with Coliforms
541	133 (25%)	87 (16%)

Summary

A total of 541 open refillable liquid soap samples were analyzed for bacteria, coliforms and *Staphylococcus aureus*. Of the 541 samples, 133 (25%) contained bacteria, 87 samples (16%) contained coliforms. The percent of bacteria isolated from open refillable liquid soap samples that were identified as coliforms was 65%. Heterotrophic bacterial numbers detected in the liquid soap samples ranged from 590 to 5.3×10^7 CFU/mL. The average number of bacteria found in one mL of soap was 3.02×10^6 CFU/mL. Coliform bacteria ranged from <10 to 6.5×10^7 CFU/mL, with an average of 3.94×10^6 per mL of soap. The frequency of contamination was similar for all cities tested, for both men and women's restrooms and for both wall mounted and counter-mounted dispensers. *Klebsiella* was the most frequently isolated genus of bacteria, followed by *Enterobacter* and *Serratia*. No *Staphylococcus aureus* were detected in any of the liquid soap samples analyzed.

Conclusions

High levels of bacterial contamination (average 3.02×10^6 CFU/mL) were found in 25% of the liquid soap samples in this study. Previous reports found no contamination in soap from sealed systems (figure 3). Since these samples represent a diverse cross section of geographical locales and individual sites, it is concluded that refillable open, or "bulk", liquid soap systems commonly found in the U.S. are routinely contaminated with bacteria. Many of the bacteria isolated are opportunistic pathogens which can cause a variety of health issues including respiratory infections, bloodstream infections, urinary tract infections and skin infections. The type and level of bacteria found in these systems represent a potential health risk to users, especially to any immunocompromised individuals.

Footnotes

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INTRODUCTION

Bulk refillable soap dispensers are manually refilled with bulk soap through an opening in the top, Figure 1.

Previous research demonstrated that up to 25% of bulk hand soap dispensers are contaminated with approximately 6 LOG₁₀(CFU/mL) heterotrophic bacteria based upon samples collected from the bulk soap¹. The contamination results from extrinsic sources and occurs when the preservative system in the soap is overcome.

This poster presents the results of a two-phase project. The goal of Phase 1 was to determine if biofilm growth within the dispensers contributed to bulk soap contamination, and Phase 2 investigated if washing the dispensers effectively reduced bacterial contamination.



Figure 1. Bulk refillable soap dispenser

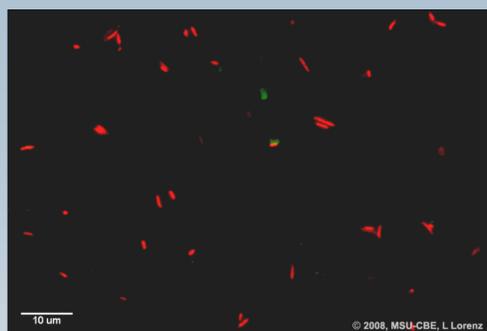


Figure 3. Epifluorescent image of cells obtained from a bulk refillable soap dispenser, filtered onto a polycarbonate membrane, and stained with Live/Dead for total cell counts. Total cell counts were an important way of determining the efficacy of the disaggregation methods. Disaggregation was determined to be efficient when single cells were seen, as shown above. 100X

Community Analysis Molecular Methods

The community analysis approach was broken down into four steps:

- Biomass collection**
 - Collect pooled bulk and surface associated pellets
- DNA preparation**
 - Cell lysis
 - Removal of cell debris via centrifugation
 - Precipitate proteins
- Clone library construction**
 - Clone gene of interest (SSU rRNA gene via PCR)
 - Ligation into plasmid & transformation into *E. coli*
 - Screen/pick colonies
- Organism identification**
 - Sequencing
 - Bioinformatic analysis

PHASE 1 – BIOFILM TESTING

Viable plate counts paired with biochemical identification assays and molecular methods were used to determine the amount of biofilm present and the ecology of the biofilm communities found in three types of dispensers. The dispenser types tested were: plastic counter-mount (from a shopping center), plastic wall-mount (from an elementary school), and stainless steel wall-mount (from middle/high schools). All dispensers tested were previously determined to be contaminated in the field.

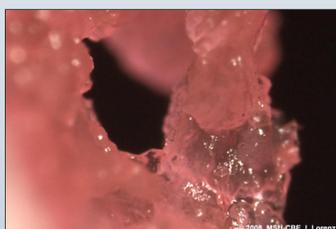


Figure 2. Stereoscope image of dried soap on the spigot opening of a plastic wall-mount dispenser. 5X

Viable Plate Count & Biochemical Identification Methods

Dispensers were received and visually inspected for any damage during shipment. Samples were collected and analyzed at three distinct steps:

- Sample A: the bulk soap (suspended bacteria)
- Sample B: the rinsed solution (loosely attached cells rinsed from the dispenser surfaces)
- Sample C: the scraped solution (surface associated cells scraped from the dispenser surfaces)

The three samples were then:

- Disaggregated and neutralized in D/E neutralizer (Disaggregation methods included sonicating and vortexing the sample with sterile 3mm glass beads, for 1 minute each, alternating with three repeats.)
- Diluted and plated for heterotrophic and coliform plate counts
- Filtered for total cell counts (Figure 3)

When possible, stereoscope images of the dispenser were taken between the rinse and scraping steps, with careful attention paid not to disrupt the biofilm within the dispenser (Figures 2, 4, 5 and 7).

Isolated colonies were picked from the heterotrophic and coliform plate counts and were sent in for biochemical organism ID.



Figures 4 and 5. Stereoscope images of unknown brown material found in all types of dispensers studied. Shown here: internal tubing from a counter-mounted dispenser (top) and lid of a plastic wall-mounted dispenser (bottom). 7.5X

BIOFILM TESTING RESULTS

Results indicated that (Figure 6) :

- The bulk soap, Sample A, was contaminated with 4-7 LOG₁₀(CFU/mL) bacteria.
- Samples B (loosely surface associated) and C (surface associated) contained 4-7 LOG₁₀(CFU/cm²), (n=6).
- Total cell counts ranged from 4-8 LOG₁₀(CFU/cm²) for all dispensers and sample types.

These results were Independent of dispenser type or construction material.

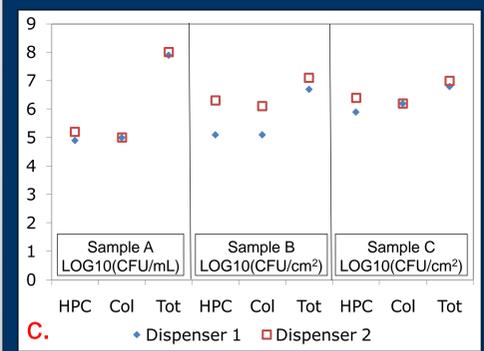
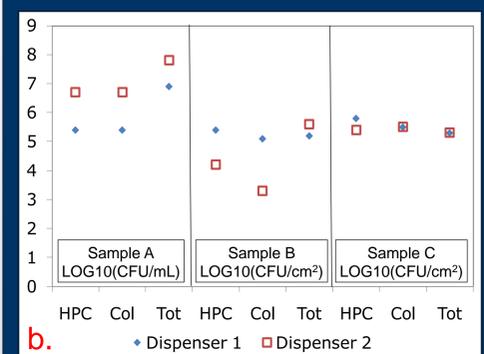
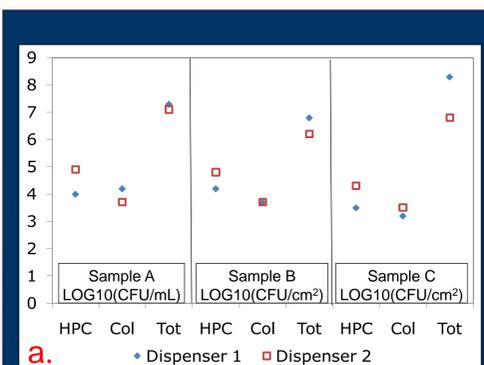


Figure 6. Panel a. is the counter-mounted dispenser results, b. the plastic wall-mounted dispenser results, and c. the stainless steel wall-mount dispenser results. For the viable plate count results, HPC refers to heterotrophic plate counts, Col refers to coliform counts and Tot refers to total cell counts. Samples A, B and C depict the bulk soap, loosely surface associate, and the surface associated biofilm counts, respectively.

METHODS COMPARISON

Overall, the results of the bacterial identification based upon biochemical assays versus molecular methods were comparable at the genus level, but some differences were observed (Table 1).

The biochemical profiling from all dispensers tested identified :

- 14 unique bacterial species
- 11 different genera

Whereas the molecular methods identified :

- 13 unique genera
- Possibly dozens of different species

All microorganisms observed are considered opportunistic pathogens and are mostly gram negative. The organisms identified were surprisingly consistent, and were independent of type and location of dispenser.

Table 1. Panel a. is an indirect comparison of field versus biochemically isolated microbes identified from the plastic wall-mounted dispensers. Panel b. is an indirect comparison of field identified microbes versus microbes identified using molecular methods from the plastic wall-mounted dispensers. Panel c. is a direct comparison of microbes identified using biochemical assays versus molecular based methods from stainless steel wall-mounted dispensers. Molecular ID isolates were based on DNA found in the dispensers, thus, viability of identified organisms could not be assessed.

Dispenser #	Field ID	Biochemical ID	Molecular ID
1	<i>Providencia rettgeri</i>	<i>Providencia rettgeri</i>	
	<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i>	
	<i>Citrobacter koseri</i>	<i>Serratia liquefaciens</i>	
	<i>Serratia odorifera</i>	<i>Klebsiella pneumoniae</i>	
2	<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i>	
	<i>Stenotrophomonas maltophilia</i>	<i>Burkholderia cepacia</i>	
	<i>Aeromonas hydrophila</i>	Yeast, not <i>C. albicans</i>	
		Gram positive bacillus (no further ID available)	
3	<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i>	
	<i>Providencia rettgeri</i>	<i>Providencia rettgeri</i>	
	<i>Serratia rubidaea</i>	<i>Achromobacter xylosoxidans</i>	
		<i>Alicyclopes xylooxidans</i>	
4	<i>Stenotrophomonas maltophilia</i>	<i>Stenotrophomonas sp.</i>	
	<i>Pseudomonas fluorescens</i>	<i>Pseudomonas aeruginosa</i>	
	<i>Pseudomonas luteola</i>	<i>Citrobacter sp.</i>	
	<i>Pseudomonas stutzeri</i>	<i>Enterobacter sp.</i>	
22	<i>Pseudomonas sp. – probably P. aeruginosa</i>	<i>Pseudomonas aeruginosa</i>	
	<i>Providencia sp. – probably P. rettgeri</i>	<i>Providencia/Proteus rettgeri</i>	
	<i>Serratia sp. – probably S. liquefaciens</i>	<i>Serratia marcescens</i>	
	<i>Providencia sp.</i>	<i>Providencia/Proteus rettgeri</i>	
40	<i>Stenotrophomonas sp.</i>	<i>Stenotrophomonas maltophilia</i>	
	<i>Pseudomonas sp.</i>	<i>Pseudomonas fluorescens/putida</i>	
	<i>Serratia sp.</i>	<i>Serratia liquefaciens</i>	
	<i>Alicyclopes/Achromobacter sp.</i>	<i>Acinetobacter lwoffii</i>	

PHASE 2 – DISPENSER WASHING STUDY

Washing studies were completed to determine if dispensers could be washed or sanitized to eliminate future contamination. The methods used were selected to mimic options that could be available during routine restroom maintenance by janitorial staff. Three washing procedures were analyzed for plastic wall mounted bulk refillable soap dispensers:

- a simple hot water rinsing technique
- a hot water rinsing and scrubbing technique
- a hot water rinse, scrub, 5,000mg/L bleach treatment, hot water rinse combination

Positive and negative control dispensers were drained and refilled with sterile soap.

Samples were collected from the rinse steps and evaluated for heterotrophic and coliform plate counts. Bulk soap sampling was performed for up to two weeks to determine washing procedure efficacy.



Figure 7. Stereoscope image of a fly found in the bottom dispenser assembly of a plastic wall-mounted dispenser. 7.5X

WASHING STUDY RESULTS

The washing study results (Figures 8-9) showed that bacterial counts in the bulk soap returned to pre-wash levels within two weeks of cleaning a dispenser and subsequently rinsing it with 5,000 mg/L bleach. The purple and blue X symbols represent the positive and negative control results, respectively.

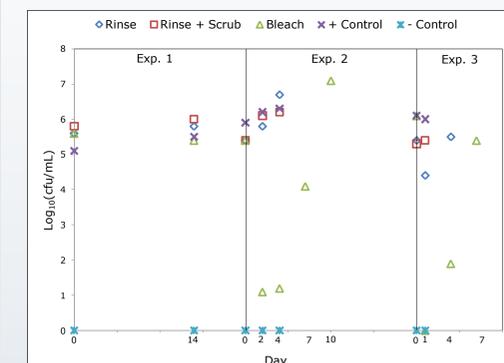


Figure 8. Dispenser washing study results: coliform counts

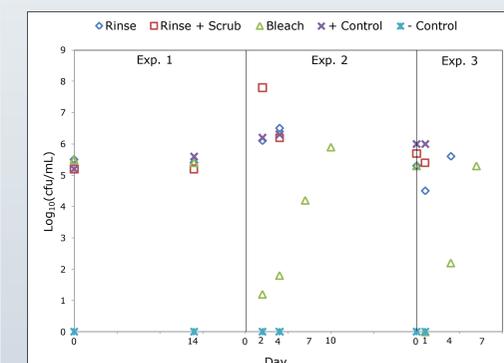


Figure 9. Dispenser washing study results: heterotrophic plate counts

CONCLUSIONS

- Dispensers contaminated with bacteria in the bulk soap also had high levels of biofilm bacteria.
- While the bacterial diversity was relatively low compared to other environments, detection of SSU rRNA gene sequences suggested the presence of organisms not detected via cultivation-based techniques (for some samples).
- The washing study results showed that bacterial counts in the bulk soap returned to pre-wash levels within two weeks regardless of the washing procedure used, although the bacterial counts in the dispensers rinsed with bleach did recover more slowly.

ACKNOWLEDGEMENTS

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Handwashing with Contaminated Soap Results in Hand Contamination and Transfer of Bacteria



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Abstract

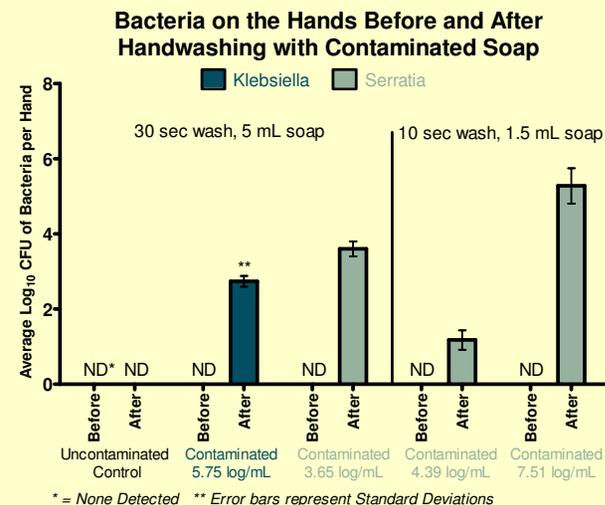
BACKGROUND/OBJECTIVE: Previous studies establish that open refillable bulk soap dispensers are often contaminated with species of *Klebsiella* and/or *Serratia* bacteria. In this study we evaluate whether these bacteria remain on the hands after handwashing and assess whether they can be transferred to other surfaces. **METHODS:** Hands were sampled using the glove juice method before and after handwashing with contaminated or uncontaminated soap. In addition, some participants touched an agar surface. **RESULTS:** No *Klebsiella* or *Serratia* were detected on the hands before using the test soaps or after using the uncontaminated control soap. Between 15 and over 190,000 of the marker bacteria remained on each hand exposed to the contaminated soaps and the transfer of the bacteria was visible on the agar touch plates. **CONCLUSIONS:** Use of contaminated soap may contribute to the transmission of opportunistic pathogens such as *Klebsiella pneumoniae* and *Serratia marcescens*.

Methods

A laboratory simulation of handwashing with contaminated bulk soap was conducted. The testing methods were based on a modification of the FDA Tentative Final Monograph (TFM) for Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash (FR59:116, 17 June 1994, pp. 31448-31450). Soap formulation chemistry, bacteria used, and levels of soap contamination tested simulated contaminated bulk soap found in public rest rooms. Two different handwash methods were tested. In the first study the handwash was designed to mimic an ideal procedure, e.g. one conducted by a healthcare worker (5 mL of soap, 30 sec wash, 30 sec rinse). In the second study the handwash was modeled after the typical washing behavior observed in the general public (1.5 mL of soap, 10 sec wash, 10 sec rinse). A total of 5 soap samples were tested; one uncontaminated control, one sample contaminated with *Klebsiella pneumoniae*, and three samples contaminated with *Serratia marcescens*. *Klebsiella* and *Serratia* were used since they were two of the most common types of bacteria found in contaminated bulk soap, accounting for over 2/3 of all contaminants. Contaminated samples were prepared by repeatedly inoculating unpreserved soap formulations with bacteria until the soap became contaminated. A range of levels of contamination were tested from relatively low (<10,000 CFU/mL, <4 Log₁₀CFU/mL) to high (>10,000,000 CFU/mL, >7 Log₁₀CFU/mL) bacterial contamination. The number of contaminating bacteria on both hands of 6 participants were measured before and after handwashing with each test soap (N=12) using the glove juice method. In addition, after washing with each soap 1 or 2 participants touched an agar surface with one or both of their hands (N=2 or N=4).

Results

- ✓ None of the participants had detectable amounts of *Klebsiella* or *Serratia* on their hands before washing
- ✓ No *Klebsiella* or *Serratia* were detected on hands after washing with an uncontaminated control soap
- ✓ After handwashing with contaminated soap between 15 to over 190,000 bacteria from the soap remained on each hand (averaging from 1.18 to 5.28 Log₁₀ CFU).
- ✓ Use of soap with the highest contamination level resulted in the greatest contamination level on the hands.



- ✓ Both *Klebsiella* and *Serratia* from the contaminated hands of participants were transferred to agar surfaces following handwashing with contaminated soap.



Background



Permanently mounted soap dispensers provided in public restrooms can be refilled either with sealed cartridges/bags or by pouring soap from a larger bulk container such as a gallon jug. Since soap contaminated with bacteria has been linked to outbreaks, the CDC recommends against the use of bulk soap dispensers in healthcare settings. However, in non-healthcare settings, bulk dispensers are still quite common and are often contaminated. Recent reports have found that 23-25% of open refillable bulk soap dispensers found in public restrooms are contaminated with unsafe levels of potentially pathogenic organisms. Sealed dispensing systems were free from contamination. With a growing immunocompromised population, it is prudent to investigate how remediation of this unnecessary health risk could reduce the risk of community-acquired infections. The objective of this study was to evaluate whether bacteria from contaminated soap remains on the hands after handwashing and to assess whether they can be transferred to other surfaces.

Conclusions

- ✓ Washing hands with contaminated soap results in contamination of the hands and transfer of the bacteria to surfaces.
- ✓ Contaminated bulk soap may contribute to the transmission of opportunistic pathogens such as *Klebsiella* and *Serratia*.
- ✓ Further research is needed to evaluate the public health risk of using contaminated bulk soap by patrons of public restrooms.

Opportunistic Pathogens From Contaminated Bulk Soap on the Hands of Students and Staff in an Elementary School

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Abstract

Previous research revealed that approximately 23% of open refillable bulk soap dispensers in public restrooms are contaminated with an average of 3,000,000 bacteria/ml soap. This study was performed to evaluate hand contamination and bacterial transmission by hands after washing with bulk soap. Gram-negative bacteria on the hands of 10 students and 10 staff were quantified before and after using either contaminated bulk soap or uncontaminated control soap. In addition, the transfer of gram-negative bacteria from the hands to an agar surface was evaluated. Hands were found to harbor over 10-fold more opportunistic pathogens after washing with contaminated bulk soap than before washing (2047 vs 179). An average of 1 gram-negative bacterium was transferred to surfaces touched by students or staff either before the hand wash or after washing with uncontaminated control soap. After washing with the contaminated soap, the average number of gram-negative bacteria transferred to surfaces increased to 38 for children and 9 for adults. These results suggest that contaminated bulk soap may play a role in the transmission of bacteria in schools, particularly among children.

Background

Hand soap dispensers used in school restrooms can be refilled with soap that is either bulk or sealed. Bulk dispensers are refilled by pouring soap from a large container into the open reservoir and typically the nozzle that the soap is ejected through is not replaced. In contrast, sealed dispensers are refilled by replacing bags or cartridges that contain soap sealed inside with a new nozzle. Soap in bulk dispensers is prone to contamination because it is constantly exposed to bacteria from the environment, such as from the hands of the person refilling the soap, the spray of toilet water after flushing, or from dust in the air. Since contaminated bulk soap dispensers have caused outbreaks in hospitals, the CDC recommends against their use in healthcare settings. However, no such guidelines exist to protect patrons of public restrooms in the community or our students in schools. In our previous studies, we tested soap from over 500 dispensers across the United States to evaluate the prevalence of contaminated soap in public restrooms. We were surprised to learn that 1 in 4 bulk dispensers are contaminated with an average of over 3 million bacteria, most of which are known to be opportunistic pathogens. Exposure to such high levels of these organisms can be a significant health risk to individuals with compromised immune systems which is estimated to be at least 20% of the population. In contrast, soap from sealed dispensing systems was free from contamination. We identified an elementary school in which the antibacterial soap in all of their plastic wall mounted bulk soap dispensers were highly contaminated with 19 different species of *Pseudomonas*, *Providencia*, *Citrobacter*, *Stenotrophomonas*, *Aeromonas*, *Enterobacter*, *Pasteurella*, and *Serratia* bacteria. The objective of this study was to evaluate bacterial hand contamination and hand transmission among children and adults in an elementary school with a contaminated bulk soap problem.

Methods

10 staff and 10 students each participated in up to 4 handwashes each using one of 14 contaminated bulk soap dispensers. 11 staff participated in up to 2 handwashes each during the follow up study which was conducted 4 months after the contaminated bulk soap dispensers were replaced with sealed soap dispensing systems. Participants were instructed to wash and dry their hands as they normally would after using the restroom. All hands were tested both before and after handwashing using one of two methods.



Method A: The number of bacteria on one hand of each participant was measured using the glove juice procedure.



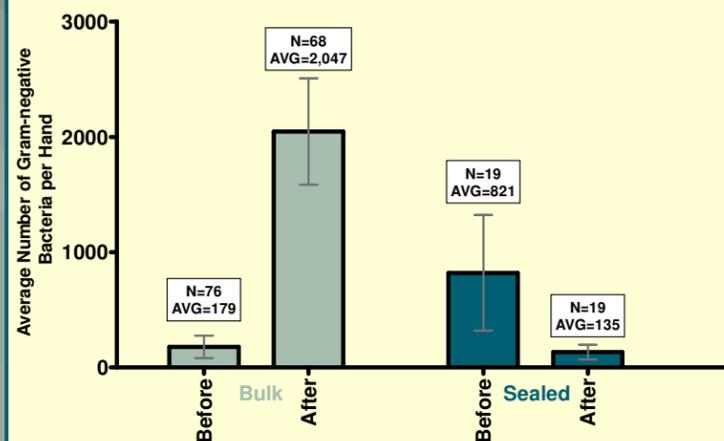
Method B: Bacterial transfer to a surface was measured with the opposite hand using the hand stamp procedure.



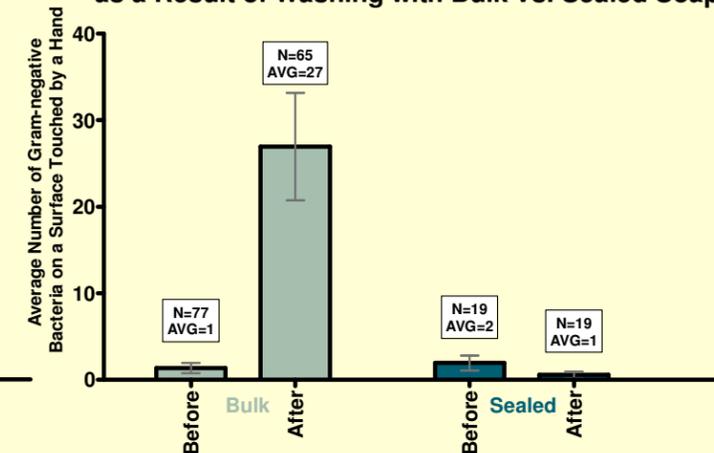
Results were obtained from counting bacteria that grew on MacConkey's agar. Statistical comparisons were performed using the Student's t-test on the Log₁₀ transformed bacterial colony counts.

Results

A) Relative Effectiveness of Handwashing with Contaminated Bulk vs. Sealed Soap



B) Bacteria Transferred by Hands to a Surface as a Result of Washing with Bulk vs. Sealed Soap



- ✓ Washing with contaminated bulk soap significantly increased the number of gram-negative bacteria per hand from 179 to 2047 on average for all students and staff ($P < 0.0001$). Students' hands retained significantly more bacteria than the staff, 3148 vs. 474 ($P < 0.01$).
- ✓ Washing with sealed soap significantly reduced the number of bacteria from 821 to 135 ($P < 0.05$).
- ✓ Hands had significantly less gram-negative bacteria after washing with sealed soap compared to after washing with contaminated bulk soap, 135 vs. 2047 ($P < 0.0001$).
- ✓ Washing with contaminated bulk soap significantly increased the number of gram-negative bacteria transferred to a surface from 1 before washing to 27 after on average for all students and staff ($P < 0.0001$). Students transferred significantly more bacteria to the surface they touched after washing with contaminated bulk soap than the staff did, 38 vs. 9 ($P < 0.01$).

Conclusions

- ✓ Hand soap dispensers which are refilled by pouring bulk soap into an open reservoir are often contaminated with opportunistic pathogens.
- ✓ Washing with contaminated bulk soap resulted in a 10-fold increase in the number of pathogenic bacteria that were found on the hands of students and staff in an elementary school.
- ✓ Hands washed with contaminated bulk soap transferred a significantly higher number of opportunistic pathogens to touched surfaces compared to hands washed with soap from a sealed refill.
- ✓ Contaminated bulk soap may play a role in the transmission of bacteria in schools, particularly among children.
- ✓ Schools using bulk soap dispensers could reduce the potential risk of infections by upgrading to dispensers which utilize only sealed soap refills.

Open Refillable Bulk Soap Dispensers in Public Restrooms: A Public Health Risk?

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Presenter Disclosures

Dr. Charles P. Gerba

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GOJO Industries, Inc.
Sponsored Research

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Learning Objectives

1. Describe how to identify open refillable bulk soap dispensers
2. Explain why open refillable soap dispensers are susceptible to bacterial contamination
3. Discuss why contaminated bulk soap in community settings could be a public health risk, particularly for susceptible populations

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Soap Microbial Quality

- Handwash products are regulated by the FDA. Excessive contamination is a violation.¹
- Soap is not expected to be sterile.
 - “It is the responsibility of the manufacturer to assure that... the species and quantity of microbes do not present a hazard to the consumer when using the product as directed...”²
- Guidelines recommend <1000 total bacteria/mL & the absence of pathogens.²

1) <http://www.cfsan.fda.gov/~dms/cos-218.html>
 2) The Cosmetic, Toiletry, and Fragrance Association, Technical Guidelines, Microbial Limits for Cosmetics and Toiletries, 2001
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Soap Dispensers

- Open Refillable Bulk
 - Refilled by pouring soap from a larger volume container
 - Open to environment
 - Same nozzle used indefinitely
- Closed Sealed Systems
 - Soap provided in a disposable sealed bag or cartridge refill
 - New nozzle with each refill



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How Does the Soap Become Contaminated?



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Contaminated Soap Causes Infection in Health-Care Settings

- Many reported infections and outbreaks¹
 - Fatal *Pseudomonas aeruginosa* infection from use of contaminated shampoo²
 - *Serratia marcescens* infections linked to contaminated soap. Hands 54 times more likely to be contaminated after washing³
- Susceptible populations are at greatest risk
 - >20% of US population is immune-compromised⁴

1) Weber D, Rutala W, and Sickbert-Bennett E. Antimicrobial Agents and Chemotherapy 2007 Dec;51(12):4217-4224.
2) Faenstein V, Andres N, Umphrey J, and Hopfer R. J. Infect. Dis. 158:655, 1988.
3) Santor C, Jacome V, Duwiver C et al. Infect. Control Hosp. Epidemiol. 2000 March;21(3):196-9.
4) Gerba, D. Rose, J. Haas C. International Journal of Food Microbiology 30 (1996) 113-123.
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CDC Health-Care Recommendation

- “Do not add soap to a partially empty soap dispenser. This practice of “topping off” dispensers can lead to bacterial contamination of soap¹.”
- Since the risk is well-documented bulk dispensers are rare in Health-Care

1) Guideline for Hand Hygiene in Health-Care Settings, Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Morbidity and Mortality Weekly Report, October 30, 2002 / Vol. 51 / No. RR-16.
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Is it Safe to Use Bulk Soap Dispensers in Community Settings?

- Prior to our research, no studies had been conducted in the US to assess this potential risk.
- Our studies indicate that patrons of public restrooms are routinely exposed to unsafe levels of bacterial contamination.
- This represents an unnecessary health risk, particularly for the immunocompromised susceptible population.

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Bulk Soap Contamination is Widespread

- Soap from over 500 bulk dispensers in public restrooms were tested from across the US
- Unsafe levels of bacteria occur in 23 - 25% of bulk soap dispensers^{1,2}
 - Fecal-based organisms found in over 16% of the soap samples
 - Average user exposed to >one million bacteria per handwash
 - Soap from sealed systems showed no contamination

1 M. Chattman, S. Maxwell and C. P. Gerba; Bacterial Contamination of Liquid Hand Soaps, University of Arizona, Tucson, AZ, American Society for Microbiology 107th General Meeting Toronto, ON, Canada, May 21-25, 2007.
2 C. P. Gerba and S. Maxwell, University of Arizona, Tucson, AZ; National Environmental Health Association 71st Annual Educational Conference & Exhibition, Atlantic City, NJ; June 18-21, 2007.
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Bacteria Remain on Hands After Washing with Contaminated Soap

- Bacterial contaminants remain on hands after handwashing and are transferred to touched surfaces^{1,2}



After washing with liquid soap that was not contaminated



After washing with contaminated liquid soap

1 BioScience Laboratories, Inc.; Bozeman, MT; Study #071209-150; Feb 22, 2008.
2 BioScience Laboratories, Inc.; Bozeman, MT; Study #080307-150; May 22, 2008.
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Contaminated Dispensers Should Be Replaced, Cleaning Is Ineffective

- New soap is re-contaminated by biofilm bacteria adhering to inside of dispenser
- Even dispensers scrubbed with hot water and sanitized with 5000 mg/L bleach were contaminated 7-10 days after new uncontaminated soap was added





Lorenz et al. Evaluation of Contaminated Bulk Soap Dispensers for Biofilm Bacteria; Comparison of Two Methods of Analysis and Effectiveness of Dispenser Washing Procedures. Montana State University Center for Biofilm Engineering Poster to be presented at the 5th ASM Conference on Biofilms, Nov 2009.
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Study Objectives

- Assess the factors contributing to contamination
 - Are some types of soap more likely to become contaminated?
 - Are certain types/models of bulk dispensers more susceptible to contamination?
 - How do contamination rates compare between different types of facilities?
- Test for the presence of specific organisms of public health concern
 - Food-borne pathogen *E. coli*
 - Antibiotic-resistant organisms

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Method- Soap Sampling

- ~ 10 mL of soap collected into sterile collection containers and tested <1 week
- 155 bulk samples collected from Ohio
 - restaurants, bars, gas stations, schools, office buildings, retail stores, health clubs, grocery stores, theaters, etc.



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Method- Soap Analysis

- Microbial load
 - Dilute into buffer with neutralizers and plate onto R2A
 - >1000 CFU/mL threshold for contamination
 - Dominant colony types identified
- Active ingredient
 - HPLC used to determine % PCMX or Triclosan
- Food-borne pathogen screen
 - Enrichment based water quality test used to determine if *Escherichia coli* bacteria were present
- Antibiotic resistance
 - Contaminants were tested for their ability to grow on media containing antibiotics, two classes were tested

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Results- High levels of Contamination Observed

- 21% (32/155) of bulk soap samples were contaminated with >1000 CFU/mL bacteria
- Average level 6.3×10^6 CFU/mL
- 13 different gram negative species isolated including *Pseudomonas*, *Providencia*, *Achromobacter*, *Citrobacter* and *Serratia*
 - These opportunistic pathogens can cause respiratory tract infections, pneumonia, urinary tract infections, pink eye, skin ulcers, gastroenteritis, soft tissue infections, etc.

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Results- All Types of Bulk Dispensers from All Types of Facilities Were Contaminated

Type of Facility	Total	Contaminated	%
Shopping	22	4	18%
Recreation	15	3	20%
Dining	28	6	21%
Other/Unknown	90	19	21%

Dispenser Type	Total	Contaminated	%
Counter	21	3	14%
Wall plastic	48	8	17%
Wall metal	16	4	25%
Other/Unknown	70	17	24%

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Results- All Types of Soap Were Contaminated

Type of Soap	Total	Contaminated	%
Bland	110	23	21%
Antimicrobial- Triclosan	26	8	31%
Antimicrobial- PCMX	14	1	7%
Other/Unknown	5	0	0%

Color of Soap	Total	Contaminated	%
Blue	6	1	17%
clear/white	33	2	6%
green	13	4	31%
orange	31	12	39%
pink	55	11	20%
peach	9	0	0%
yellow	6	2	33%
Other/Unknown	2	0	0%

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Results- *E. coli* and Antibiotic Resistant Bacteria Were Found

- *E. coli* was detectable in 28% (7/25) of the contaminated soaps tested
- Resistance to quinolones or ceftazidime was observed in 28% (22/78) of the isolates, most frequently in species of *Pseudomonas*, 68% (15/22), but also in *Klebsiella*, *Serratia*, *Burkholderia* and *Enterobacter* species.
 - 5% (4/78) of the isolates were resistant to both antibiotics.

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Conclusions

- Bulk hand soap is prone to bacterial contamination.
- Contamination is associated with the open design of the dispenser.
 - it is not limited to any particular type of soap or type of bulk dispenser
- Contaminated soap can harbor food-borne pathogens and antibiotic resistant organisms.

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Conclusions

- The species typically found in contaminated soap can cause infections.
- Immune-compromised handwashers with poor skin integrity are at greatest risk of acquiring an infection.
- Further research is warranted to determine the extent to which contaminated bulk soap in public restrooms poses an unnecessary public health risk.

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What Can You Do?

- Notice what type of soap dispensers are used in the areas you service
- Educate facilities about the potential risk
- If reoccurring infections due to gram negative pathogens occur, consider testing the soap as a possible reservoir
- Particularly in settings with high proportions of susceptible patrons, recommend the use of sealed systems

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 - Brad Ramsay

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Thank You

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Issue Attachment:

Elimination of Open, Refillable Soap Dispensers

Health Canada

"Guidance Document: Human-Use Antiseptic Drugs" Effective 11/27/2009

Page 33/34 Section 7.4 Labelling

"Do not refill container."

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/antiseptic_guide_ld-eng.pdf

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 068
Issue: 2010 III-023**

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

All information above the line is for conference use only.

Title:

Food Establishment Response Procedure to Vomiting & Diarrheal Contamination

Issue you would like the Conference to consider:

Many food establishments, including several institutional facilities that serve large populations have targeted the reduction of transmission of viruses and other pathogens by instituting procedures for cleaning and disinfection in the wake of a vomiting and diarrheal event in the facility. However, the 2009 Food Code is silent on what should be required of food establishments in terms of responding to such contamination events within a food establishment. Prompt and proper response is important to reduce the risk of transmission of norovirus and other pathogens that may be present in vomitus or fecal matter and that may become widely dispersed throughout a facility in the event of an uncontrolled discharge.

Public Health Significance:

Studies have shown that norovirus can survive on fomite surfaces for up to 12 days and that routine cleaning, without a disinfectant specifically to address norovirus, may be ineffective in eliminating its presence on fomite surfaces and can even serve as a means of spreading the virus to other fomites.(7, See Attached References) Noroviruses are the most common cause of sporadic cases and outbreaks of acute gastroenteritis (AGE) and transmission occurs via foodborne and person-to-person routes, airborne inhalation of vomitus droplets, and also through contact with contaminated environmental surfaces.(3) Food employees exposed to vomitus are at risk of contracting norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers.

Clean up of norovirus is different from routine cleaning and sanitizing and involves a more stringent cleaning and disinfecting process. For example, quaternary ammonium compounds are often used for routinely sanitizing food preparation surfaces or disinfecting large surfaces (e.g. countertops and floors), however, such compounds (which act by disrupting viral envelopes) do not have significant activity against certain pathogens, including norovirus. (4) It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus or diarrheal contamination events that address, among other items, the use of proper disinfectants.

Noroviruses (genus *Norovirus*, family *Caliciviridae*) are a group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. (3) Noroviruses

are transmitted primarily through the fecal-oral route, either by consumption of fecally contaminated food or water or by direct person-to-person spread. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed.(3)

CDC estimates that 23 million cases of acute gastroenteritis are due to norovirus infection annually. (8) In 2006, the most recent year for which surveillance for Foodborne Disease Outbreak data have been analyzed, norovirus was the most common cause, accounting for 54% of outbreaks and 11,879 cases. Calicivirus caused 337 (98%) of the confirmed foodborne disease outbreaks attributed to viruses; all calicivirus outbreaks reported were attributed to norovirus. (1)

Norovirus is highly contagious, and it is thought that an inoculum of as few as 10 viral particles may be sufficient to infect an individual. (2) In addition, the potential transmission level of norovirus shed in the feces at levels up to 1 trillion viral particles per gram of feces and one projectile vomiting incident can contaminate the environment with 300,000 viral particles. (6, 9) One study found that employees who reported having cleaned up vomitus were more likely to contract illness than those who did not. (5)

Norovirus is the most common cause of gastroenteritis in people of all ages and it is responsible for greater than 50% of all foodborne gastroenteritis outbreaks. Norovirus causes acute onset of vomiting (often explosive) and diarrhea (also often explosive) which can contaminate surfaces and become airborne increasing the chances of additional infections.

When the food employee has been diagnosed, has a recent history or exposure to, or is the suspect source of a confirmed disease outbreak of norovirus, it must be reported to the person in charge per the FDA Food Code in subparagraphs 2-201.11(A)(2)(a), 2-201.11(A)(4)(a), 2-201.11(A)(5)(a), and 2-201.11.(B). If a food employee has been diagnosed with norovirus it must also be reported to the regulatory authority. (10)

The Food Code also instructs the Person in Charge to exclude or restrict a food employee who exhibits, or reports a symptom, or who reports a diagnosed illness or a history of exposure to norovirus, but it is silent on instruction to the Person in Charge on how to address a situation where the food employee or other individual becomes physically ill in areas where food may be prepared, stored or served. Once such an episode has occurred, timely effective clean-up is imperative.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting modification of the 2009 Food Code to require that food establishments:

- 1) Develop and 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; and
- 2) That such a plan address:
 - the procedures for containment and removal of any discharges, including airborne particulates;
 - the procedure for cleaning, sanitizing, and, as necessary, the disinfection of any surfaces that may have become contaminated;
 - the procedures for the evaluation and disposal of any food that may have been exposed to discharges;

- the availability of effective disinfectants, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and the proper use and disposal of such;
- the circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;
- notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;
- the availability of effective disinfectants, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and the proper use and disposal of such;
- the segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;
- minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in 2-201.12 of the Food Code;
- minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and
- the conditions under which the plan will be implemented.

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Attachments:

- "Attachment A-References:Procedure to Vomiting & Diarrheal Contamination"

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

Attachment A-References: Procedure to Vomiting & Diarrheal Contamination

Page 1 of 1

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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 071
Issue: 2010 III-016**

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

All information above the line is for conference use only.

Title:

Sequential Application of Hand Antiseptic for Use in No-Water Situations

Issue you would like the Conference to consider:

Effective hand hygiene for situations where soap and water are unavailable remains a challenge for food safety. Under the 2009 FDA Model Food Code, Section 2-301.16, employees may use a hand antiseptic to clean hands when food exposure is limited and handwashing sinks are not conveniently available. In addition, employees may use chemically treated disinfectant towelettes per Section 5-203.11(C).

It has now been found that an effective hand cleansing, equivalent to handwashing with soap and water as specified in Section 5-203.11, can be achieved by sequential use of alcohol-based hand antiseptics, wherein a first application is wiped off with a dry single-use towel, followed immediately by a second application that is allowed to dry as per normal use directions. The latest testing of this hand cleansing/degerming technique shows it to be effective in the presence of organic food soils. This adds an additional safety factor to support incorporation of the method into food safety practices for select situations.

This protocol is not a substitute for handwashing in stationary facilities where cleaning can be accomplished per 2-301.12.

[Note: After the near unanimous vote for adoption by Council III in 2008, this issue was extracted during the Assembly of Delegates, citing the need for additional testing which has now been concluded along with an additional two years of field testing under the guidance of the Southern Nevada Health District. SNHD has also cleared this intervention for school foodservice use during water outages.]

Public Health Significance:

Potential contamination of ready-to-eat foods is increased in situations where access to soap and water are limited or simply unavailable. The new proposed option increases the odds of effective hand degerming in those situations, including its use between single-use glove changes.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA requesting the following change to the Model Food Code:

5-203.11 Handwashing Sinks

(A)(B)(C)

(D) When food exposure is limited and handwashing sinks are not conveniently located, such as at outdoor events, mobile or temporary food service and some vending machine locations, employees may use 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 instruction.

(i) Said hand antiseptic shall meet requirements of 2-301.16

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

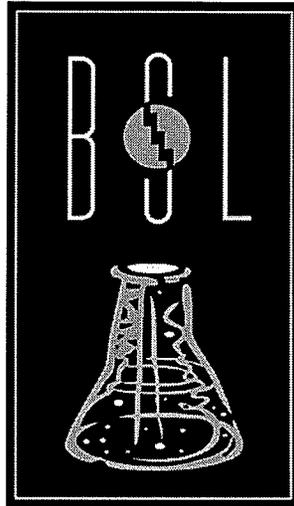
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Attachments:

- "Determination of the Antimicrobial Efficacy of Three Test Articles (2008)"
- "Determination of the Antimicrobial Efficacy of Three Test Articles (2009)"
- "Sequential Application of Hand Antiseptic for Use in No-Water Situations"
- "SaniTwice: A Hand Hygiene Solution for Food Handlers"
- "Test Results For Heavy Soil Pilot SaniTwice Study"

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.



January 17, 2008

FINAL REPORT #070723-150

**DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES
USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

Prepared for:

(SPONSOR)

Prepared by:

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EXECUTIVE SUMMARY

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles using a modification of the Health Care Personnel Handwash evaluation. The indicator microorganism used for hand contaminations was *Escherichia coli* (ATCC #11229). Eleven (11) subjects used each of the three (3) test articles (reference Section 14.0 of this Final Report and a Protocol and/or SOP Deviation Recording Form [Form No. 99-QA-004] in Addendum I of this Final Report), one (1) at a time. Subjects performed two (2) consecutive hand contaminations with the challenge suspension in a beef broth medium, the first followed by a sample for baseline, and the second by a product application. Subjects then decontaminated their hands with a 70% Ethanol rinse and a nonmedicated soap wash, and then used a second Test Article. This procedure was repeated again with the remaining Test Article. The baseline and post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The testing methods were based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash*. (FR59:116, 17 June 94) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations*.

The critical index for this study was a two (2) log₁₀ reduction in baseline populations after product application.

STATISTICAL ANALYSIS #1

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.80 after product application and met the critical index of the study.

For Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log₁₀ reduction of 2.64 after product application and met the critical index of the study.

For Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean log₁₀ reduction of 2.47 after product application and met the critical index of the study.

STATISTICAL ANALYSIS #2

Upon completion of the statistical analysis, Subject #12's data were determined to be outliers. Further investigation revealed that the subject appeared to have a learning disability and needed repeated instruction by the monitoring laboratory technician to be able to perform each of the steps required by the study protocol. The conclusions below results from a statistical analysis excluding data from testing of Subject #12.

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.93 after product application and met the critical index of the study.

Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log₁₀ reduction of 2.83 after product application and met the critical index of the study.

Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean log₁₀ reduction of 2.63 after product application and met the critical index of the study.

January 17, 2008

FINAL REPORT # 070723-150

1.0 **TITLE:** **DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

2.0 **TESTING FACILITY:** **BIOSCIENCE LABORATORIES, INC.**
300 N. Willson Avenue
Bozeman, Montana 59715

3.0 **STUDY DIRECTORS:**

Robert R. McCormack - Principal Study Director
Kendra F. Drake - Associate Study Director

4.0 **PURPOSE OF STUDY:**

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles for use in the food service industry. Testing was performed per methodology based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations*.

5.0 **SCOPE:**

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles using a modification of the Health Care Personnel Handwash evaluation. The indicator microorganism used for hand contaminations was *Escherichia coli* (ATCC #11229). Eleven (11) subjects used each of the three (3) test articles, one (1) at a time. Subjects performed two (2) consecutive hand contaminations with the challenge suspension in a beef broth medium, the first followed by a sample for baseline, and the second by a product application. Subjects then decontaminated their hands with a 70% Ethanol rinse and a nonmedicated soap wash, and then used a second Test Article. This procedure was repeated again with the remaining Test Article. The baseline and post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The testing methods were based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash*. (FR59:116, 17 June 94) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations*. The Study Protocol was approved by the Gallatin Institutional Review Board (GIRB) on 12/04/07 (See Addendum I of this Final Report). One (1) deviation from the methodology described in the Study Protocol occurred (reference Section 14.0 of this Final Report), and as is detailed on a Protocol and/or SOP Deviation Recording Form (Form No. 99-QA-004) in Addendum I of this Final Report, it had no adverse effect upon the study outcome. No deviations from BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

6.0 **STUDY DATES:**

STUDY INITIATION DATE: 11/30/07
EXPERIMENTAL START DATE: 12/19/07
EXPERIMENTAL END DATE: 01/07/08
STUDY COMPLETION DATE: 01/17/08

7.0 **TEST MATERIALS:**

The test articles were provided to the Testing Facility by the Sponsor. Responsibility for determination of the identity, strength, purity, composition, stability, and solubility of the test articles, as well as responsibility for retention of the test articles, remained with the Sponsor. All documentation provided with the test articles is included in Addendum IX of this Final Report.

Test Article #1: Bland Foaming Handwash
Lot Number: 275543
Expiration Date: 01/2010

Test Article #2: Instant Hand Sanitizer Gel
Active Ingredient: 62% Ethanol
Lot Number: 240041 5179
Expiration Date: 06/2008

Test Article #3: Sanitizing Hand Wipes
Active Ingredient: 68.15% Ethanol
Lot Number: 973-12
Expiration Date: 04/19/08

8.0 **TEST ARTICLE APPLICATION PROCEDURES:**

Test Period

8.1 Each subject was in testing for approximately four (4) hours on a single day and used each of the three (3) test articles. Prior to being admitted into testing, subjects were questioned regarding their adherence to the Protocol requirements. Subjects clipped their fingernails to a free edge of ≤ 1 mm, if they had not already done so. All jewelry was removed from the hands and arms prior to washing.

NOTE: Each subject used each of the three (3) test articles, one (1) at a time, per specified application procedures. After the Glove Juice Sampling Procedure was performed following test article application and prior to use of another test article, the subjects were required to decontaminate their hands by performing a one (1) minute rinse with 70% Ethanol and an air-dry, followed by a thirty (30) second handwash using a nonmedicated soap. The subjects waited a minimum of twenty (20) minutes following the use of the nonmedicated soap and prior to use of another test article.

8.2 A handwash was performed using a nonmedicated soap to remove dirt and oil from the hands. A technician instructed subjects in the appropriate technique and verified its proper execution by subjects. The temperature of the water used for all wash or rinse procedures was controlled at $40^{\circ} \pm 2^{\circ}\text{C}$ (see Water Temperature Monitoring Sheets [Form No. 96-CT-017] in Addendum VII of this Final Report]).

Inoculum Application Procedure

- 8.3 Four and one-half (4.5) mLs of the beef broth suspension containing at least 1×10^9 CFU/mL of *Escherichia coli* (ATCC #11229) were transferred into each subject's cupped hands in three (3) aliquant amounts of one and one-half (1.5) mLs.
- 8.4 The suspension was distributed over the entire surface of the hands (front and back), not reaching above the wrists, for twenty (20) \pm five (5) seconds. Following distribution of the inoculum, the hands were held motionless, away from the body, and allowed to air-dry for thirty (30) \pm five (5) seconds.
- 8.5 The procedure in Section 8.4 was repeated.
- 8.6 A final one and one-half (1.5) mL aliquant amount of the challenge suspension was dispensed into the subject's cupped hands and distributed over the entire surface of the hands (front and back), not reaching above the wrists, for twenty (20) \pm five (5) seconds. The hands were allowed to air-dry for ninety (90) seconds.
- 8.7 After the timed ninety (90) second air-dry, the Glove Juice Sampling Procedure was performed. This first contamination cycle provided the baseline population level. It was followed with a thirty (30) second handwash using nonmedicated soap.
- 8.8 The challenge suspension was again dispensed into each subject's cupped hands and distributed as described above. After a timed ninety (90) second air-dry, the subjects applied their randomly assigned test article according to the directions below.

Test Article #1 Application Procedure

- 8.9 The subject wet hands within ten (10) seconds of completing the drying step.
- 8.10 Two (2) pumps (1.4 mL) of Test Article #1 were placed in the subject's cupped hands.
- 8.11 The subject lathered Test Article #1 for fifteen (15) seconds, followed by a ten (10) second rinse with water.
- 8.12 Following the water rinse, the subject used two (2) paper towels to pat-dry hands for ten (10) seconds.

Test Article #2 Application Procedure

- 8.13 Two (2) pumps (3.0 mL) of Test Article #2 were placed in the subject's cupped hands within ten (10) seconds of completing the drying step.
- 8.14 The subject rubbed Test Article #2 into the hands in a vigorous manner for fifteen (15) seconds.
- 8.15 Following Test Article #2 application, the subject used two (2) paper towels to pat-dry hands for ten (10) seconds.
- 8.16 An additional one (1) pump of Test Article #2 was placed in the subject's cupped hands (1.5 mL), and the hands were rubbed together until dry.

Test Article #3 Application Procedure

- 8.17 Within ten (10) seconds of completing the drying step, the subject wiped both hands with Test Article #3 in a standardized fashion for twenty-five (25) seconds.
- 8.18 Following the wiping procedure, one (1) pump of Test Article #2 was placed in the subject's cupped hands, and hands were rubbed together until dry.

9.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used for this study are summarized in the Study Protocol, included in Addendum I of this Final Report, and are also detailed on Clinical Trials Equipment Tracking Forms (Form No. 01-L-009) and Clinical Trials Supplies Tracking Forms (Form 01-L-008) in Addendum VII of this Final Report.

10.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on Media/Diluent Tracking Forms (Form No. 97-L-007) in Addendum VIII of this Final Report.

11.0 SUBJECT DEMOGRAPHICS:

Twenty-seven (27) overtly healthy subjects, at least eighteen (18) years of age were admitted into the study. Eleven (11) subjects completed the study (reference Protocol and/or SOP Deviation Recording Form [Form No. 99-QA-004] in Addendum I of this Final Report). Insofar as possible, the group of subjects selected was of mixed sex, age, and race. Hands and forearms were free from clinically evident dermatoses, other injuries to the area, and/or any other disorders that may have compromised the subject and the study. All subjects who participated in the Study signed the Study Description and Informed Consent Form, Subject Confidential Information and Acceptance Criteria, and Authorization to Use and Disclose Protected Health Information Form (Appendix I of Addendum I of this Final Report) and List of Restricted Products (Appendix II of Addendum I of this Final Report) prior to participating in the study. The demographics of the study are presented in the table below.

DEMOGRAPHIC SUMMARY	ALL SUBJECTS	
	Recruited	Received Product
AGE		
Minimum Age	19	19
<i>Median Age</i>	35	45
Maximum Age	69	69
SEX		
Males (M)	14	5
Females (F)	13	6
<i>Total</i>	27	11
RACE		
White/Caucasian (C)	26	10
Latino (L)	1	1
<i>Total</i>	27	11

DID NOT PARTICIPATE IN TESTING	
SC = Schedule Conflict	1
QC = Qualification (Inclusion/Exclusion) Criteria Failure	10
NS = No Show	5

12.0 ADVERSE EVENTS:

No subject experienced an adverse event during or following completion of this study.

13.0 NEUTRALIZATION EVALUATION :

The results of a neutralization evaluation (BSLI SOP CT-1006) indicated that the neutralizer(s) used in the recovery medium successfully quenched the antimicrobial activity of the test articles. Study procedures followed guidelines set forth in ASTM E 1054-02, *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents*, except that the microorganism was added to the neutralizer prior to the addition of the test articles. *Escherichia coli* (ATCC #11229) was used as the challenge species in the neutralizer validation study. All data resulting from the Neutralization Assay are included in Addendum VI of this Final Report.

14.0 DEVIATION FROM PROTOCOL:

Section 12.40 in Protocol 070723-150 states, "Within ten (10) seconds of completing the drying step (Section 12.31), the subject will wipe both hands with Test Article #3 in a standardized fashion for twenty-five (25) seconds." Subject 21 did not use Test Article #3 on both hands in a standardized fashion nor for the full twenty-five (25) seconds. Subject 21 dropped wipe with three (3) seconds left on the rub, continued without wipe, and one (1) pump of Test Article #2 was then placed in the subject's cupped hands. Subject 21 failed to follow applications instructions as directed by the monitoring laboratory technician. Subject 21's data for Test Article #3 were disregarded from the analysis, so there is no effect on the outcome of the study.

15.0 RESULTS - TABLES I THROUGH XII:

15.1 Table I presents the statistical summary of the log₁₀ values following performance of Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]).

Table I: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	22	8.18	0.24	8.08 to 8.29
Application 1	22	5.38	0.58	5.13 to 5.64
Application 1 Log ₁₀ Reduction	22	2.80	0.68	2.50 to 3.10

15.2 Table II presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]).

Table II: Log₁₀ Values and Log₁₀ Reduction from Baseline Values, by subject, following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543])

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.31	5.66	2.65
	Right	8.12	5.81	2.31
16	Left	8.34	4.33	4.01
	Right	8.34	5.27	3.07
3	Left	8.23	5.12	3.11
	Right	8.11	5.60	2.51
9	Left	8.43	4.97	3.46
	Right	8.19	5.11	3.07
20	Left	8.04	4.82	3.22
	Right	8.11	4.69	3.42
7	Left	8.19	4.14	4.05
	Right	8.14	4.69	3.45
18	Left	8.01	6.00	2.01
	Right	8.04	6.09	1.95
12	Left	7.66	5.87	1.79
	Right	7.58	6.22	1.36
21	Left	8.58	5.64	2.94
	Right	8.48	5.96	2.52
27	Left	8.21	5.55	2.67
	Right	8.21	5.76	2.44
26	Left	8.32	5.47	2.85
	Right	8.38	5.60	2.78

15.3 Table III presents the statistical summary of the log₁₀ values following performance of Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table III: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	22	8.14	0.31	8.00 to 8.28
Application 1	22	5.50	0.79	5.15 to 5.85
Application 1 Log ₁₀ Reduction	22	2.64	0.89	2.24 to 3.03

15.4 Table IV presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table IV: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by subject following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179])

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.14	5.96	2.18
	Right	8.23	5.80	2.43
16	Left	8.28	5.99	2.29
	Right	8.25	6.45	1.80
3	Left	8.02	5.36	2.67
	Right	8.21	5.34	2.87
9	Left	8.43	4.96	3.47
	Right	8.39	5.56	2.84
20	Left	8.11	4.74	3.37
	Right	8.03	5.82	2.21
7	Left	8.29	4.19	4.10
	Right	8.20	4.85	3.35
18	Left	7.74	4.33	3.40
	Right	7.88	3.66	4.22
12	Left	7.25	6.47	0.78
	Right	7.45	6.90	0.55
21	Left	8.44	5.85	2.59
	Right	8.27	5.90	2.37
27	Left	8.27	6.21	2.06
	Right	8.31	5.61	2.69
26	Left	8.42	5.77	2.66
	Right	8.42	5.34	3.08

- 15.5 Table V presents the statistical summary of the log₁₀ values following performance of Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table V: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.07	0.34	7.92 to 8.23
Wash 1	20	5.60	0.64	5.30 to 5.90
Wash 1 Log ₁₀ Reduction	20	2.47	0.76	2.12 to 2.83

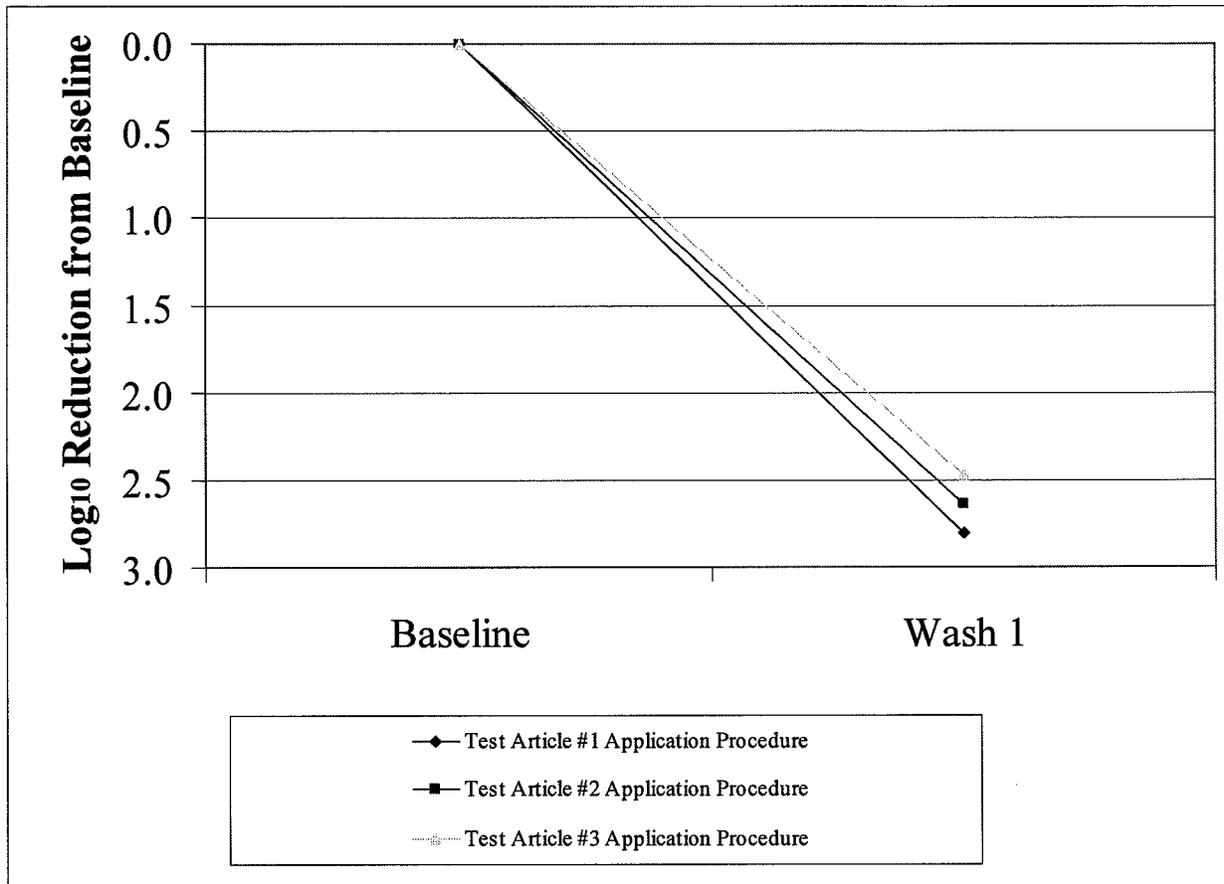
- 15.6 Table VI presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table VI: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by subject following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179])

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.37	6.20	2.17
	Right	8.33	6.37	1.97
16	Left	8.13	5.31	2.82
	Right	8.29	5.81	2.48
3	Left	8.09	4.88	3.21
	Right	8.22	4.14	4.08
9	Left	8.41	5.18	3.23
	Right	8.35	5.33	3.02
20	Left	7.69	4.75	2.94
	Right	7.70	5.48	2.22
7	Left	8.16	5.07	3.09
	Right	8.23	6.32	1.91
18	Left	7.79	5.65	2.14
	Right	8.25	5.18	3.07
12	Left	7.23	6.21	1.03
	Right	7.35	6.30	1.05
21	Left	*	*	*
	Right	*	*	*
27	Left	8.16	5.33	2.83
	Right	8.23	5.86	2.38
26	Left	8.24	6.28	1.96
	Right	8.27	6.39	1.88

15.7 Figure 1 presents the graphical presentation of the mean log₁₀ reductions from baseline from each of the three (3) test article application procedures.

Figure 1: Graphical Presentation of the Mean log₁₀ Reductions from Baseline From the Three (3) Test Article Application Procedures



15.8 Table VII presents the statistical summary of the log₁₀ values following performance of Test Article #1 Application Procedure (Bland Foaming Handwash (Lot Number 275543)) excluding data from Subject 12.

Table VII: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.24	0.16	8.17 to 8.31
Application 1	20	5.32	0.56	5.05 to 5.58
Application 1 Log ₁₀ Reduction	20	2.93	0.58	2.66 to 3.19

15.9 Table VIII presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding data from Subject #12.

Table VIII: Log₁₀ Values and Log₁₀ Reduction from Baseline Values, by subject, following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding Data from Subject #12

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.31	5.66	2.65
	Right	8.12	5.81	2.31
16	Left	8.34	4.33	4.01
	Right	8.34	5.27	3.07
3	Left	8.23	5.12	3.11
	Right	8.11	5.60	2.51
9	Left	8.43	4.97	3.46
	Right	8.19	5.11	3.07
20	Left	8.04	4.82	3.22
	Right	8.11	4.69	3.42
7	Left	8.19	4.14	4.05
	Right	8.14	4.69	3.45
18	Left	8.01	6.00	2.01
	Right	8.04	6.09	1.95
12	Left	*	*	*
	Right	*	*	*
21	Left	8.58	5.64	2.94
	Right	8.48	5.96	2.52
27	Left	8.21	5.55	2.67
	Right	8.21	5.76	2.44
26	Left	8.32	5.47	2.85
	Right	8.38	5.60	2.78

15.10 Table IX presents the statistical summary of the log₁₀ values following performance of Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table IX: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.22	0.19	8.13 to 8.30
Application 1	20	5.38	0.73	5.05 to 5.72
Application 1 Log ₁₀ Reduction	20	2.83	0.66	2.53 to 3.14

15.11 Table X presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table X: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by subject following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding Data from Subject #12

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.14	5.96	2.18
	Right	8.23	5.80	2.43
16	Left	8.28	5.99	2.29
	Right	8.25	6.45	1.80
3	Left	8.02	5.36	2.67
	Right	8.21	5.34	2.87
9	Left	8.43	4.96	3.47
	Right	8.39	5.56	2.84
20	Left	8.11	4.74	3.37
	Right	8.03	5.82	2.21
7	Left	8.29	4.19	4.10
	Right	8.20	4.85	3.35
18	Left	7.74	4.33	3.40
	Right	7.88	3.66	4.22
12	Left	*	*	*
	Right	*	*	*
21	Left	8.44	5.85	2.59
	Right	8.27	5.90	2.37
27	Left	8.27	6.21	2.06
	Right	8.31	5.61	2.69
26	Left	8.42	5.77	2.66
	Right	8.42	5.34	3.08

15.12 Table V presents the statistical summary of the log₁₀ values following performance of Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table XI: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	18	8.16	0.22	8.05 to 8.27
Wash 1	18	5.53	0.63	5.21 to 5.85
Wash 1 Log ₁₀ Reduction	18	2.63	0.61	2.33 to 2.93

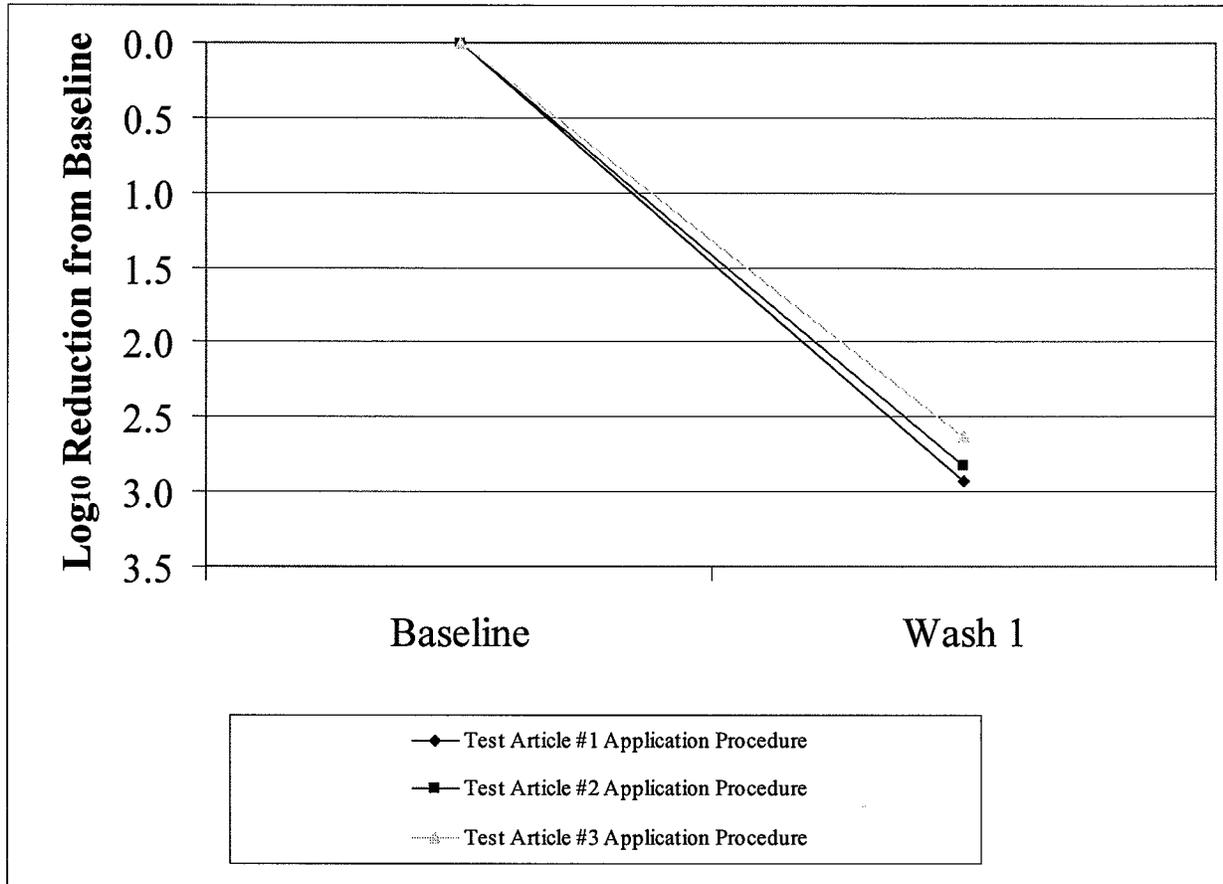
15.13 Table XII presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table XII: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by subject following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179]) excluding Data from Subject #12

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.37	6.20	2.17
	Right	8.33	6.37	1.97
16	Left	8.13	5.31	2.82
	Right	8.29	5.81	2.48
3	Left	8.09	4.88	3.21
	Right	8.22	4.14	4.08
9	Left	8.41	5.18	3.23
	Right	8.35	5.33	3.02
20	Left	7.69	4.75	2.94
	Right	7.70	5.48	2.22
7	Left	8.16	5.07	3.09
	Right	8.23	6.32	1.91
18	Left	7.79	5.65	2.14
	Right	8.25	5.18	3.07
12	Left	*	*	*
	Right	*	*	*
21	Left	*	*	*
	Right	*	*	*
27	Left	8.16	5.33	2.83
	Right	8.23	5.86	2.38
26	Left	8.24	6.28	1.96
	Right	8.27	6.39	1.88

15.14 Figure 2 presents the graphical presentation of the mean log₁₀ reductions from baseline from each of the three (3) test article application procedures excluding data from Subject #12.

Figure 2: Graphical Presentation of the Mean log₁₀ Reductions from Baseline From the Three Test Article Application Procedures excluding Data from Subject #12



16.0 CONCLUSION:

The critical index for this study was a two (2) log₁₀ reduction in baseline populations after product application.

STATISTICAL ANALYSIS #1

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.80 after product application and met the critical index of the study.

For Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log₁₀ reduction of 2.64 after product application and met the critical index of the study.

For Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean log₁₀ reduction of 2.47 after product application and met the critical index of the study.

STATISTICAL ANALYSIS #2

Upon completion of the statistical analysis, Subject #12's data were determined to be outliers. Further investigation revealed that the subject appeared to have a learning disability and needed repeated instruction by the monitoring laboratory technician to be able to perform each of the steps required by the study protocol. The conclusions below results from a statistical analysis excluding data from testing of Subject #12.

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.93 after product application and met the critical index of the study.

Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log₁₀ reduction of 2.83 after product application and met the critical index of the study.

Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean log₁₀ reduction of 2.63 after product application and met the critical index of the study.

17.0 LABORATORY PERSONNEL:

The following employees of BioScience Laboratories, Inc., were involved in the testing or ancillary support of this Study. The laboratory personnel have been appropriately trained, and their training records are on file in the Quality Assurance Unit at the Testing Facility.

STUDY DIRECTOR:	Robert R. McCormack Microbiologist
Sabrina Bakich Marketing Manager/Product Handling	Paul O' Brien Clinical Laboratory Technician
Amanda Berry Subject Recruitment	Alicia Pfile Microbiologist
Stephanie Cebulla Laboratory Support Technician	Christine Roath Microbiologist
Kendra F. Drake Associate Study Director, Microbiologist	Lori Schlotfeldt Supervisor of Laboratory Support

LABORATORY PERSONNEL (Continued)

Collette Duley
Microbiologist

Jessica Sheehy
Laboratory Support Technician

Erika Ecton
Subject Recruitment

Carl Schmidt
Microbiologist

Amanda Henry
Microbiologist

Brian Stancil
Clinical Laboratory Technician

August Grace Johnson
Microbiologist

Robert H. Stancil
Microbiologist

Jacqueline Joyner
Subject Recruitment

Clare Wilson
Microbiologist

Lisa Lehman
Microbiologist

Annette C. Woods
Microbiologist

Ron Neibauer
Manager of Clinical Laboratories

Kristy Wuebber
Microbiologist

18.0 QUALITY ASSURANCE PERSONNEL:

Liv Graving
Quality Assurance Associate

John A. Mitchell, Ph.D.
Director of Quality Assurance

Amy Juhnke
Manager of Quality Assurance/Document
Control

Janis Smoke
Quality Assurance Associate

Scott McCommon
Manager of Quality Control

19.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records were compiled, analyzed, and will be retained by BioScience Laboratories, Inc., at its facility in Bozeman, Montana. All raw data for this study, as well as the Final Report, will be retained in safe storage by the Testing Facility for a period of at least three (3) years.

20.0 **ACCEPTANCE:**

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

<u>Phase</u>	<u>Date</u>
Neutralization Assay	01/04/08
Product Testing	12/19/07 and 12/26/07
Data Audit	01/14/08
Final Report Review	01/17/08
Reports to Study Director and Management	12/19/07, 12/26/07, 01/04/08, and 01/17/08

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (reference CFR 21 Parts 50, 56, 312, and 314), with the following exception: test article preparations were not analyzed at BioScience Laboratories, Inc., to confirm concentration, stability, or homogeneity.

INDEX OF ADDENDA

- I GIRB-Approved Protocol #070723-150
Protocol and/or SOP Deviation Recording Form (Form No. 99-QA-004)

- II Qualification Criteria for Study 070723-150

- III Sampling Data Sheets for Healthcare Personnel Handwash Study 070723-150
Irritation Evaluations for Study 070723-150

- IV Q-Count™ Plate Counter Data Sheets (Form No. 00-L-009)
Q-Count™ Plate Count Data and Calculations

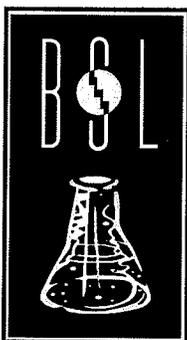
- V Statistical Analysis

- VI Neutralization Evaluation
 - Project Notes (Form No. 95-G-001) for Neutralization Assay
 - Neutralization Evaluation Data Sheets for Study 070723-150
 - Neutralization Statistics

- VII Study Notes and General Records
 - Age Calculation and Demographics Worksheet
 - Project Notes (Form No. 95-G-001)
 - Protocol 070723-150 Randomization Scheme
 - Clinical Trials Equipment Tracking Forms (Form No. 01-L-009)
 - Clinical Trials Supplies Tracking Forms (Form No. 01-L-008)
 - Water Temperature Monitoring Sheets (Form No. 96-CT-017)
 - Incubator Log Forms (Form No. 96-L-008)
 - Refrigerator Log Form (Form No. 96-L-015)
 - Inoculum Preparation Tracking Forms - Flask Preparation (Form No. 07-CT-001)
 - Inoculum Preparation Tracking Forms - Solid Media Preparation (Form No. 07-CT-002)
 - Autoplate® 4000 Data Sheets for Healthcare Personnel Handwash Study 070723-150

- VIII Media/Diluent Tracking Forms (Form No. 97-L-007)

- IX Product Information
 - Product Receipt Log (Form No. 92-L-023)
 - Sample Submission Form and Document Compliance Statement (Form No. 94-G-007)
 - Material Safety Data Sheets (MSDS)
 - Product-Tracking Forms (Form No. 93-L-029)



BIOSCIENCE
LABORATORIES•INC

March 12, 2009

FINAL REPORT #081211-150

**DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES
USED IN FOUR (4) APPLICATION CONFIGURATIONS
USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

Prepared for:

GOJO INDUSTRIES, INC. (SPONSOR)
One GOJO Plaza, Suite 500
Akron, Ohio 44311

Prepared by:

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EXECUTIVE SUMMARY

Twelve subjects used each of the four test article configurations over the course of two consecutive hand contaminations with *Escherichia coli* (ATCC #11229) in a beef broth medium as the indicator microorganism for each configuration. The four test configurations were assigned randomly according to an incomplete crossover design; that is, the order of use of each configuration was randomly determined. The first was followed by a sample for baseline, and the second by a product application. The subject then decontaminated their hands with a 70% ethanol rinse and a nonmedicated soap wash, and used a second test article configuration. This procedure was repeated twice more with the remaining test article configurations. The baseline and all post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). Testing was performed per a modification of the methodology in the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450).

The critical index for this study was a 2.0 log₁₀ reduction in baseline populations after product application.

For Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), applied per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] of Test Article #1 into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.92 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] of Test Article #2 rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #2 Application Procedure, produced a mean log₁₀ reduction of 4.44 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL] of Test Article #2, pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #3 Application Procedure, produced a mean log₁₀ reduction of 4.61 after product application and met the critical index of the study.

For Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), applied per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL] of Test Article #3, pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 produced a mean log₁₀ reduction of 3.64 after product application and met the critical index of the study.

March 12, 2009

FINAL REPORT #081211-150

1.0 **TITLE:** **DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USED IN FOUR (4) APPLICATION CONFIGURATIONS USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

2.0 **SPONSOR:** **GOJO INDUSTRIES, INC.**
One GOJO Plaza, Suite 500
Akron, Ohio 44311

3.0 **TESTING FACILITY:** **BIOSCIENCE LABORATORIES, INC.**
300 N. Willson Avenue
Bozeman, Montana 59715

4.0 **STUDY DIRECTORS:**

Robert R. McCormack - Principal Study Director
Kendra Drake - Associate Study Director

5.0 **PURPOSE OF STUDY:**

The purpose of this study was to evaluate the antimicrobial efficacy of three test articles used in four application configurations using a modification of the Health Care Personnel Handwash evaluation for use in the food service industry.

6.0 **SCOPE:**

A total of twelve subjects used each of the four test article configurations over the course of two consecutive hand contaminations with *Escherichia coli* (ATCC #11229) in a beef broth medium as the indicator microorganism for each configuration. The first was followed by a sample for baseline, and the second by a product application. The subject then decontaminated their hands with a 70% ethanol rinse and a nonmedicated soap wash, and used a second test article configuration. This procedure was repeated twice more with the remaining test article configurations. The baseline and all post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The four test configurations were assigned randomly according to an incomplete crossover design; that is, the order of use of each configuration was randomly determined. Testing was performed per a modification of the methodology in the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450). The Study Protocol was approved by the Gallatin Institutional Review Board (GIRB) on 02/10/09. No deviations from the methodology described in the Study Protocol or from BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

7.0 **STUDY DATES:**

STUDY INITIATION DATE: 02/06/09

EXPERIMENTAL START DATE: 02/13/09

EXPERIMENTAL END DATE: 02/23/09

STUDY COMPLETION DATE: 03/12/09

8.0 TEST MATERIALS:

The test articles were provided to the Testing Facility by the Sponsor. Responsibility for determination of the identity, strength, purity, composition, stability, and solubility of the test articles, as well as responsibility for retention of the test articles, remained with the Sponsor.

Test Article #1: GOJO Luxury Foam Handwash (5400-520)
Active Ingredient: N/A
Lot Number: 322503
Expiration Date: 11/2011

Test Article #2: PURELL® Hand Sanitizing Gel VF481 (9900-501)
Active Ingredient: 70% ethanol
Lot Number: 306273
Expiration Date: 04/2010

Test Article #3: PURELL® Instant Hand Sanitizer Foam (9800-502)
Active Ingredient: 62% ethanol
Lot Number: 320887
Expiration Date: 11/2010

9.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used for this study are summarized in the Study Protocol, included as Addendum I of this Final Report, and are also detailed on the Clinical Trials Equipment Tracking Forms (Form No. 01-L-009) and the Clinical Trials Supplies Tracking Forms (Form 01-L-008) in Addendum VII of this Final Report.

10.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on the Media/Diluent Tracking Forms (Form No. 97-L-007) in Addendum VII of this Final Report.

11.0 SUBJECT DEMOGRAPHICS:

Twenty overtly healthy subjects at least 18 years of age were admitted into the study. Twelve subjects received product during testing. Insofar as possible, the group of subjects selected was of mixed sex, age, and race. Hands and forearms were free from clinically evident dermatoses, injuries, and/or any other disorders that may have compromised the subject and the study. All subjects who participated in the Study signed the Study Description and Informed Consent Form, Subject Confidential Information and Acceptance Criteria, and Authorization to Use and Disclose Protected Health Information Form (Appendix I of Addendum I of this Final Report) and List of Restricted Products (Appendix II of Addendum I of this Final Report) prior to participating in the study. The demographics of the study are presented in the table below.

DEMOGRAPHIC SUMMARY	ALL SUBJECTS	
	Recruited	Received Product
AGE		
Minimum Age	18	19
Median Age	42	49
Maximum Age	71	71
SEX		
Males (M)	8	3
Females (F)	12	9
<i>Total</i>	<i>20</i>	<i>12</i>
RACE		
White/Caucasian (C)	20	12
<i>Total</i>	<i>20</i>	<i>12</i>
DID NOT PARTICIPATE IN TESTING		
QC = Qualification (Inclusion/Exclusion) Criteria Failure		6
NS = No Show		2

12.0 ADVERSE EVENTS:

No subject experienced an adverse event during or following completion of this study.

13.0 NEUTRALIZATION:

A neutralization assay was performed to assure that the neutralizer(s) used in the recovery medium quenched the antibacterial properties of the test articles. Study procedures were based on guidelines set forth in ASTM E 1054-08, *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents*. *Escherichia coli* (ATCC #11229) was used as the challenge species in the neutralizer validation study.

14.0 TEST METHODS:

14.1 Each subject was in testing for approximately five hours on a single day and used each of the four test article configurations. Prior to being admitted into testing, subjects were questioned regarding their adherence to protocol requirements. Subjects clipped their fingernails to a free edge of ≤ 1 mm, if they had not already done so. All jewelry was removed from the hands and arms prior to washing.

14.2 A handwash was performed using a nonmedicated soap to remove dirt and oil from the hands. A technician instructed subjects in the appropriate technique and verified its proper execution. The temperature of the water used for this and any subsequent wash or rinse procedures was controlled at $40^{\circ} \pm 2^{\circ}\text{C}$.

Inoculum Application Procedure

14.3 A total of 4.5 mL of the beef broth suspension containing at least 1×10^9 CFU/mL of *Escherichia coli* (ATCC #11229) was transferred into each subject's cupped hands in three aliquant amounts.

- 14.3.1 A 1.5 mL aliquot of the challenge suspension was dispensed into the subject's cupped hands. The suspension was distributed over the entire surface of the hands (front and back), not reaching above the wrists, for 20 ± 5 seconds. Following distribution of the inoculum, the hands were held motionless, away from the body, and allowed to air-dry for 30 ± 5 seconds.
- 14.3.2 The procedure in Section 14.3.1 was repeated.
- 14.3.3 A final 1.5 mL of the challenge suspension was dispensed into the subject's cupped hands and distributed over the entire surface of the hands (front and back), not reaching above the wrists, for 20 ± 5 seconds. The hands were allowed to air-dry for 90 seconds.
- 14.4 After the timed 90-second air-dry, the Glove Juice Sampling Procedure (Section 12.45 of the Study Protocol) was performed. This first contamination cycle provided the baseline population level. It was followed with a 30-second handwash using nonmedicated soap.
- 14.5 The challenge suspension was again dispensed into each subject's cupped hands and distributed. After a timed 90-second air-dry, the subjects applied their randomly assigned test article configuration according to the directions below.
- 14.6 Test Article Configuration #1 Application Procedure
- 14.6.1 Subject wet their hands within 10 seconds of completing the drying step (Section 14.5).
- 14.6.2 Two pumps (approximately 1.4 mL) of Test Article #1 were placed in the subject's cupped hands.
- 14.6.3 Subject lathered Test Article #1 for 15 seconds, followed by a 10-second rinse with water.
- 14.6.4 Following the water rinse, the subject used two paper towels to pat-dry hands for 10 seconds.
- 14.7 Test Article Configuration #2 Application Procedure
- 14.7.1 Within 10 seconds of completing the drying step (Section 14.5), one pump (approximately 1.5 mL) of Test Article #2 was placed in the subject's cupped hands, and the hands were rubbed together until dry.
- 14.8 Test Article Configuration #3 Application Procedure
- 14.8.1 Two pumps (approximately 3.0 mL) of Test Article #2 were placed in the subject's cupped hands within 10 seconds of completing the drying step (Section 14.5).
- 14.8.2 Subject rubbed Test Article #2 into the hands in a vigorous manner for 15 seconds.
- 14.8.3 Subject then used two paper towels to pat-dry hands for 10 seconds.
- 14.8.4 An additional one pump (approximately 1.5 mL) of Test Article #2 was placed in the subject's cupped hands, and the hands were rubbed together until dry.
- 14.9 Test Article Configuration #4 Application Procedure
- 14.9.1 Four pumps (approximately 2.8 mL) of Test Article #3 were placed in the subject's cupped hands within 10 seconds of completing the drying step (Section 14.5).

- 14.9.2 Subject rubbed Test Article #3 into the hands in a vigorous manner for 15 seconds.
- 14.9.3 Subject then used two paper towels to pat-dry hands for 10 seconds.
- 14.9.4 An additional two pumps (approximately 1.4 mL) of Test Article #3 were placed in the subject's cupped hands, and the hands were rubbed together until dry.
- 14.10 Each subject used each of the four test article configurations, one at a time, per specified application procedures. After the Glove Juice Sampling Procedure was performed following test article application, and prior to use of another test article configuration, subjects were required to perform a 1-minute rinse with 70% ethanol and an air-dry, followed by a 30-second handwash using a nonmedicated soap. Subjects waited a minimum of 20 minutes following the use of the nonmedicated soap before using another test article.

15.0 STATISTICAL ANALYSIS:

- 15.1 Minitab[®] Statistical Software package was used for all statistical calculations. All statistical tests were calculated using the 0.05 level of significance for Type I (α) error.
- 15.2 Descriptive statistics and confidence intervals were calculated using the 0.05 level of significance for Type I (α) error. Statistical calculations of means and standard deviations were generated on the \log_{10} recovery data from baseline samples, post-product application samples, and the \log_{10} differences between baseline and post-application samples.
- 15.3 The critical index for this study was a 2.0 \log_{10} reduction after product application.

16.0 RESULTS - TABLES I THROUGH VIII AND FIGURE 1:

- 16.1 Table I presents a statistical summary of the \log_{10} recovery values following application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels).
- 16.2 Table II presents the \log_{10} values and \log_{10} reduction from baseline values, by subject and hand, following application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels).
- 16.3 Table III presents a statistical summary of the \log_{10} recovery values following application of Test Article #2, PURELL[®] Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry).
- 16.4 Table IV presents the \log_{10} values and \log_{10} reduction from baseline values, by subject and hand, following application of Test Article #2, PURELL[®] Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry).
- 16.5 Table V presents a statistical summary of the \log_{10} recovery values following application of Test Article #2, PURELL[®] Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry).

- 16.6 Table VI presents the \log_{10} values and \log_{10} reduction from baseline values, by subject and hand, following application of Test Article #2, PURELL[®] Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry).
- 16.7 Table VII presents a statistical summary of the \log_{10} recovery values following application of Test Article #3, PURELL[®] Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry).
- 16.8 Table VIII presents the \log_{10} values and \log_{10} reduction from baseline values, by subject and hand, following application of Test Article #3, PURELL[®] Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry).
- 16.9 Figure 1 presents a graphical presentation of the mean \log_{10} reductions from baseline following application of each test article per the four test article application procedures.

Table I: Statistical Summary of the log₁₀ Recovery Values Following Application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.77	0.31	7.64 to 7.90
Application 1	24	4.85	0.53	4.63 to 5.07
Application 1 Log ₁₀ Reduction	24	2.92	0.61	2.66 to 3.18

Table II: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by Subject and Hand Following Application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels)

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	7.91	4.82	3.09
	Right	7.87	4.96	2.91
2	Left	7.55	5.11	2.43
	Right	7.72	5.17	2.56
3	Left	7.82	4.69	3.13
	Right	7.77	4.96	2.81
6	Left	8.01	3.49	4.52
	Right	7.99	3.18	4.82
7	Left	8.07	5.08	2.99
	Right	8.11	5.38	2.73
8	Left	7.99	4.90	3.09
	Right	7.96	5.25	2.72
10	Left	6.92	4.51	2.41
	Right	6.93	4.76	2.16
11	Left	7.64	5.28	2.36
	Right	7.71	5.44	2.28
13	Left	7.78	4.70	3.08
	Right	7.98	5.04	2.94
14	Left	7.47	4.75	2.72
	Right	7.56	4.96	2.60
15	Left	7.84	4.81	3.04
	Right	7.86	4.80	3.06
16	Left	8.00	5.02	2.98
	Right	7.99	5.29	2.70

Table III: Statistical Summary of the log₁₀ Recovery Values Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.88	0.29	7.76 to 8.00
Application 1	24	3.44	0.47	3.24 to 3.64
Application 1 Log ₁₀ Reduction	24	4.44	0.47	4.24 to 4.64

Table IV: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by Subject and Hand Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry)

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	7.99	3.18	4.81
	Right	7.99	3.18	4.81
2	Left	7.89	3.18	4.71
	Right	7.95	3.18	4.76
3	Left	7.86	3.18	4.69
	Right	7.95	3.18	4.78
6	Left	7.99	3.18	4.81
	Right	8.02	3.18	4.84
7	Left	8.13	4.36	3.77
	Right	8.19	4.72	3.48
8	Left	7.98	3.18	4.80
	Right	7.98	3.18	4.80
10	Left	6.99	3.18	3.82
	Right	7.05	3.18	3.88
11	Left	8.03	4.14	3.89
	Right	8.02	4.39	3.63
13	Left	7.87	3.49	4.39
	Right	8.05	3.49	4.57
14	Left	7.63	3.49	4.14
	Right	7.63	3.66	3.97
15	Left	7.87	3.18	4.69
	Right	8.05	3.18	4.87
16	Left	8.03	3.18	4.86
	Right	7.98	3.18	4.80

Table V: Statistical Summary of the log₁₀ Recovery Values Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.79	0.33	7.65 to 7.93
Wash 1	24	3.18	0.00	3.18 to 3.18
Wash 1 Log ₁₀ Reduction	24	4.61	0.33	4.47 to 4.75

Table VI: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by Subject and Hand Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry)

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	7.90	3.18	4.73
	Right	7.96	3.18	4.78
2	Left	7.58	3.18	4.40
	Right	7.71	3.18	4.53
3	Left	7.95	3.18	4.78
	Right	7.98	3.18	4.79
6	Left	7.99	3.18	4.82
	Right	7.95	3.18	4.77
7	Left	8.19	3.18	5.02
	Right	8.23	3.18	5.06
8	Left	7.89	3.18	4.71
	Right	7.90	3.18	4.73
10	Left	7.34	3.18	4.16
	Right	7.21	3.18	4.03
11	Left	7.95	3.18	4.77
	Right	7.89	3.18	4.71
13	Left	7.75	3.18	4.58
	Right	7.85	3.18	4.68
14	Left	7.07	3.18	3.89
	Right	6.98	3.18	3.81
15	Left	7.80	3.18	4.62
	Right	7.73	3.18	4.55
16	Left	8.01	3.18	4.83
	Right	8.16	3.18	4.98

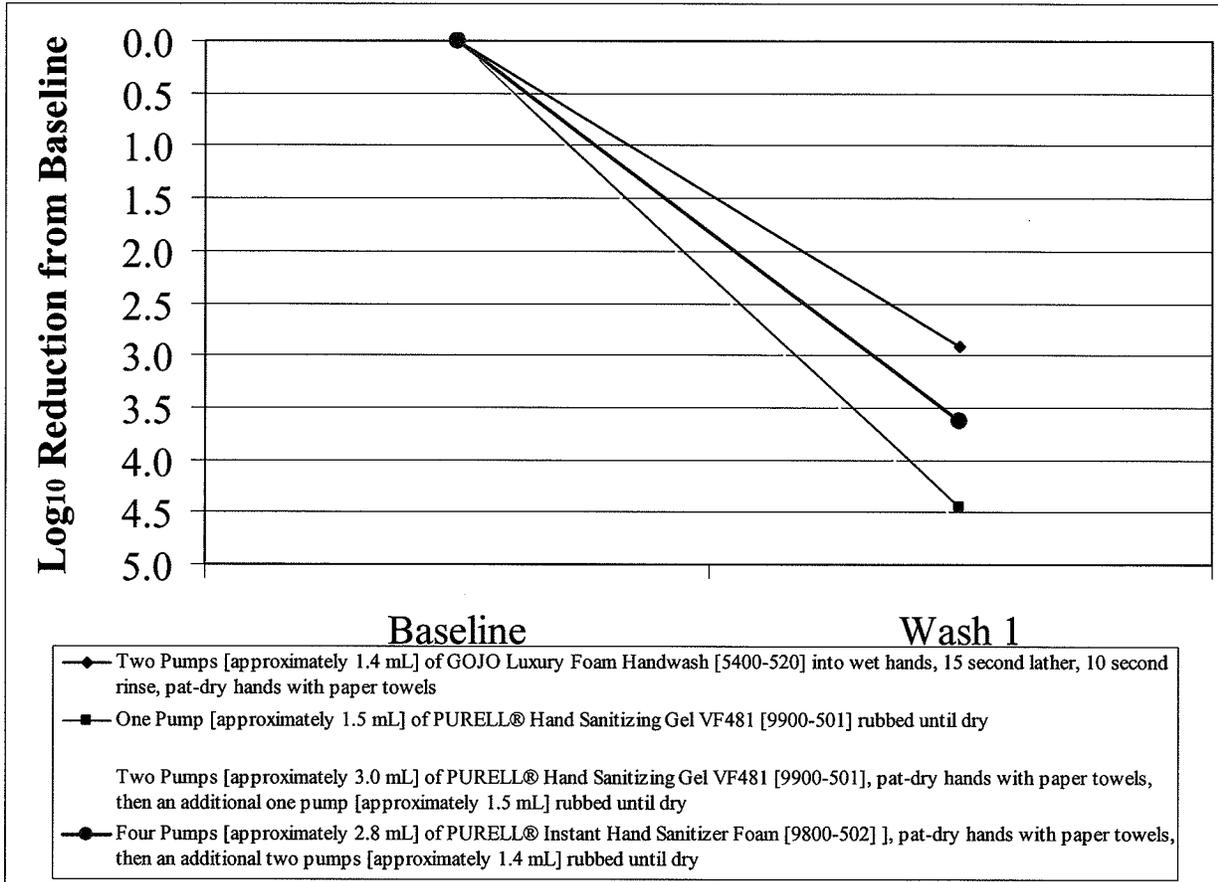
Table VII: Statistical Summary of the log₁₀ Recovery Values Following Application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.80	0.34	7.66 to 7.94
Wash 1	24	4.16	0.56	3.93 to 4.40
Wash 1 Log ₁₀ Reduction	24	3.64	0.57	3.40 to 3.88

Table VIII: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by Subject and Hand Following Application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry)

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	7.98	4.19	3.79
	Right	8.03	4.55	3.48
2	Left	7.89	4.53	3.37
	Right	7.79	4.51	3.28
3	Left	7.64	3.79	3.85
	Right	7.73	4.23	3.51
6	Left	7.79	4.72	3.08
	Right	7.80	4.81	2.99
7	Left	8.08	3.18	4.90
	Right	8.10	4.03	4.07
8	Left	8.18	4.23	3.95
	Right	8.19	5.03	3.16
10	Left	7.32	3.18	4.14
	Right	7.02	3.18	3.84
11	Left	7.96	4.57	3.39
	Right	7.88	4.58	3.29
13	Left	7.91	4.27	3.64
	Right	7.80	4.58	3.22
14	Left	7.21	4.85	2.36
	Right	7.03	3.79	3.24
15	Left	7.84	3.96	3.87
	Right	7.94	3.18	4.75
16	Left	8.06	4.23	3.83
	Right	8.11	3.79	4.32

Figure 1: Graphical Presentation of the Mean \log_{10} Reductions from Baseline Following Application of Each Test Article per the Four Test Article Application Procedures



17.0 CONCLUSION:

The critical index for this study was a 2.0 \log_{10} reduction in baseline populations after product application.

For Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), applied per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] of Test Article #1 into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean \log_{10} reduction of 2.92 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] of Test Article #2 rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #2 Application Procedure, produced a mean \log_{10} reduction of 4.44 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL] of Test Article #2, pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #3 Application Procedure, produced a mean log₁₀ reduction of 4.61 after product application and met the critical index of the study.

For Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), applied per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL] of Test Article #3, pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 produced a mean log₁₀ reduction of 3.64 after product application and met the critical index of the study.

18.0 LABORATORY PERSONNEL:

The following employees of BioScience Laboratories, Inc., were involved in the testing or ancillary support of this Study. The laboratory personnel have been appropriately trained, and their training records are on file in the Quality Assurance Unit at the Testing Facility.

STUDY DIRECTOR:	Robert R. McCormack Microbiologist
ASSOCIATE STUDY DIRECTOR:	Kendra Drake Microbiologist
Tammy Anderson IRB Coordinator	Nathan Nash Microbiologist
Jessica Baumgartner Microbiologist	Ron Neibauer Manager of Clinical Laboratories
Amanda Berry Supervisor of Subject Recruitment	Jeana Paulson Microbiologist
Stephanie Cebulla Laboratory Support Technician	Stephanie Scarff Laboratory Support Technician
Collette Duley Microbiologist	Amanda Shaffer Microbiologist
B. Cole Irvin Microbiologist	Jessica Sheehy Microbiologist
Patricia A. Mays Suko Supervisor of Laboratory Support	Clare Wilson Microbiologist

19.0 QUALITY ASSURANCE PERSONNEL:

Alicia Bogert
Quality Assurance Associate/Product Handling

John A. Mitchell, Ph.D.
Director of Quality Assurance

Scott D. Ferraro
Manager of Quality Control

Janis Smoke
Quality Assurance Associate

Amy L. Juhnke
Manager of Quality Assurance/Document Control

20.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records were compiled, analyzed, and will be retained by BioScience Laboratories, Inc., at its facility in Bozeman, Montana. All raw data for this study, as well as the Final Report, will be retained in safe storage by the Testing Facility for a period of at least three years. BioScience Laboratories, Inc. will notify the Sponsor before any documents or records are destroyed.

21.0 **ACCEPTANCE:**

BIOSCIENCE LABORATORIES, INC. (TESTING FACILITY)
300 N. Willson Avenue
Bozeman, Montana 59715

President & CEO: Daryl S Paulson 03-12-09
Daryl S. Paulson, Ph.D. Date

Principal Study Director: Robert R. McCormack 03/12/09
Robert McCormack Study Completion Date

Associate Study Director: Kendra Drake 03/12/09
Kendra Drake Date

Senior Clinical Director: Christopher M. Beausoleil 03/12/09
Christopher M. Beausoleil, CCRP Date

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

<u>Phase</u>	<u>Date</u>
Neutralization Assay	02/13/09
Product Testing	02/18/09
Data Audit	03/03/09 and 03/04/09
Final Report Review	03/11/09
Reports to Study Director and Management	02/13/09, 02/18/09, and 03/12/09

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (reference CFR 21 Parts 50, 56, 312, and 314), with the following exception: test article preparations were not analyzed at BioScience Laboratories, Inc., to confirm concentration, stability, or homogeneity.

Quality Assurance/ Associate: Janis E. Smoke 03/12/09
Janis Smoke Date

INDEX OF ADDENDA

- I GIRB-Approved Protocol #081211-150
- II Qualification Criteria Questionnaire for Study 081211-150
Qualification Criteria of the Subject for Study 081211-150
- III Sampling Data Sheets for Healthcare Personnel Handwash Study 081211-150
Irritation Evaluations for Study 081211-150
- IV Neutralization Evaluation
 - Neutralization Evaluation Results for Study 081211-150
 - Project Notes (Form No. 95-G-001)
 - Neutralization Evaluation Data Sheets for Protocol 081211-150
 - Neutralization Statistics
- V Q-Count™ Plate Counter Data Sheets (Form No. 00-L-009)
Q-Count™ Plate Count Data
- VI Statistical Analysis
- VII Study Notes and General Records
 - Project Notes (Form No. 95-G-001)
 - Age Calculation and Demographics Worksheet
 - Study 081211-150 Randomization Scheme
 - Clinical Trials Equipment Tracking Forms (Form No. 01-L-009)
 - Clinical Trials Supplies Tracking Forms (Form No. 01-L-008)
 - Water Temperature Monitoring Sheet (Form No. 96-CT-017)
 - Incubator Log Forms (Form No. 96-L-008)
 - Refrigerator Log Form (Form No. 96-L-015)
 - Inoculum Preparation Tracking Form - Solid Media Preparation (Form No. 07-CT-002)
 - Inoculum Preparation Tracking Form - Flask Preparation (Form No. 07-CT-001)
 - Autoplate® 4000 Data Sheet for Healthcare Personnel Handwash Study 081211-150
 - Media/Diluent Tracking Forms (Form No. 97-L-007)
- VIII Product Information
 - Product Receipt Log (Form No. 92-L-023)
 - Sample Submission Form and Document Compliance Statement (Form No. 94-G-007)
 - Material Safety Data Sheet (MSDS)
 - Product-Tracking Forms (Form No. 93-L-029)

Sequential Application of Hand Antiseptic for Use in No-Water Situations (dubbed SaniTwice)

A New Hand Hygiene Option

Robert R. McCormack
BioScience Laboratories, Inc.
March 25, 2009



BioScience Laboratories,
Inc.

www.biosciencelabs.com

[Background]

- Current FDA Model Food Code requires food handlers to wash with soap and water to maintain clean hands.
- A reliable method of hand sanitization is needed for remote locations where water is not readily available. Among the many situations is the need to cleanse hands between changes of single-use gloves in no-water locations.



[Background]

- To meet this need, the “Sequential Application of Hand Antiseptic for Use in No-Water Situations” was developed:
 - A method of cleansing and sanitizing light to moderately soiled hands when soap and water are unavailable
 - Purpose is the removal and reduction of transient microorganisms from the hands



[Study Objectives]

- To demonstrate the antimicrobial effectiveness of this method as compared to standard handwashing with soap and water
- To evaluate the comparative effectiveness of various hand sanitizers for the reduction of bacteria when used in this methodology.

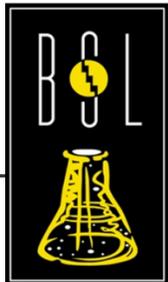


Modified Handwash Method

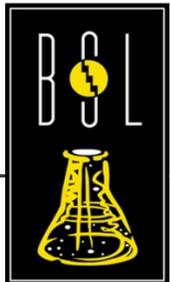
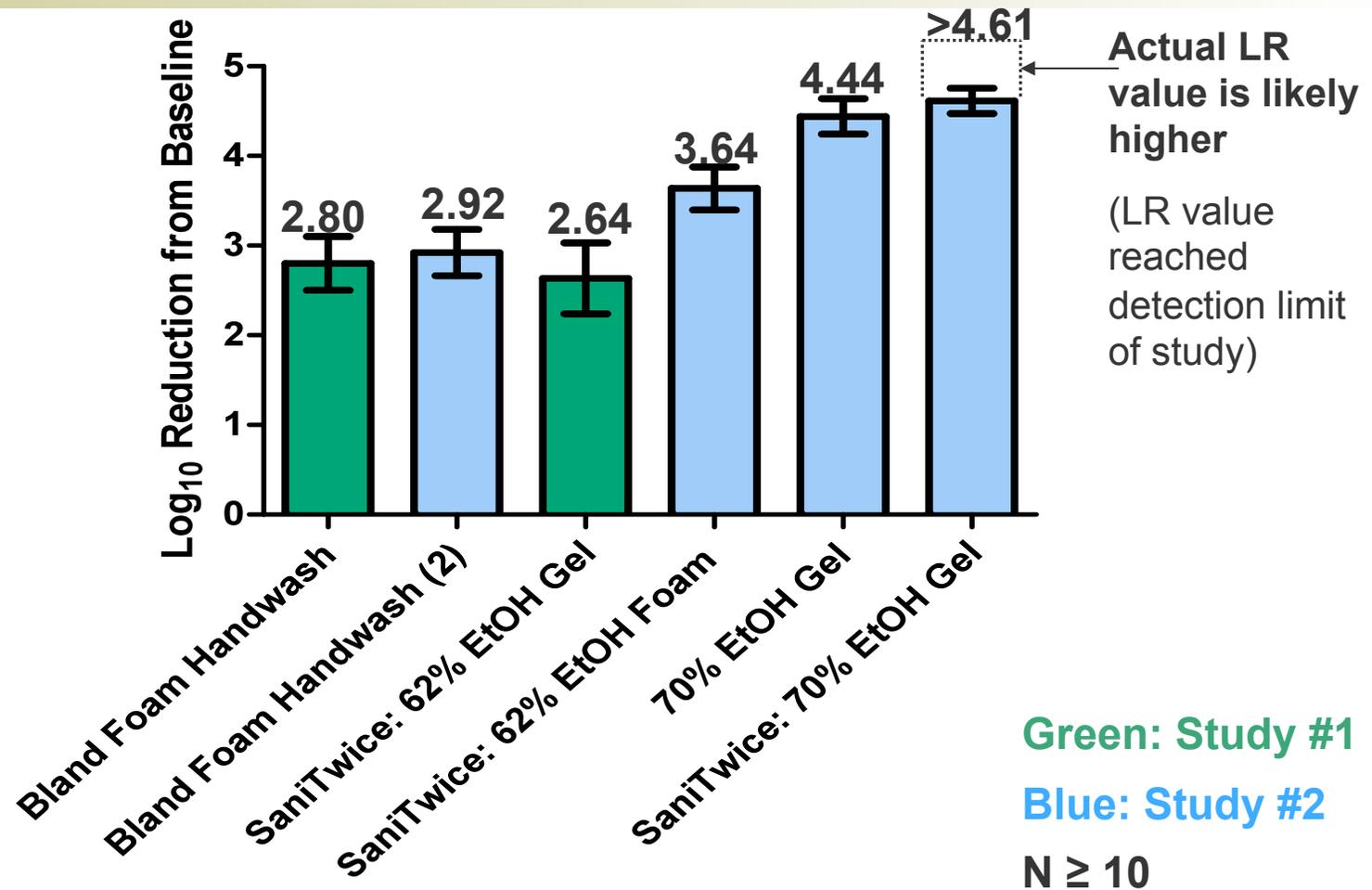
ASTM E1174

Step 1: Inoculate hands with about 1×10^9
Escherichia coli (ATCC #11229)
suspended in beef broth
(moderate soil conditions)

Step 2: Apply test product according to
label application instructions



Results



Statistical Analysis

- The antimicrobial efficacy of SaniTwice with 62% EtOH gel is equivalent to a typical bland handwash product
- SaniTwice with 62% EtOH foam is significantly better at reducing microorganisms on the hands than a typical bland handwash product
- SaniTwice with a high efficacy 70% EtOH gel is significantly better at reducing microorganisms on the hands than a typical bland handwash and the SaniTwice with 62% EtOH



What Does Your Hand Look Like After SaniTwice?



Hand contaminated
with *E. coli*



Hand after performing
SaniTwice with 70% EtOH gel



[Conclusions]

- Sequential Application of Hand Antiseptic for Use in No-Water Situations (SaniTwice) is an acceptable alternative to handwashing with soap and water
 - All SaniTwice regimens tested were equivalent or better at reducing the number of microorganisms on the hands than standard washing with soap and water



Conclusions

- There are statistically differentiated SaniTwice options based on antimicrobial efficacy requirements:
 - Good (62% EtOH gel)
 - Better (62% EtOH foam)
 - Best (High efficacy 70% EtOH gel)



Conclusions

- Use of a high efficacy product (70% EtOH gel) with the SaniTwice method results in superior reduction of bacteria on the hands
 - Complete kill of microorganisms (>4.61 LR)
 - SaniTwice is effective at cleansing and sanitizing the hands whereas using the product according to label instructions only sanitizes and does not clean the hands



Why Use SaniTwice?

- SaniTwice is a simple method that requires only a supply of hand sanitizer and paper towels
- Use of the SaniTwice method in remote locations is an acceptable alternative to handwashing
- Use of the SaniTwice method with a high efficacy hand sanitizer will result in improved sanitization over soap and water alone



Why Use SaniTwice?

- It is actually used as confirmed by extended field testing under the guidance of the Southern Nevada Health District
- Superior to currently approved hand hygiene interventions for no-water situations as seen in the following two photos taken in Illinois
- (Other photos are available from the 2008 CFP venue in San Antonio Texas.)



Food Code Approved Intervention



Food Code Approved Intervention



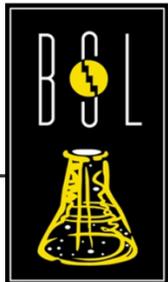
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SaniTwice[®]: A Hand Hygiene Solution for Food Handlers When Water is Unavailable

Sarah Edmonds¹, Cara Bondi¹, Robert McCormack³, David Macinga¹, James Arbogast¹, James Mann², Michael Dolan¹

1. GOJO Industries, Inc.
2. Handwashing for Life
3. BioScience Laboratories



Agenda

- Why “Sink-less” Hand Hygiene
- The SaniTwice[®] Solution
- FDA Model Food Code Considerations
- Conclusions

“Sink-less” Hand Hygiene

- Definition: hand hygiene (degerming) performed in settings where water is not available or is in limited supply
- Historically, a challenge without practical and effective solutions

Food Safety Challenge: Portable Bars



Food Safety Challenge: Military Buffet Line



Food Safety Challenge: Community Event



Food Safety Challenge: Cookoff



Food Safety Challenge: The Picnic



Food Safety Challenge: Symposium Serving Line



“Sink-less” Hand Hygiene

- Why not just have portable hand washing (i.e., the current paradigm)?

Food Safety Reality: Trickle Handwashing



Food Safety Reality: Trickle Handwashing



Is This Effective Hand Hygiene?



The SaniTwice[®] Solution

The SaniTwice Solution

- A reliable method of hand sanitization for (remote) locations where water is not available or in short supply
- A two stage method, “clean and kill”, for cleansing and sanitizing light to moderately soiled hands when soap and water are unavailable
- Purpose is the removal and reduction of transient microorganisms from the hands
- Benefit is reduction in risk of foodborne illness due to inadequate hand hygiene

SaniTwice Method

Step 1:

Apply excess of hand sanitizer (about 3 mL) and “wash” hands vigorously for 15 seconds



Step 2:

Remove remaining hand sanitizer and soil forcefully with paper towel while hands are still wet



Step 3:

Rub recommended amount (about 1.5 mL) of hand sanitizer on hands until dry



The SaniTwice Solution

Performance Study:

- *In vivo* microbiological efficacy

Study Objectives:

- Determine the effectiveness of the SaniTwice method as compared to standard handwashing with soap and water
- Compare effectiveness of various hand sanitizers when used in the SaniTwice methodology

Test Product Configurations

Test Product	Active	Application Method
Non-Antimicrobial Foam Handwash	N/A	Wash (Apply ~1.5ml, wash for 15s, rinse for 10s, towel dry)
Instant Hand Sanitizer Gel	62% ethanol	SaniTwice
Instant Hand Sanitizer Foam	62% ethanol	SaniTwice
Advanced Formula Instant Hand Sanitizer Gel	70% ethanol	Sanitize (Apply ~1.5ml, rub until dry)
Advanced Formula Instant Hand Sanitizer Gel	70% ethanol	SaniTwice

Two studies were conducted at BioScience Laboratories (2008-09)

Modified Handwash Method

ASTM E1174

Step 1: Contaminate hands with about 1×10^9
Escherichia coli (ATCC #11229)
suspended in beef broth
(moderate soil conditions)

Step 2: Apply test product according to
application instructions

Bacterial Measurement Steps

Step 3. Placement of sterile, latex glove



Step 4. Addition of sterile sampling fluid (GJ)



Step 5. Massage hand for 60 seconds

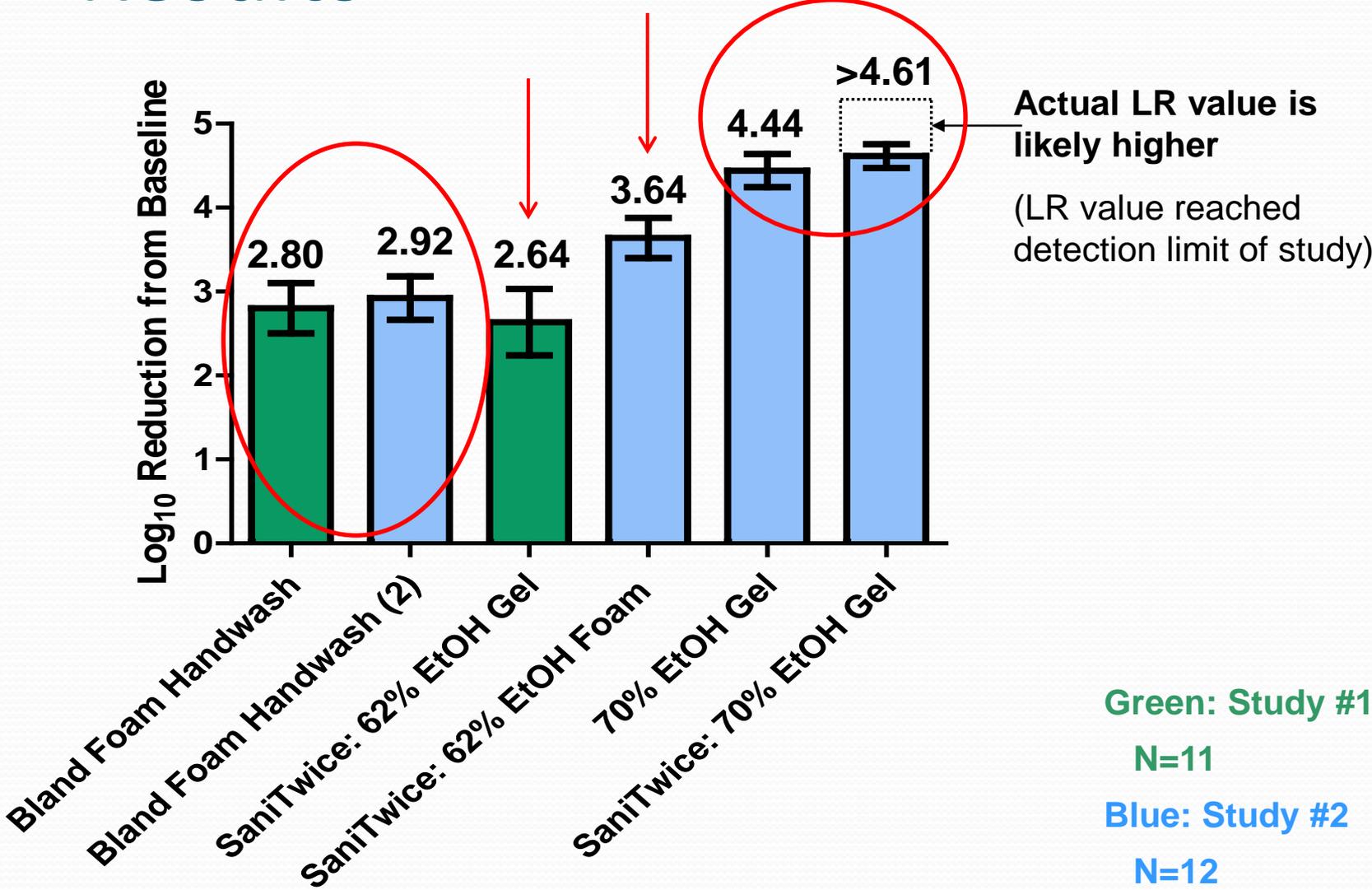


Step 6. Remove sample of glove-juice



Step 7: Serially dilute in neutralizing solution, plate on MacConkey Agar, grow overnight and compare to baseline values to calculate log reductions

Results



Statistical Analysis

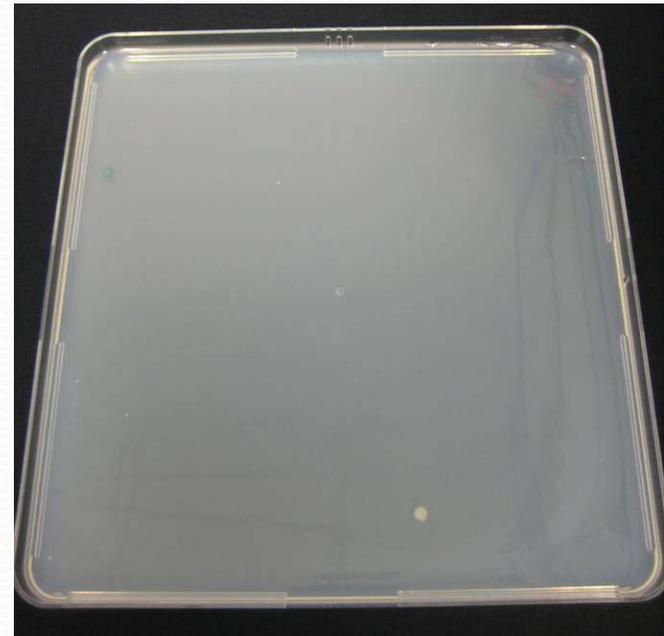
	SIGNIFICANTLY BETTER →		
Non-antimicrobial foam handwash	■		
SaniTwice: 62% ethanol IHS gel	■		
SaniTwice: 62% ethanol IHS foam		■	
Advanced Formula 70% ethanol IHS gel			■
SaniTwice: Advanced Formula 70% ethanol IHS gel			■

1 way ANOVA followed by post-hoc analysis ($p < 0.05$)

What Does Your Hand Look Like After SaniTwice?



**Hand contaminated
with *E. coli***



**Hand after performing
SaniTwice with Advanced
Formula 70% ethanol gel**

Conclusions

- SaniTwice is an acceptable alternative to handwashing with soap and water
 - All SaniTwice regimens tested were equivalent or better than standard washing with soap and water
- SaniTwice is a good substitute to trickle handwashing for “sink-less” food handling situations

Conclusions

- There are statistically differentiated SaniTwice options based on efficacy results:
 - Good (62% ethanol IHS gel)
 - Better (62% ethanol IHS foam)
 - Best (Advanced Formula 70% ethanol IHS gel)

Conclusions

- Use of the Advanced Formula 70% ethanol gel with the SaniTwice method resulted in superior reduction of bacteria on the hands compared to washing with a non-antimicrobial handwash and water alone
 - Complete kill of microorganisms (>4.61 LR)
- The Advanced Formula 70% ethanol gel was highly effective at reducing bacteria on the hands when used alone; however, the SaniTwice method has the additional benefit of skin cleansing and soil removal

SaniTwice Field Research Study: The Venetian Portable Bars

High User Acceptability and Compliance to the SaniTwice Regimen



FDA Model Food Code (2005)

- Section 2-301.16 outlines parameters for hand antiseptics:
 - “applied only to hands that are cleaned as specified under § 2-301.12.”

There is now clear scientific and practical rationale for including the SaniTwice approach in the Food Code

- SaniTwice has been shown to be an effective hand hygiene regimen, equivalent in degerming to handwashing with soap and water as specified in Section 2-301.12(B)

In Conclusion...

Prayer is Good;

SaniTwice, Even Better!



GOJO INDUSTRIES

Internal Communication

CONFIDENTIAL

TO: Geo Money, Chris Fricker, Amy Stokes
FYI: Dave Macinga, Jim Arbogast, Mike Dolan, Jim Mann
FROM: Sarah Edmonds
SUBJECT: TEST RESULTS FOR HEAVY SOIL PILOT SANITWICE STUDY
DATE: December 2, 2009

STUDY OBJECTIVES:

- Preliminary evaluation of whether SaniTwice is as effective as handwashing for reducing bacteria on heavily soiled hands
- Determine optimal soil type for full heavy soil SaniTwice study

TEST PRODUCT CONFIGURATIONS:	ACTIVE:
GOJO Luxury Foam Handwash (5200-502) Wash for 15s with 2 pumps (~1.4 ml), rinse for 10s, towel dry	N/A
SaniTwice with PURELL Foam (9800-504) Apply 4 pumps (~2.8 ml), towel dry, apply 2 pumps (~1.4 ml) and rub until dry	62% ethanol

TEST METHOD: A modification of the USFDA Tentative Final Monograph for: *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp.31448-31450) using *Escherichia coli* (ATCC #11229) suspended in either chicken chunks or raw hamburger patties

TESTING LAB: Bioscience Laboratories, Bozeman, Montana, Study #091010-150

RESULTS:

Test Configuration	LR	SD	95% CI
Chicken Chunk Contamination			
GOJO Luxury Foam Handwash	2.96	0.48	2.62-3.30
SaniTwice with PURELL Foam	3.32	0.43	3.01-3.63
Raw Hamburger Contamination			
GOJO Luxury Foam Handwash	2.58	0.41	2.28-2.87
SaniTwice with PURELL Foam	2.69	0.34	2.45-2.93
Results Below from Previous SaniTwice Study # 081211-150 (beef broth as soil load)			
GOJO Luxury Foam Handwash	2.92	0.61	2.66-3.18
SaniTwice with PURELL Foam	3.64	0.57	3.40-3.88

LR=log reduction from baseline; SD=standard deviation; CI=confidence interval; N=10

CONCLUSIONS:

- SaniTwice was as effective as handwashing for reducing bacteria on heavily soiled hands
 - Effective with chicken and raw beef soils
- As expected the raw beef appears to be a more difficult soil to penetrate
 - Both the handwash and PURELL Foam SaniTwice achieved about a 0.5 higher log reduction with the chicken than the beef

NEXT STEPS:

- Design and conduct full SaniTwice study with raw hamburger to represent “worst-case” heavy soils found in foodservice (SE)

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 080
Issue: 2010 III-003**

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

All information above the line is for conference use only.

Title:

Food Allergen Poster Endorsement

Issue you would like the Conference to consider:

The Food Allergen Committee seeks endorsement from the Conference for Food Protection and the FDA of the attached poster titled "What You Should Know About Food Allergies."

Public Health Significance:

It is well documented by physicians and food allergy advocacy organizations, that restaurants and other food establishments pose a number of dangers for food allergic individuals particularly with respect to cross-contamination and unexpected ingredients in certain foods. Approximately 13.7% of registrants in the United States Peanut and Tree Nut Allergy Registry have reported reactions associated with such establishments. (Furling TJ, DeSimone J, Sicherer SH "Peanut and tree nut allergic reactions in restaurants and other food establishments *J Allergy Clin Immunol*, 2001 Nov;108(5):867-70) Education and awareness about food allergies is paramount for restaurant staff as they are key communicators with patrons at any given food establishment. The poster "What you Should Know Food Allergies" serves to provide restaurant staff; managers and other foodservice personnel, with an additional educational tool to help increase awareness and provide basic understanding about food allergy and what to do in an emergency.

Recommended Solution: The Conference recommends...:

that the Conference for Food Protection endorse the educational poster titled "What You Should Know About Food Allergies."

The Conference further recommends that a letter be sent to the FDA requesting their endorsement of this educational poster.

Note: poster is attached to this Issue as a PDF file.

Submitter Information:

Name: Tony Flood, Co-Chair
Organization: Food Allergen Committee
Address: International Food Information Council (IFIC)1100 Connecticut Avenue, NW, Suite 430

City/State/Zip: Washington, DC 20036
Telephone: 202-296-4630 Fax:
E-mail: flood@ific.org

Attachments:

- "What you Should Know About Food Allergies"

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.

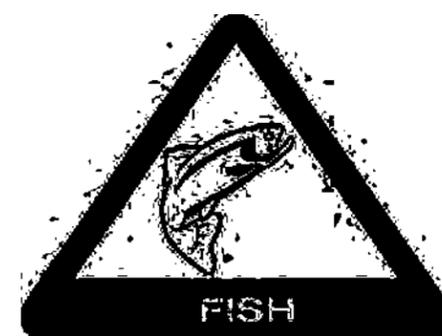
WHAT YOU SHOULD KNOW ABOUT

FOOD Allergies

MOST COMMON FOOD ALLERGIES



PEANUTS
Ground nuts, peanut butter



FISH
Tuna, salmon, anchovies



CRUSTACEAN SHELLFISH
Crab, lobster, shrimp



EGGS
Albumin, mayonnaise



SOY
Soy milk, soy bean, tempeh, tofu



TREENUTS
Walnuts, pecans, almonds, cashews



WHEAT
Bread, cereal, grains, bran, flour, semolina



MILK
Also listed as casein

NOTE:
Tony-there are several icons for tree nuts on the <http://www.foodprotection.org/resources/food-allergen-icons.php> website. Should I use all?

Symptoms of a Food Allergic Reaction

▶ SYMPTOMS CAN RANGE FROM MILD TO LIFE THREATENING

 **Call 911 if a customer experiences any of the following symptoms**

- Itching on or around the mouth, face, scalp, hands and/or feet
- Abdominal cramps
- Vomiting
- Diarrhea
- Hives (welts) or rash
- Swelling of the face, eyelids, lips, hands and/or feet
- Tightening of the throat (difficulty swallowing)
- Wheezing and hoarseness
- Shortness of breath
- Difficulty breathing
- Loss of consciousness

▶ WHAT TO DO:

 **If a guest informs you that he or she has a food allergy**

- Inform the cook, manager and/or person in charge
- Check the ingredient lists for all components of the meal for potential allergens
- Review the meal preparation procedure to check for potential cross contact
- Share all information with the customer

To help avoid cross contact between allergen and non-allergen foods

- Use clean and sanitized equipment and work surfaces
- Never use the same utensil to serve different prepared dishes and sauces
- Remember that cooking oils, splatter and steam released from foods, can be sources of cross contact

▶ STILL NOT SURE WHAT TO DO?

 **Ask a manager!**

If you are not 100% sure about the ingredients in a menu item, say so. Don't guess. A life may depend on it!



CONTACT INFO HERE? WEBSITE?



WHAT YOU SHOULD KNOW ABOUT

FOOD Allergies

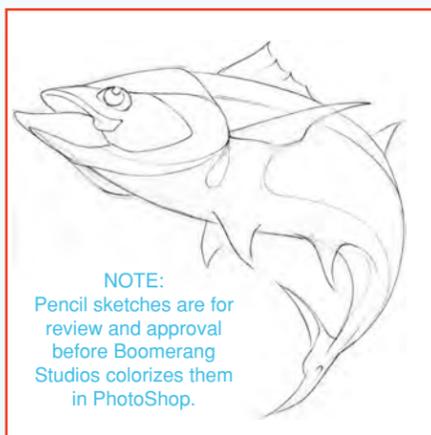


MOST COMMON FOOD ALLERGIES



PEANUTS

Ground nuts, peanut butter



NOTE:
Pencil sketches are for review and approval before Boomerang Studios colorizes them in PhotoShop.

FISH

Tuna, salmon, anchovies



CRUSTACEAN SHELLFISH

Crab, lobster, shrimp



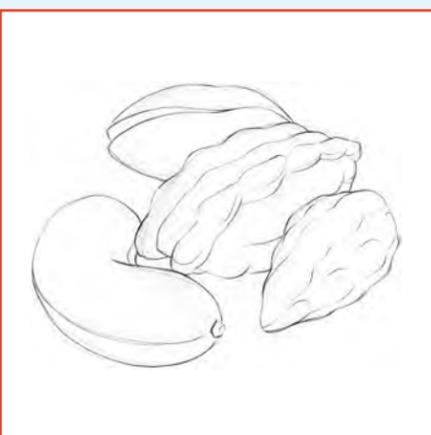
EGGS

Albumin, mayonnaise



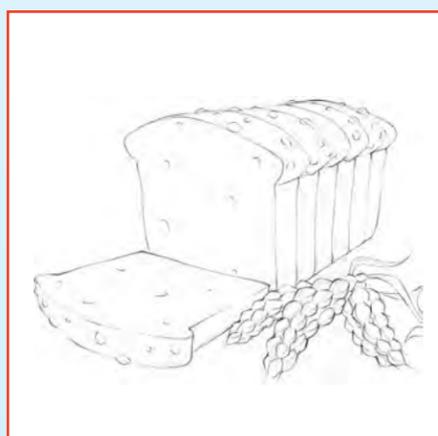
SOY

Soy milk, soy bean, tempeh, tofu



TREENUTS

Walnuts, pecans, almonds, cashews



WHEAT

Bread, cereal, grains, bran, flour, semolina



MILK

Also listed as casein

Symptoms of a Food Allergic Reaction

▶ SYMPTOMS CAN RANGE FROM MILD TO LIFE THREATENING



Call 911 if a customer experiences any of the following symptoms

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- Wheezing and hoarseness
- Shortness of breath
- Difficulty breathing
- Loss of consciousness

▶ WHAT TO DO:



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▶ STILL NOT SURE WHAT TO DO?



Ask a manager!

If you are not 100% sure about the ingredients in a menu item, say so. Don't guess. A life may depend on it!

Stay informed, visit:



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**Conference for Food Protection
2010 Issue Form**

**Internal Number: 085
Issue: 2010 III-007**

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

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Title:

Reduced Minimum Temperatures for Mechanical Warewashing Equipment

Issue you would like the Conference to consider:

Standards and Codes have evolved over the years to be performance based rather than construction based which fosters innovation and progress while still maintaining the desired requirement. Toward the goal of enabling performance based design, sections 4-501.110 and 4-501.112 should be revised to eliminate the minimum temperature requirements and substitute wording that will allow equipment that has been verified as meeting the sanitization equivalent to 5 log reduction of microorganisms of public health importance. Section 4-703.11 must also be revised to allow a utensil surface temperature less than the current requirement of 160°F.

For far too long the minimum hot water sanitizing temperatures for commercial dishwashers have been wasting valuable energy. Approximately 18% of a typical restaurant's energy consumption is for water heating and sanitation[1]. It is time to reverse this trend and establish guidelines that can provide significant reductions in energy consumption and green-house gas emissions while still maintaining an approved level of sanitization.

The attached research data from the Ohio State University confirms that a 5 log reduction in pathogens of public health concern can be obtained in a conveyor dishwasher with reduced wash and final rinse temperatures. This same machine was also tested for the hot water sanitizing efficacy of 3600 heat unit equivalents (HUE) using NSF International Standard 3-2009 for Warewashing Equipment. These test results are also attached. If adopted in the Food Code, this revision has the potential to reduce the energy consumption for a single tank conveyor dishwasher by approximately 5,300 kW-hrs each year. The potential savings in one year for all conveyor dishwashers could approach 1.8 million kW-hrs. The North American Association of Food Equipment Manufacturers (NAFEM) and the Pacific Gas and Electric, Food Service Technology Center (FSTC) supports this proposal (see attached letters).

Section 4-703.11 of the Food Code must be revised to allow a reduced utensil surface temperature for machines with a reduced final rinse temperature. The 160°F utensil surface temperature was never intended to be a performance criterion, but was adapted as merely an inspection tool. The Food Code paragraphs 4-501.11, 4-501.14 (B), and 4-501.15 require the proper operation of a mechanical dishwasher. If the machine is operating in

accordance with the nameplate times, temperatures, conveyor speed, etc. and if the wash and final rinse arms are spraying properly, adequate sanitization will take place. As an alternative to the 160°F utensil surface temperature, there are devices available that can record the time and temperature through the complete process to verify adequate sanitization on-site.

An additional benefit of reduced tank and final rinse temperatures is the potential to reduce cold water tempering of drain water required by section 701.7 and 803.1 of the 2009 International Plumbing Code. This code limits the temperature of water entering the sanitary drainage piping to 140°F to minimize expansion and contraction damage and softening of ABS and PVC pipes.

[1] Young, R., 2008, Greening Food Service Energy Efficiency: Issues and Resources, PG & E Food Service Technology Center

Public Health Significance:

This proposed change will maintain the current Code requirement of 5-log reduction in pathogens of public health concern. This can be confirmed by the NSF International Standard 3-2009 sanitizing efficacy performance requirement, or other means acceptable to the Authority Having Jurisdiction (AHJ). As long as the equipment is operated in accordance with the manufacturer's instructions, as required by 4-501.15 (A), adequate sanitization will be achieved. Research has shown that mechanical washing is more effective than manual warewashing and therefore is more flexible in operational parameters[2].

[2] Pascall, M., 2009, The number of warewashing cycles single batches of different chemical detergents can support in meeting the FDA Food Code mandates for commercial dishwashing machines in restaurants, Dept. of Food Science and Technology, The Ohio State University.

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.

(A) The temperature of the wash solution in spray type warewashers that use hot water to SANITIZE may not be less than:

(1) For a stationary rack, single temperature machine, 74°C (165°F); ^{Pf}

(2) For a stationary rack, dual temperature machine, 66°C (150°F); ^{Pf}

(3) For a single tank, conveyor, dual temperature machine, 71°C (160°F); ^{Pf} or

(4) For a multitank, conveyor, multitemperature machine, 66°C (150°F). ^{Pf}

(B) The temperature of the wash solution in spray-type warewashers that use chemicals to SANITIZE may not be less than 49°C (120°F). ^{Pf}

(C) As an alternative to (A) above, the temperature of the wash solution in spray type warewashers that use hot water to SANITIZE may not be less than the marked minimum temperatures on the equipment data plate when the equipment has been evaluated and verified as meeting the sanitizing performance criteria of 5 log reduction of pathogens of public health concern. ^{Pf}

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(A) Except as specified in ¶ (B) of this section, in a mechanical operation, the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90°C

(194°F), or less than: ^{Pf}

(1) For a stationary rack, single temperature machine, 74°C (165°F); ^{Pf} or

(2) For all other machines, 82°C (180°F). ^{Pf}

(B) The maximum temperature specified under ¶ (A) of this section, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and SANITIZING of EQUIPMENT such as meat saws.

(C) As an alternative to (A) above, in a mechanical operation, the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90°C (194°F), or less than the marked minimum temperature on the equipment data plate when the equipment has been evaluated and verified as meeting the sanitizing performance criteria of 5 log reduction in pathogens of public health concern. ^{Pf}

4-703.11 Hot Water and Chemical.

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

(A) Hot water manual operations by immersion for at least 30 seconds and as specified under § 4-501.111; ^P

(B) 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 for machines with a marked minimum final rinse temperature of 180°F (82°C). For machines with a marked minimum final rinse temperature other than 180°F (82°C), the utensil surface temperature shall be as marked on the machine (typically 20°F (11°C) below the marked minimum final rinse temperature); ^P or...

{Note - this modification will require a new marking on the machine data plate for hot water sanitizing models with less than 180°F final rinse temperature. This will require a similar change to NSF 3.}

Submitter Information:

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Organization: Hobart, ITW Food Equipment Group

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Fax:

(937) 332-2624

E-mail: joel.hipp@hobartcorp.com

Attachments:

- "OSU_Study_on_sanitizing_efficiency_with_reduced_temperatures.doc"
- "HUE_Test_Result.doc"
- "NAFEM_Support-Food_Code_Change.doc"
- "FSTC_Letter_of_Support_for_FDA_Code_Change-January_8_2010.pdf"
- "History_of_Dishwashing_Machine_Sanitation_12_14_09-JH.pdf"

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 sanitization efficacy of a mechanical warewashing process with
reduced wash and rinse temperatures**

Final Report

Melvin Pascall, Jaesung Lee

Department of Food Science and Technology

The Ohio State University

Introduction:

Current FDA Food Code guidelines and NSF International Standard 3 requirements include minimum wash and final rinse temperatures for mechanical warewashing processes in the foodservice industry. These guidelines have been carried over since the early 1950's when studies were carried out to show the amount of heat, water volume, pump pressure and exposure time necessary for adequate sanitizing. These physical design constraints were included in the National Sanitation Foundation Standard 3 for Commercial Dishwashers. The Food Code also relied upon design criteria to assure adequate sanitization. In 1977, NSF 3 was updated to remove some of the design constraints and rely more on the performance criteria of 3600 Heat Unit Equivalent (HUE), based on the USDA milk pasteurization curve. This study showed that a further reduction in the design restriction but retaining the performance criteria will in fact maintain the same level of public health safety while substantially reducing energy consumption.

In the choice of a procedure to determine if washing and rinsing protocols meet the requirements of the Food Code, the choice of the test utensil, contaminating food type, challenge bacteria, reagent type and concentration/temperatures and exposure time should be carefully chosen so that a worst case scenario is created. Thus, less difficult to clean utensils, which include typical real world applications, would be properly sanitized by the chosen protocol. A milk-based product, soft cream cheese, was selected because an initial study performed by authors Lee and Pascall (2007), showed that milk products left on dirty dishes were found to harbor the highest bacterial load when compared with other types of food soils.

Objective:

The main goal of this study was to determine if reduced wash and rinse temperatures in a mechanical dishwashing process will have a negative impact on sanitization compared to existing minimum wash and rinse temperatures.

To meet the stated goal above, the objectives of this project were:

1. To evaluate the hot-water sanitization efficacies of a mechanical dishwashing processes on **ceramic plates cleaned at two different washing and rinsing temperatures** (160°F washing followed by 180°F rinsing, and 155°F washing followed by 170°F rinsing).
2. To demonstrate that reduced wash and rinse temperatures can maintain the sanitizing performance criteria of 5-log reduction in bacterial load, or 3600 heat unit equivalents.

Methods:

Bacterial Sample

Escherichia coli K12 (ATCC 29181) and *Listeria innocua* Seeliger (ATCC 33090) were used as surrogate organisms during this study. The cultures were stored frozen (-176°F) in 30% (v/v) sterile glycerol. When required for testing, a loopful of each organism was revived in 10 ml Trypticase soy broth supplemented with 0.3% (w/w) yeast extract (TSBYE) and incubated at 98.5°F for 24 h. A loopful of broth from this was inoculated on a Tryptic soy agar with a 0.3% (w/w) yeast extract (TSAYE) slant and incubated for 18 h at 98.5°F. The cells grown on the slant were stored at 37.5°F and used as a stock culture. At each experiment, a loopful of this stock culture was transferred to 20 ml TSBYE and incubated at 98.5°F until the final concentration of cells in the medium reached about 1.0×10^9 cfu ml⁻¹. Cells in the broth were harvested by centrifugation at 10,000 g for 10 min at 39°F. The supernatant was discarded and the pellets were resuspended in 20 ml sterile deionized potassium phosphate buffer (pH 7.2). Each cell suspension was separately mixed with each of the food samples to be tested in this study.

Preparation of the Food Samples

The contaminating organic matter (food items) used in this study was processed semi-solid cream cheese (15% fat). All food items were purchased from a local store the day before each experiment and kept at 39°F. There was no evidence of microbial growth on the TSAYE plated 10^{-1} diluted (w/w) food items. Cell suspensions of *E. coli* or *L. innocua* were inoculated into the cream cheese (1:10 w/w) and mixed to give an initial cell count of at least 1.0×10^8 cfu per food item. The cream cheese was pasted on to 8.5 inch ceramic plates (5 g for each plate). Contaminated plates were air-dried for 1 h at 75°F then exposed to varying washing cycles using a CL44e mechanical dishwasher manufactured by Hobart Corporation (Troy, OH). In order to determine the effect of air drying on the bacterial survival and to estimate the initial number of inoculated organisms on the food contaminated plates to be washed, each food type pasted on to a

set of the plates was sampled after air drying. After serial dilutions, bacteria survival numbers were determined by the plate count method.

Dishwashing Process on Test Plates

The inoculated plates were washed in the mechanical dishwasher. In each experiment, three different racks containing three plates were tested. The plates were placed in different positions in the rack. During the experiment, the plates in the racks were washed with 1,000 ppm of a Guardian Score (Ecolab, Inc., St. Paul, MN) detergent at 160°F and rinsed at 180°F. Prior to using the mechanical dishwasher, it was cleaned with hot water and filled with fresh detergent and water. The wash water was sprayed onto the plates at a flow rate of approximately 165 gallons per minute. Subsequently, the plates were rinsed with fresh water at a pressure of 20 psi. After washing and rinsing, all plates were placed on a sterile rack and air-dried for 15 min at 75°F prior to sampling. At the reduced temperature experiment, the test was performed at a wash temperature of 155°F and rinsed at 170°F.

Microbiological Sampling of the Utensil Surfaces

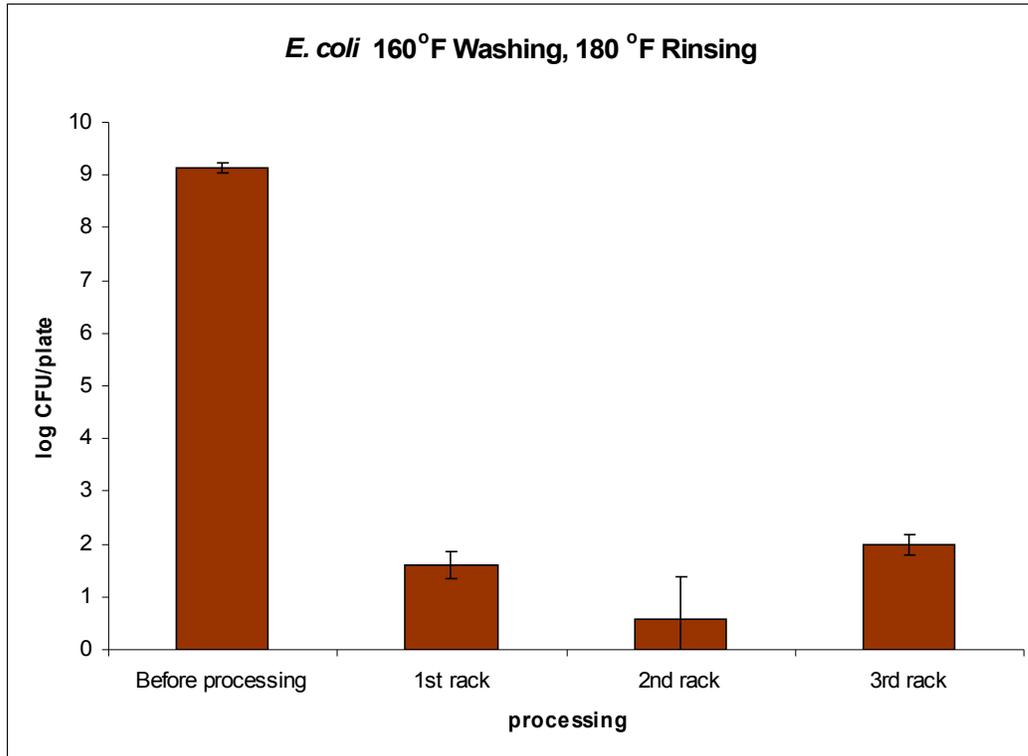
In the sampling for microbial enumeration, hygiene swabs were used to collect organisms from the surface of the plates that were previously washed. The swabs, made with sterile calcium alginate fiber tips on a wood applicators (Fisher Scientific, Pittsburgh, PA), were moistened before use with sterile peptone water. These swabs were transferred to test-tubes containing 2 ml of the peptone water. These tubes were then vigorously vortexed to release any bacterial cells from the fiber tip of the applicators.

Microbiological and Statistical Analysis

All cells were serially diluted and plated onto TSAYE to determine their viable counts after 24 h incubation at 98.5°F. The detection limit for the test organisms was 2 CFU per the plate. In order to determine if the bacterial count on the washed samples resulted from organisms that were inoculated into the food, we simultaneously tested a comparable sample of food that was not inoculated with the bacterial species. The presence of any colonies in the comparable sample after washing would be evidence of contamination and in such cases, the entire batch of samples would be discarded. No less than two trials were used in each experiment. Variances of

microbial viability were analyzed by equal-variance *t*-test using a Microsoft Excel data analysis program (Ontario, Canada). The level of significance was set for $P < 0.05$.

Figure 1. Enumeration of *E. coli* on plate before and after processing at different temperature using the mechanical dishwasher.



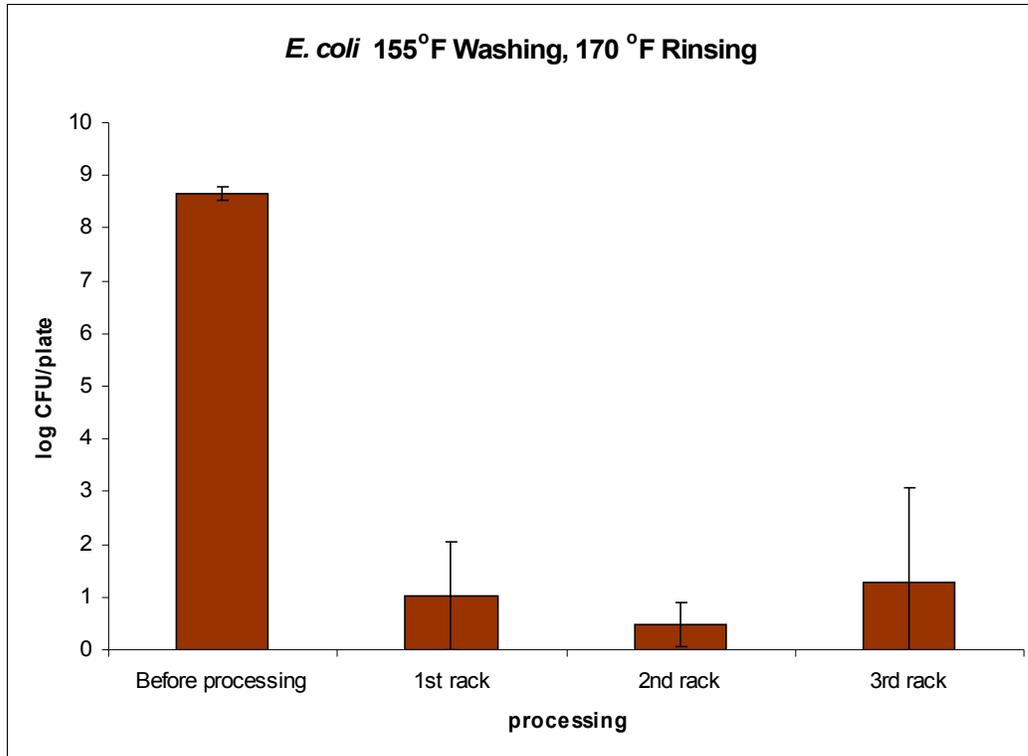
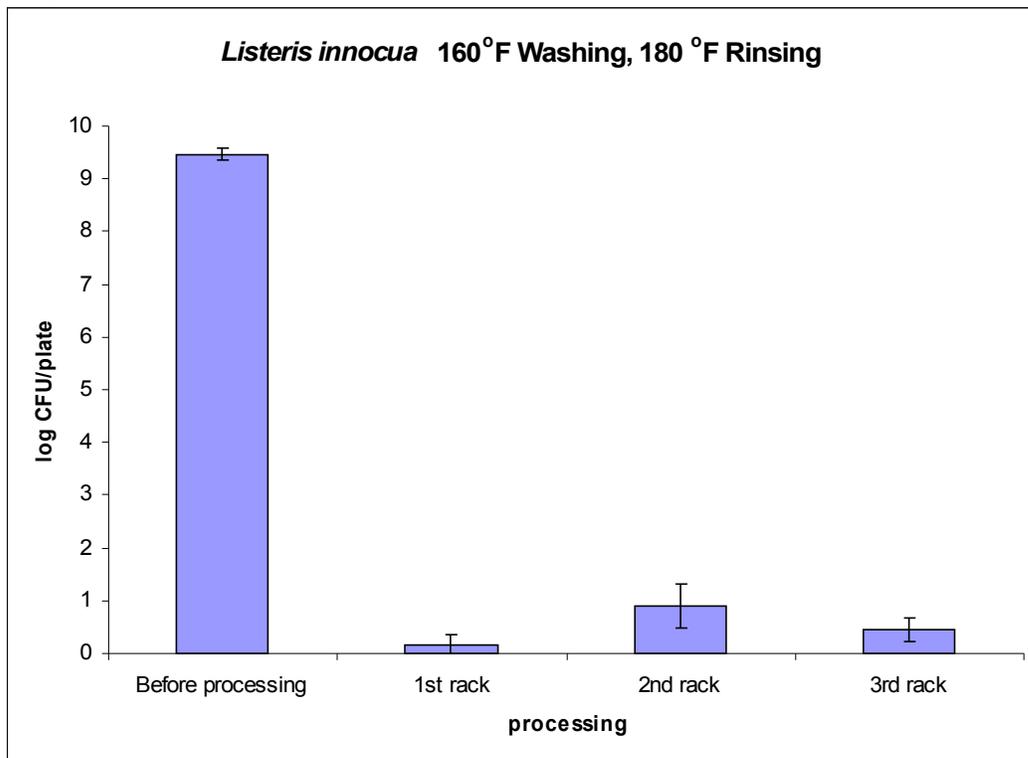
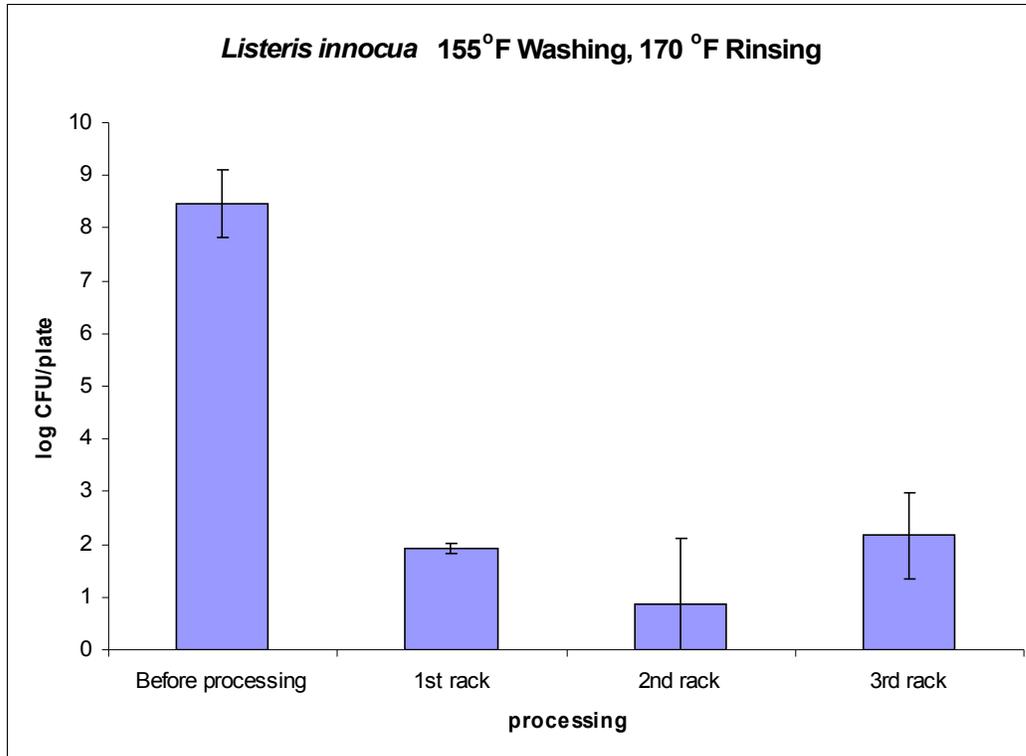


Figure 2. Enumeration of *L. innocua* on plate before and after processing at different temperature using the mechanical dishwasher.





Findings

- The application of lower washing and rinsing temperatures did not significantly ($P>0.05$) reduce the efficacy of the mechanical dishwashing process for bacterial numbers on the test plates compared with that on plates processed at standard temperatures (160°F wash and 180°F rinse).
- The results in Figures 1 and 2 show that all dishwashing processes had the ability to produce the 5-log bacterial load reduction.



Temperature Analysis Report

Machine Tested: CL44e

Test Info:

Test Notes: 157 wash 172 rinse dual upper rinse 2.1 gal 205 racks 9-22-09

Test Date: 09/22/2009

Test Time: 08:51 AM

Test File: 157wash172rinsedual

Duration of Test: 1m 10s

Channel Temperature Summary-

Channel:	1	2	3	4	5	6
Description:	wash	rinse	inlet	plate 1	plate 2	plate 3
Maximum Temp:	157.0°F	172.4°F	174.5°F	166.6°F	164.8°F	166.0°F
Minimum Temp:	156.0°F	170.1°F	173.9°F	86.6°F	86.1°F	85.3°F
Average Temp: (based on)	156.4°F All	171.9°F All	174.3°F All	144.2°F All	143.7°F All	138.6°F All
Total HUEs:	n/a	n/a	n/a	3765.5	3910.9	4388.7

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NAFEM Support-
Food Code Change



January 4, 2010

Dear Conference for Food Protection Council Members

The North American Association of Food Equipment Manufacturers (NAFEM), supports changing the FDA Food Code to modify the temperature requirements for commercial dish machines.

The proposed change removes the temperature requirements for wash and rinse cycles and maintains the performance criteria currently required by the FDA (5-log pathogen reduction). Research has confirmed that sanitation requirements can be met while operating at lower temperatures – resulting in a machine that uses less energy which, in turn, reduces CO₂ emissions and lowers energy bills.

If the proposed changes are instituted, an operator of a rack conveyor machine, for example, could realize an estimated annual savings of 0.042 kW-hours per dish rack. This could save up to \$539 *per machine* annually. With an estimated 6,000 new conveyor machines sold per year, the potential annual savings could be as high as \$3,234,000 in energy costs and over 1.8 million kW-hours of energy – and this is representative for one type of dish machine only. These energy savings are the equivalent of:

- 1,314 metric tons of CO₂
- 280 acres of pine or fir forests (or preserving 12.5 acres of forest from deforestation)
- Enough energy to supply electricity to 171 homes for one year

We hope the council agrees with this proposal and approves this change. Thank you in advance for your consideration.

Sincerely,

Charlie Souhrada, CFSP
Director, Member Services
NAFEM



Food Service Technology Center

January 8, 2010

Joel Hipp
Hobart, ITW Food Equipment Group
701 S. Ridge Ave
Troy/Ohio/45374

Joel,

The Food Service Technology Center (FSTC) supports the industry's effort to reexamine the minimum temperatures required to achieve sanitation in commercial dishmachines. If commercial dishmachines are able to expose the dishes to enough heat over time to effectively sanitize the dishes at a lower operating temperature, then the energy savings could be quite substantial.

It is estimated that foodservice operations in California consume an estimated 350 million therms of gas annually for hot water heating – representing 20% of the total gas consumed by commercial facilities. If this value were prorated for the Continental U.S., the commercial water heating load would approach 3.5 billion therms per year for commercial foodservice operations alone.

In most commercial foodservice operations, the operating temperature of the water heating system is driven by the needs of the commercial dishmachine. The rinse operation of the dishwasher requires inlet water temperatures typically in the 140° F range to the dishmachine (for low-temp applications) or to the booster heater (for high-temp applications) to ensure clean dishes. The water heater energy use required to heat and maintain proper operating temperatures could be reduced significantly if the standard operating temperatures were lower.

The FSTC estimates that 16 million therms of natural gas would be saved if all food service facilities in California that use gas water heating and have high-temp dishwashers were able to retrofit or purchase a new (Euro style) dishwasher that allowed the establishment to turn down the thermostat by 10°F. If these savings were projected to the continental U.S, the savings potential would be 160 million therms per year. This significant savings potential is possible if the FDA Food Code were modified to specify the minimum operating temperatures determined by NSF Standard 2 as meeting the sanitizing performance criteria of 5 log reduction of pathogens of public health concern.

Regards,

David Zabrowski
Food Service Technology Center



Sanitation is a way of life. It is the quality of living that is expressed in the clean home, the clean farm, the clean business and industry, the clean neighborhood, the clean community. Being a way of life it must come from within the people; it is nourished by knowledge and grows as an obligation and an ideal in human relations.

Where did 3600
HUE come from?



Early Days

- Ordinance and Code Regulating Eating and Drinking Establishments – U.S. Public Health Service, 1943
 - ... irrespective of whether by hand or machine
 - Immersion at least 2 minutes at 170-180°F or ½ minute in boiling water (41,616 HUE's by today's standard)
- Mallmann, DeKoning, April 1947¹
 - A rinse period of 10 sec. at 170°F for a single tank machine.
 - Test soil was designed so that it would *not* be removed during the entire process.
- Mallmann, Kahler, NSF 1949
 - Immersion at least 30 seconds at 170°F (10,404 HUE's today)

1 – Original study unavailable. Notes are from subsequent research report.

HUE is “invented” and milk pasteurization levels established

- Bactericidal Value of Dishwashing Machine Sprays, Fuchs, 1951
 - Curve defined by:
 - M. tuberculosis and milk pasteurization
 - 143°F for 1800 seconds, 161°F for 15 seconds \equiv 1800 HUE
 - At an arbitrary temperature:
 - » $\text{HUE/sec} = H = 3.03438\text{E-}17 \times e^{0.265972 \times T}$
 - No *extra* credit for temperatures above 165°F

Pasteurization Defined

- High temperature/short time (HTST) Pasteurization
- The HTST pasteurization standard was designed to achieve a 5-log reduction (0.00001 times the original) in the number of viable microorganisms in milk. This is considered adequate for destroying almost all yeasts, mold, and common spoilage bacteria and also to ensure adequate destruction of common pathogenic heat-resistant organisms (including particularly *Mycobacterium tuberculosis*, which causes tuberculosis and *Coxiella burnetii*).

FDA Food Code “Definition” of Sanitization

- FDA Food Code in Chapter 1 Purpose and Definitions under the section on sanitization.
 - **"Sanitization"** means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

NSF

- NSF Summary Report: Study of Commercial Multiple-tank Spray-type Dishwashing Machines, March 1964
 - *M. phlei* (more heat resistant than *M. tuberculosis*)
 - Lower heat factors were required to destroy microorganisms in water than in milk
 - Organisms were suspended in capillary tubes at the dish surface (thus preventing dilution or wash off)
 - 1900 HUE required for “kill”
 - “Kill” not yet defined as 5-log
 - Concluded that the HUE method can be related to micro-biological results

NSF 1964

- For Multiple Tank Conveyor Units
 - Wash water 150°F
 - Pumped rinse 160°F
 - Final rinse 180°F
 - Without reference to time exposures - However typical timing would yield 9900 HUE!

NSF 1977

- NSF Standard No.3, amended November, 1977
 - 3600 HUE recommended
 - Twice the recommended HUE for milk pasteurization
 - More than sufficient to kill *M. phlei*
- **Literature research suggests that 3600 was established as an “arbitrary” safety factor of 2 times the value established for milk pasteurization**

Evaluation of Household Dishwashing Machines for Use in Small Institutions – Bryan, DeHart - 1975

- Regard 3600 HUE as providing considerable margin
 - It is twice the heat exposure required for pasteurizing milk
 - Bacteria in water are killed by a lower cumulative heat factor than is required to kill bacteria in milk because water is less viscous than milk
 - The standard for pasteurizing milk, provides a considerable margin of safety
 - Pasteurization standards are based on the destruction of large numbers of *M. tuberculosis*.

The Sanitizing Efficiency Of Dishwashing Machines – Vaughan 1979

- ...effective soil removal should be the primary feature of any dishwasher.
- 99.9% of the bacteria can be removed simultaneously with the removal of soil
 - Suggesting, mathematically, that only 2 log reduction would be needed by sanitization

Conclusions

- There is significant data and discussion indicating that 1800 heat equivalent units is a conservative requirement for the pasteurization of milk
- Doubling the HUE requirement for a warewashing machine adds an arbitrary additional factor of 2
- Dishes are an indirect food borne illness path to the human body, thus further reducing the risk factor