Conference for Food Protection
2012 Issue Form

Internal Number: 028
Issue: 2012 I-001

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

All information above the line is for conference use only.

Title:
Report - Plan Review Committee

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

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

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

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

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

2. Thank the Committee members.

Submitter Information:
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Organization: Plan Review Committee
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Attachments:

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

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

Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: Plan Review

COUNCIL (I, II, or III): I

DATE OF REPORT: January 3, 2012

SUBMITTED BY: Liza Frias

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

a. Temporary Food Establishment
b. Permanent Outdoor Cooking Operations

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

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

Charge 1 – Temporary Food Establishments

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

Charge 2 – Permanent Outdoor Cooking Operations

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

Recommendation(s) for future charge:

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

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

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

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

ATTACHMENTS:

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

Committee Name: 2010-2012 Plan Review Committee Roster

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

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Temporary Food Establishments 2011 Final Document

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

TABLE OF CONTENTS

PREFACE

This document is intended to assist local health regulatory authorities and the food industry in understanding the review, approval and operation of Temporary Food Establishments. However, it does not establish regulatory requirements and the recommendations contained herein are not intended to supplant, or otherwise serve as, the rules and regulations applicable to food establishments in a given Federal, State, local or tribal jurisdiction.

This document:

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

DEFINITIONS

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

"Food establishment" includes "an operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD."

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

(a) *An establishment that offers only pre*PACKAGED FOODS *that are not* POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY) FOODS;
(b) *A produce stand that only offers whole, uncut fresh fruits and vegetables*;
(c) *A* FOOD PROCESSING PLANT*; including those that are located on the PREMISES of a FOOD ESTABLISHMENT*
(d) *A kitchen in a private home if only* FOOD *that is not* POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY) FOOD, *is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by* LAW *and if the* CONSUMER *is informed by a clearly visible placard at the sales or service location that the* FOOD *is prepared in a kitchen that is not subject to regulation and inspection by the* REGULATORY AUTHORITY*;*

"Temporary food establishment" means a FOOD ESTABLISHMENT that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

INTRODUCTION

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

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

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

TEMPORARY FOOD EVENT COORDINATION

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

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

PLAN REVIEW AND APPLICATION PROCESS

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

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

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

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

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

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

TEMPORARY FOOD ESTABLISHMENT CLASSIFICATIONS

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

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

Food Service (FS) Type 1

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

Food Service (FS) Type 2

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

Food Service (FS) Type 3

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

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

MONITORING AND PLANNING FOR TEMPORARY FOOD EVENTS

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

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

TEMPORARY FOOD ESTABLISHMENT OPERATIONS CHECKLIST

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

The applicable 2009 Model Food Code Sections have been italicized.

PERSONNEL

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

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

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

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

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

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

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

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

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

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

FS Type 1

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

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

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

Sample for Type 1


Sample for Type 2

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

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

FOOD SOURCE

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

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

FOOD PREPARATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EQUIPMENT

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

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

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

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

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

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

FOOD AND UTENSIL STORAGE

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

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

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

CLEANING AND SANITIZING

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

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

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

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

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

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

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

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

WATER SUPPLY AND WASTEWATER DISPOSAL

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

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

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

PREMISES

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

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

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

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

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

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

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

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

APPLICATION TO OPERATE A TEMPORARY FOOD ESTABLISHMENT

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

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

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

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

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

TEMPORARY FOOD ESTABLISHMENT REQUIREMENTS

Booth Construction

Overhead Covering □ Canvas □Wood □Other: _____

Floor □ Asphalt □Concrete □Wood □Other:_____

Walls □ Screens □Concrete □Wood □Other:_____

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

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

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

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

Applicants Name (Print): _____Applicants Signature:_____

DO NOT COMPLETE INFORMATION BELOW – FOR OFFICE USE ONLY

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

*Reason(s) for Disapproval:

_____

_____

_____

_____

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

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

Temporary Food Establishment - Expanded Process Flow

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

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

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

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

EVENT ORGANIZER APPLICATION TO OPERATE TEMPORARY FOOD ESTABLISHMENTS

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

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

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

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

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

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

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

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

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

DO NOT COMPLETE INFORMATION BELOW – FOR OFFICE USE ONLY

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

Permit Restrictions: _____

Permit Effective Dates: _____

*Reason(s) for Disapproval: _____

_____

_____

_____

_____

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

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

Conference for Food Protection
2012 Issue Form

Internal Number: 029
Issue: 2012 I-002

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

All information above the line is for conference use only.

Title:
Temporary Food Establishments 2011 Final Document

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

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

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

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

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

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 030
Issue: 2012 I-003

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

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Title:
Re-Create Plan Review Committee

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

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

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

Submitter Information:

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

Internal Number: 001
Issue: 2012 I-004

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

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Title:
Change definition of PHF/TCS to TCS

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

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

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

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

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

Submitter Information:

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Attachments:

- ""Technologists, 2010""

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

Conference for Food Protection
2012 Issue Form

Internal Number: 004
Issue: 2012 I-005

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

All information above the line is for conference use only.

Title:
Sore throat with fever

Issue you would like the Conference to consider:
Food and Drug Adminstration 2009 Food Code , section 2-201.13(G) requires a person with sore throat and fever to not return to work until they have medical documentation of being free of ***Streptococcus pyogenes*** or have received professional medical treatment for same.
This requirement is too strict considering the risk.

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

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

Top 5 pathogens contributing to foodborne illness

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

Trends in Foodborne Illness in the US

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

Get Smart: Know when antibiotics work - Sore throat

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

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

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

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 057
Issue: 2012 I-006

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

All information above the line is for conference use only.

Title:
Report-Wild Harvested Mushroom Committee

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

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

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

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

Submitter Information:

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

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

Committee Name: Wild Harvested Mushroom Committee

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

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

Environmental Health in MMWR — 1961–2010

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

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

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Introduction

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

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

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

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

Methods

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

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

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

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

Results

Environmental Disease

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

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

Childhood Lead Poisoning (110 Reports)

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

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

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

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

Carbon Monoxide Poisoning (45 Reports)

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

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

The case/cluster reports can be grouped as follows:

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

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

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

New and Reemerging Epidemic Diseases (30 Reports)

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

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

Asthma (26 Reports)

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

Environmental Tobacco/Secondhand Smoke (21 Reports)

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

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

Environmental Threats and Risks

Specific Chemicals, Toxins, and Risk Factors

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

Pesticides (28 reports)

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

Metals (24 reports)

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

Organic compounds (25 reports)

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

Substances of abuse (40 reports)

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

Dietary supplements (18 reports)

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

Consumer products (21 reports)

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

Drugs, devices, and therapeutics (12 reports)

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

Environmental Media

Water (60 reports)

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

Air (13 reports)

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

Food (46 reports)

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

Hazardous wastes (14 reports)

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

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

Environmental Places

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

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

Disasters

Natural disasters (153 reports)

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

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

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

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

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

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

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

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

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

Terrorism

World Trade Center attack (15 reports)

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

Discussion

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Wild Mushrooms Can Kill, California Health Officer Warns

by News Desk | Nov 26, 2011

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

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

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

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

- Two people died.

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

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

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

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

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

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

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

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

More Headlines from For Foodies »

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

PRESS RELEASE
FOR IMMEDIATE RELEASE
August 27, 2011

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

DHHS Issues Warning about Accidentally Eating Poison Mushrooms

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

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

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

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

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

# # #

2 discover tasty mushrooms can be dangerous

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

BY JOE STEPHENS

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

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

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

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

"They tasted good."

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

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

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

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

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

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

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

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

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

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

stephensj@washpost.com

Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: **Wild Harvested Mushrooms Committee**

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

DATE OF REPORT: December 5, 2011

SUBMITTED BY: *Chris Gordon and Lisa Roy*

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

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

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

REQUESTED ACTION:

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

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

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

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

Conference for Food Protection
2012 Issue Form

Internal Number: 062
Issue: 2012 I-007

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

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

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

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

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

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

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 058
Issue: 2012 I-008

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

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Title:
Resources and Criteria to Select Wild Mushroom Species

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

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

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

Recommended Committee Resources

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

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

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

Criteria to Select Wild Mushroom Species

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

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

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

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Conference for Food Protection
2012 Issue Form

Internal Number: 059
Issue: 2012 I-009

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

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Title:
Wild Harvested Mushroom Record-Keeping and Traceability

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

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

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

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

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

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

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 060
Issue: 2012 I-010

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

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Title:
Wild Harvested Mushroom Curriculum

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

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

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

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

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

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

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

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

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Conference for Food Protection
2012 Issue Form

Internal Number: 061
Issue: 2012 I-011

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

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Title:
Wild Harvested Mushroom Exam

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

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

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

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

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

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

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

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Conference for Food Protection
2012 Issue Form

Internal Number: 015
Issue: 2012 I-012

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

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Title:
Re-create Wild Harvested Mushroom Committee

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

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

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

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

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Conference for Food Protection
2012 Issue Form

Internal Number: 117
Issue: 2012 I-013

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

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

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

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

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

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

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

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

Recommended Solution: The Conference recommends...:

1. That a Committee be established to:

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

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

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

(d) report back to the 2014 Biennial Meeting.

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

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Attachments:

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

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A RETAIL FOOD ESTABLISHMENT GUIDE FOR DEVELOPING A HACCP PLAN

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

Table of Contents

Section 1: Introduction to Food Safety Systems

About HACCP

What is HACCP?

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

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

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

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

HACCP Requirements in the Food Code

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

Retail Processes or Operations that Require a HACCP Plan:

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

Additional Requirements

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

Definitions:

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

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

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

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

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

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

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

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

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

Deviation: *Failure to meet a critical limit.*

Food Code: *Minnesota Rules 4626*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

An Introduction to Preliminary Steps

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

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

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

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

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

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

An Introduction to the 7 HACCP Steps

Principle 1: Conduct a Hazard Analysis

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

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

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

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

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

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

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

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

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

Principle 3: Establish Critical Limits for Each CCP

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

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

Principle 4: Establish CCP Monitoring Procedures

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

Monitoring serves three main purposes:

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

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

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

Monitoring Requires Precision

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

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

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

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

Principle 5: Establish Corrective Actions

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

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

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

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

Principle 6: Establish Recordkeeping Procedures

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

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

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

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

Principle 7: Establish Verification Procedures

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

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

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

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

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

Verification procedures help makes the HACCP plan work correctly.

Section 2: The Preliminary Steps

Introduction

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

They are:

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

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

Step 1: Assemble the HACCP Team

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

The HACCP team needs to be aware of the following:

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

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

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

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

Working with the "HACCP Team" Form

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

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

Step 1
HACCP Team Form

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

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

Step 2: Identify Products/Processes to be Covered

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

Product/Process Description Form

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

Products/Processes Covered

Store Name *General J's Market*

Street Address *123 XYZ Street*

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

Products/Processes Covered under the HACCP Plan

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

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

Food Additives
Acidified rice

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

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

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

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

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

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

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

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

Smokehouse Operations Formulation/Recipe

Step 3
Ingredients and Raw Materials Form

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

Product/Examples: *Beef Jerky*

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

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

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

Equipment List

Store Name *General J's Market*

Street Address *123 XYZ Street*

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

Smokehouse Operations Equipment List

Walk-in Cooler: Brand _____ Size _____

Other products/Operations Supported _____

Grinder: Brand _____ Size _____

Mixer: Brand _____ Size _____

Stuffer: Brand _____ Size _____

Smokehouse: Brand _____ Size _____

Smoke generator/liquid smoke _____

Digital Thermometer _____

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

_____

Reduced Oxygen Packaging Equipment List

Slicer: Brand _____ Model # _____

Vacuum Packaging Machine _____

Digital Thermometer _____

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

Vacuum plastic pouch _____

Scale/labeling machine _____

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

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

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

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

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

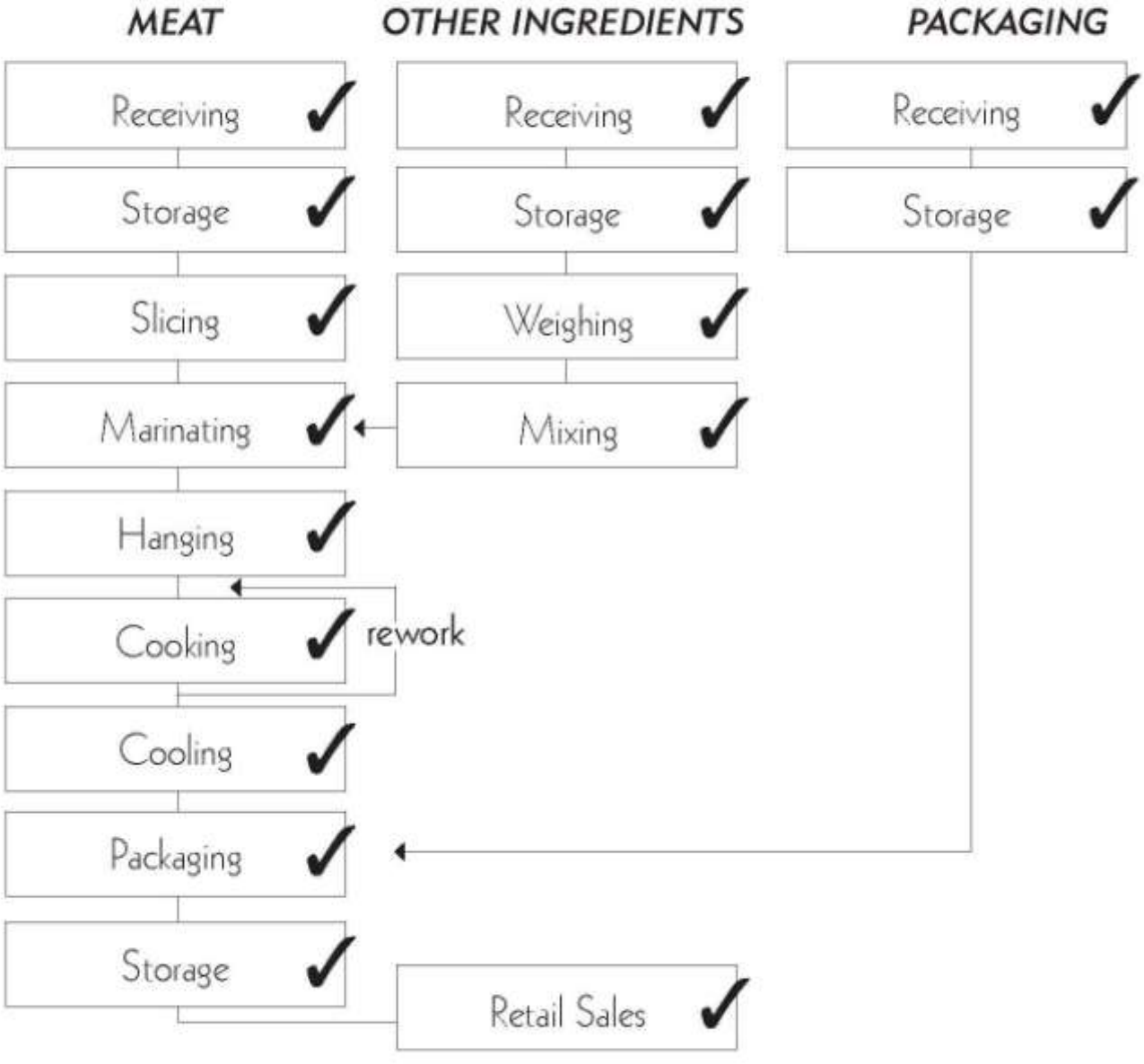
The Example Facility divided their flow diagram into three paths. Each of these paths represents one or more ingredients or raw materials. It made sense to combine certain categories. They grouped all meat items into "Meat", all-nonmeat food ingredients such as spices and preservatives into "Other Ingredients",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

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

Steps 4 & 5
Process Flow Diagram Development & Verification Form

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

Flow Diagram:



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

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

Conclusion:

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

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

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

Section 3: Utilizing the 7 Principles of HACCP

Understanding Hazards and Controls

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Chemical Hazards

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

Physical Hazards

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

Table 3-1

BACTERIA - CHARACTERISTICS OF GROWTH

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

Table 3-2

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

Table 3-3

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

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

Table 3-4

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

Table 3-5

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

Table 3-6

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

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

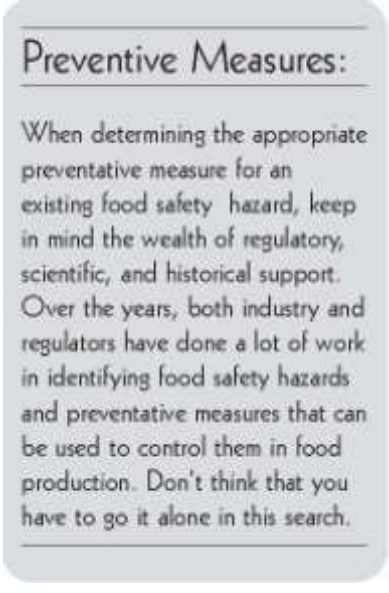
Principle 1: Hazard Analysis

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

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

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

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



Hazard Identification and Evaluation

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

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

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

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

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

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

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

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

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

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

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

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

Finding Preventive Measures

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

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

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

Here's A Tip

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

Working with the "Hazard Analysis" Form

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

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

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

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

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

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

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

HACCP Principle 1
Hazard Analysis Form

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

Process Step from Flow Diagram: Receiving Meat

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

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

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

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

M

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

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

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

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

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

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

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

HACCP Principle 1
Hazard Analysis Form

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

Process Step from Flow Diagram: Cooking

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

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

Smokehouse temperature is 190°F.

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

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

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

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

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

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

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

HACCP Principle 1
Hazard Analysis Form

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

Process Step from Flow Diagram: Cooling

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

Is the hazard reasonably likely to occur?

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

What is the basis for your decision?

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

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

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

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Principle 2: Identify Critical Control Points

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

Some of the most common CCPs are:

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

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

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

Working with the "CCP Decision Tree" Form

Critical Control Point Decision Tree

For the production of cooked products. Process Step Receiving Meat

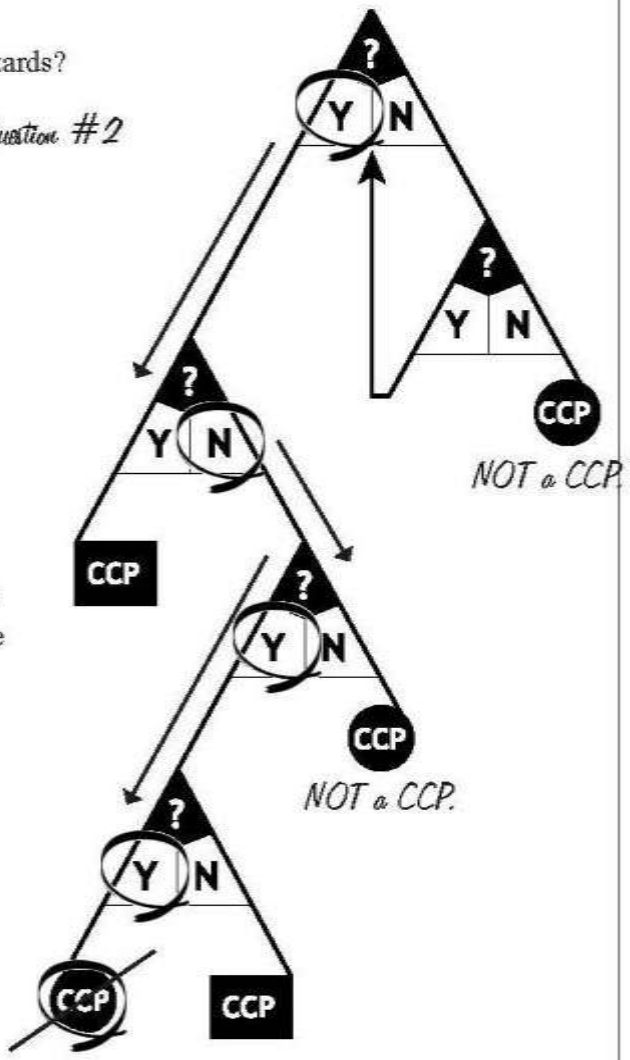
Question 1A
Do preventative measures exist for the identified hazards?
If no - go to Question 1B.
If yes - go to Question 2. Yes, go to Question #2

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

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

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

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



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

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

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

The second step they looked at was cooking.

Question 1a

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

Question 1b

As in the receiving example, move onto question 2.

Question 2

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

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

Critical Control Point Decision Tree

For the production of cooked products. Process Step Cooking

–

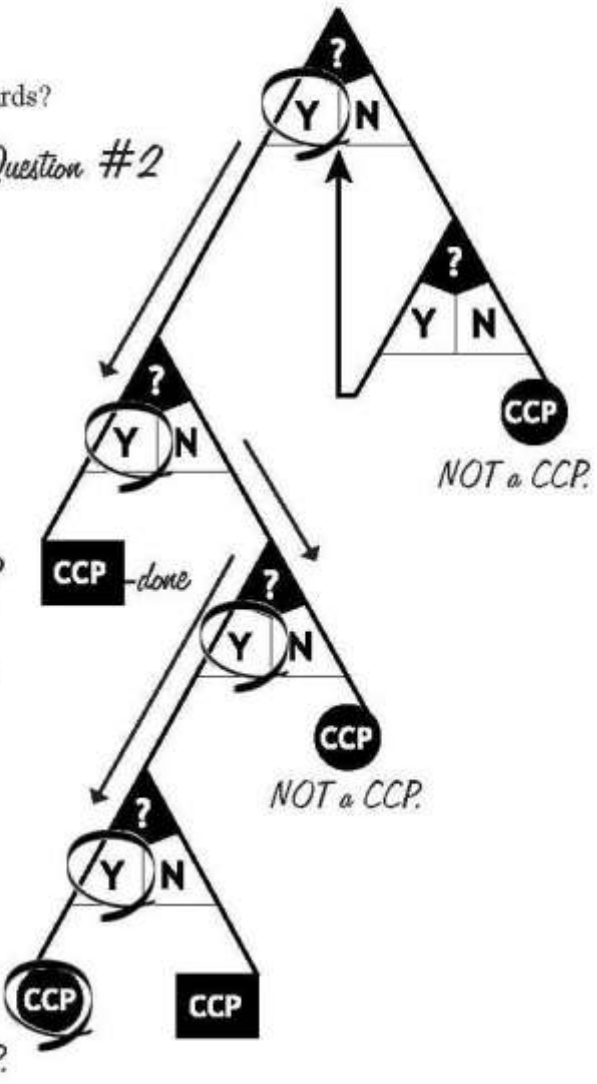
Question 1A
Do preventative measures exist for the identified hazards?
If no - go to Question 1B.
If yes - go to Question 2. *Yes, go to Question #2*

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

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

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

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



Results:

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

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

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

Principle 3: Establish Critical Limits for Each Critical Control Point

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

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

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

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

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

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

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

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

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

Here are some controls commonly used as preventative measures.

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

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

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

Working with the "Critical Limits" Form

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

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

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

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

Documenting the Source

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

supporting documents you also provide verification material when needed.

HACCP Principle 3
Critical Limits Form

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

Process Step/CCP: Cooking CCP#01B

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

Internal temperature: 165 degrees Fahrenheit for 15 seconds.

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

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

Meets regulatory requirements

Laboratory tests and results

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

Principle 4: Establish Monitoring Procedures

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

What are the 3 things monitoring can do for you?

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

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

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

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

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

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

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

Who's Responsible?

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

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

Monitoring will be most effective when:

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

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

Working with the "Monitoring Procedures" Form

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

For the Example Facility:

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

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

Remembering your Monitoring

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

HACCP Principle 4
Monitoring Procedures Form

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

Process Step/CCP: Cooking CCP #01B

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

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

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

Principle 5: Establish Corrective Actions

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

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

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

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

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

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

Some examples of corrective actions are:

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

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

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

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

Working with the "Corrective Action Procedures" Form

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

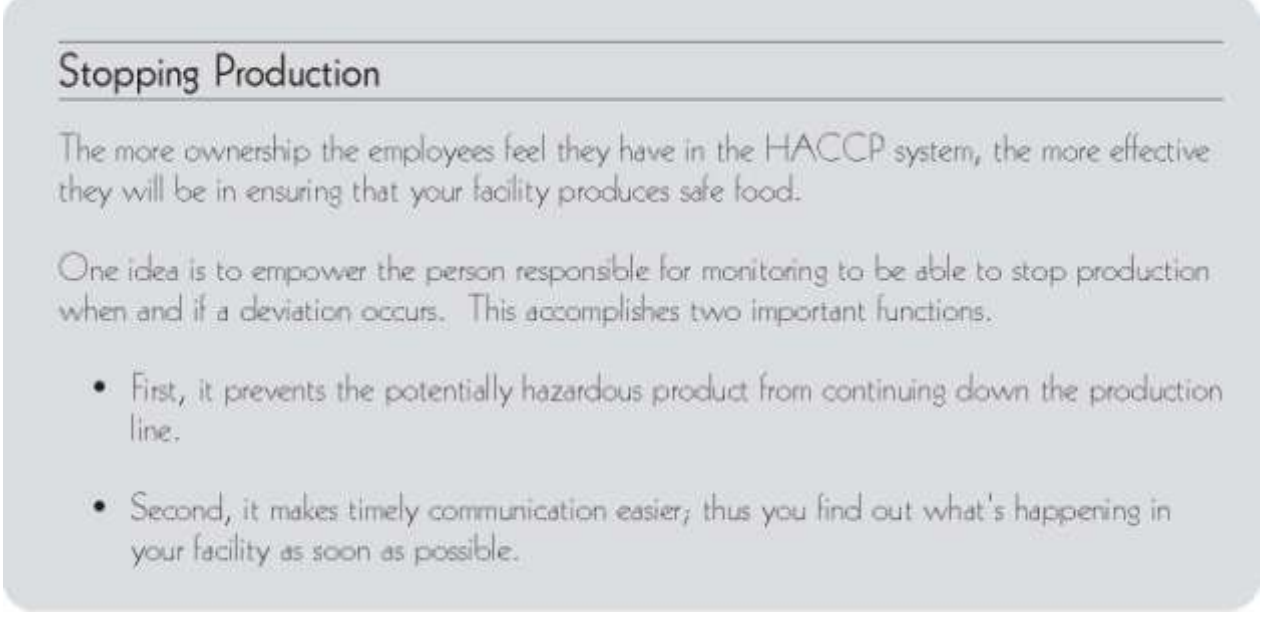
- **Under the "Problem" heading.**
  They state the critical limit that has been established for this CCP.

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

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

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

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



Stopping Production

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

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

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

HACCP Principle 5
Corrective Action Procedures Form

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

Process Step/CCP: Cooking CCP # 01B

Problem - (Critical limit exceeded)

Oven temp, below 190 degrees Fahrenheit

Disposition of product - (Hold, Rework, Condemn)

Hold, rework if possible.

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

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

3. Determine cause of deviation: broken oven thermostat.

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

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

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

Compliance procedures

Recalibrate/Replace oven thermostat.

Monitor CCP as usual during rework.

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

Principle 6: Establish Record Keeping Procedures

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

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

Well maintained records protect both your customers and YOU.

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

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

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

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

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

Tips on Designing Records

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

Working with the "Recordkeeping Procedures" Form

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

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

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

HACCP Principle 6
Recordkeeping Procedures Form

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

Process Step/CCP: Cooking CCP # 01B

Records

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

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

Principle 7: Establish Verification Procedures

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

Initial Validation

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

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

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

Ongoing Verification

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

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

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

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

Reassessment of the HACCP Plan

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

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

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

Working with the "Verification Procedures" Form

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

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

For the Example Facility:

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

Finishing Your HACCP Plan

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

The HACCP System

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

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

HACCP Principle 7
Verification Procedures Form

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

Process Step/CCP: Cooking CCP # 01B

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

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

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

Section 4: Food Code Requirements

Introduction

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

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

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

Contents of a HACCP Plan

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

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

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

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

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

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

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

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

Compliance with the HACCP Plan

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

A. Comply with a properly prepared HACCP plan, and

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

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

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

Variances and the HACCP Plan

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

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

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

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

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

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

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

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

Reduced Oxygen Packaging

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

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

Reduced Oxygen Packaging Criteria

The HACCP plan shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 5: Sample Forms

HACCP Team

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Team Members	Role

Developed by: _____ Date _____

Product/Process Covered

Store Name _____

Street Address _____

City _____State _____Zip Code _____

Product/Process Covered Under the HACCP Plan

Smoking/Curing

_____

_____

_____

_____

_____

Reduced Oxygen Packaging

_____

_____

_____

_____

_____

Food Additives

_____

_____

_____

_____

_____

Variances

_____

_____

_____

_____

_____

Developed by: _____ Date_____

Ingredients and Raw Materials

Store Name_____

Street Address _____

City_____State_____Zip Code _____

Product/Process Category _____

Product Examples _____

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

Developed by: _____ Date_____

Process Flow Diagram

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

Flow Diagram

Developed by: _____ Date_____

Verified by: _____ Date_____

Equipment List

Store Name _____

Street Address _____

City _____State _____Zip Code_____

Process

Developed by: _____ Date_____

Identifying Critical Control Points

Store Name_____

Street Address _____

City _____State _____Zip Code_____

Process/Step_____

Critical Control Point Decision Tree

Question 1A

Do preventative measures exist for the identified hazards?

If "no" - go to Question 1B.

If "yes" - go to Question 2.

Question 1B

Is control at this step necessary for safety?

If "no" - not a CCP

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

Question 2

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

If "no" - go to Question 3.

If "yes" - CCP.

Question 3

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

If "no" - not a CCP.

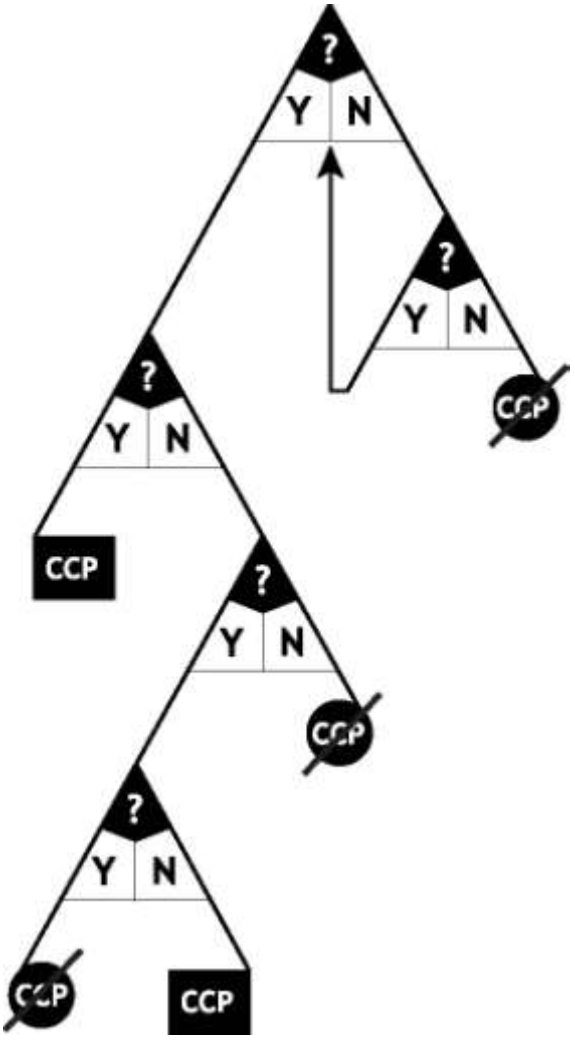
If "yes" - go to Question 4.

Question 4

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

If "no" - CCP.

If "yes" - not a CCP.



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

Developed by: _____ Date_____

Critical Limits

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

Process Step/CCP _____

CRITICAL LIMITS

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

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

Developed by: _____ Date_____

Monitoring Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

Process Step/CCP _____

MONITORING PROCEDURES

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

Developed by: _____ Date_____

Corrective Action Procedures

Store Name_____

Street Address_____

City _____State _____Zip Code_____

Product/Process Name_____

Process Step/CCP_____

Problem (critical limit exceeded*)* -_____

_____

_____

_____

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

_____

_____

_____

Corrective Action Procedure/Steps - _____

_____

_____

_____

Who is responsible for performing these corrective actions? - _____

_____

_____

_____

Compliance Procedures - _____

_____

_____

_____

Developed by: _____ Date_____

Recordkeeping Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

RECORDS

Name and Location

Developed by: _____ Date_____

Verification Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

VERIFICATION PROCEDURES

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

Developed by: _____ Date_____

Hazard Analysis Form

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name: _____

Process Step from Flow Diagram: _____

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

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

_____

_____

_____

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

Hazard Analysis Worksheet

Store Name_____

Street Address _____

City _____State _____Zip Code_____

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

Developed by: _____ Date_____

HACCP Plan

Store Name_____

Street Address_____

City _____State _____Zip Code _____

Product/Process _____Date _____

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

HACCP Plan

Store Name_____ Store Address_____

Product/Process_____ Developed by_____ Date_____

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

Appendix: Common Foodborne Bacterial Pathogens Sample HACCP Plans

Common Foodborne Bacterial Pathogens

Bacillus cereus

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

RESERVOIR: WIDELY DISTRIBUTED IN THE ENVIRONMENT.

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

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

GROWTH REQUIREMENTS

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

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

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

Campylobacter

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

RESERVOIR: CHICKENS, COWS, FLIES, CATS, PUPPIES

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

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

GROWTH REQUIREMENTS

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

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

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

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

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

Clostridium botulinum

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

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

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

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

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

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

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

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

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

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

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

CONTROLS: DESTRUCTION: THERMAL PROCESSING

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

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

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

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

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

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

Clostridium perfringens

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

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

IMPLICATED FOODS: MEAT, POULTRY, GRAVY, CASSEROLES

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

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

GROWTH REQUIREMENTS

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

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

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

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

Escherichia coli

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

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

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

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

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

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

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

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

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

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

Listeria

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

RESERVOIR: SOIL, SILAGE, OTHER ENVIRONMENTAL SOURCES.

IMPLICATED FOODS: DAIRY PRODUCTS, VEGETABLES, MEAT,

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

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

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

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

GROWTH REQUIREMENTS

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

CONTROLS: COOKING, PASTEURIZATION, PREVENTION OF RECONTAMINATION

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

Salmonella

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

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

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

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

IMPLICATED FOODS: RAW MEAT, POULTRY, SEAFOOD, EGGS, DAIRY PRODUCT, YEAST, SAUCES, SALAD DRESSINGS, CAKE MIXES, CREAM FILLED DESSERTS, CONFECTIONERY, ETC.

Salmonella often live in animals - especially poultry and swine - as well as in a number of environmental sources. The organisms have been found in water, soil and insects, on factory and kitchen surfaces, and in animal feces. They can also survive in a variety of foods, including raw meats and poultry, dairy products and eggs, fish, shrimp and frog legs, yeast, coconut, sauces and salad dressing, cake mixes, cream-filled desserts and toppings, dried gelatin, peanut butter, orange juice, cocoa and chocolate.

GROWTH REQUIREMENTS

TEMPERATURE (F)	41 - 115
MINIMUMWATERACTIVITY	0.94
PH	3.7 - 9.5
MAXIMUM SALT (%)	8

ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . SENSITIVE TO MODERATE HEAT

Salmonella spp. are also mesophilic organisms which grow best at moderate temperatures and pH, and under conditions of low salt and of high water activity. They are killed rapidly by moderate heat treatment, yet mild heat treatment may give them the ability to develop heat resistance up to 185°F. Similarly, the organisms can adapt to an acidic environment.

CONTROLS: SANITATION TO PREVENT RECONTAMINATION, COOKING, PASTEURIZATION, PROPER HOLDING TEMPERATURES.

Ordinary household cooking, personal hygiene to prevent recontamination of cooked food, and control of time and temperature are generally adequate to prevent salmonellosis.

Shigela

There are actually four species of Shigella. Because there is little difference in their behavior, however, they will be discussed collectively.

Illness is Shigellosis, typical symptoms include fever, cramps, inflammation and ulceration of intestine, and diarrhea. This disease is easily transmitted from person to person.

RESERVOIR: HUMAN, ANIMAL

IMPLICATED FOODS: SALADS, RAW VEGETABLES, POULTRY, MEAT, FISH, FRUIT, DAIRY PRODUCTS, BAKERY PRODUCTS.

The only significant reservoir for Shigella is humans. Foods associated with shigellosis include salads (potato, tuna, shrimp, macaroni and chicken), raw vegetables, milk and dairy products, poultry, fruits, bakery products, hamburger and fin fish.

GROWTH REQUIREMENTS

TEMPERATURE (F) . . . . . 43 - 117
MINIMUM WATER ACTIVITY 0.96
PH . . . . . 4.8 - 9.3
MAXIMUM SALT (%) 5
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . SURVIVES ACIDIC CONDITIONS

The growth conditions for *Shigella*, which are mesophilic organisms, are similar to those of *Salmonella*. *Shigella* can survive under various environmental conditions, including low acid.

CONTROLS: COOKING, PROPER HOLDING TEMPERATURES, SANITATION TO PREVENT RECONTAMINATION, ADEQUATE WATER TREATMENT.

Shigella can spread rapidly under the crowded and unsanitary conditions often found in such places as summer camps, refugee camps and camps for migrant workers, and at mass gatherings such as music festivals.

The primary reasons for the spread of Shigella in foods are poor personal hygiene on the part of food handlers, and the use of improper holding temperatures for contaminated foods; conversely, the best preventive measures would be good personal hygiene and health education. Chlorination of water and sanitary disposal of sewage would prevent waterborne outbreaks of shigellosis.

Staphylococcus aureus

Staphylococcus aureus produces a highly heat-stable toxin. Staphylococcal food poisoning is one of the most economically important foodborne diseases in the U.S., costing approximately $1.5 billion each year in medical expenses and loss of productivity. The most common symptoms are nausea, vomiting, abdominal cramps, diarrhea and prostration.

RESERVOIR: HUMANS, ANIMALS, AIR, DUST, SEWAGE, WATER

IMPLICATED FOODS: POULTRY, MEAT, SALADS, BAKERY PRODUCTS, SANDWICHES, DAIRY PRODUCTS.

Staph can be found in air, dust, sewage and water, although humans and animals are the primary reservoirs. *Staph* is present in and on the nasal passages, throats, hair and skin of at least one out of two healthy individuals. Food handlers are the main source of contamination, but food equipment and the environment itself can also be sources of the organism.

Foods associated with *Staph* include poultry, meat, salads, bakery products, sandwiches and dairy products.

Due to poor hygiene and temperature abuse, a number of outbreaks have been associated with cream-filled pastries and salads such as egg, chicken, tuna, potato, and macaroni.

GROWTH REQUIREMENTS
TEMPERATURE (F) GROWTH. . . . . 45 - 122
TOXIN PRODUCTION . . . . . 50 - 118
MINIMUM WATER ACTIVITY GROWTH 0.83
TOXIN PRODUCTION 0.85
PH . . . . . 4.0 - 10.0
MAXIMUM SALT (%) GROWTH 25
TOXIN PRODUCTION 10
ATMOSPHERE . . . . . FACULATIVE ANAEROBIC
SURVIVAL CONDITIONS . . . . TOLERANT OF HIGH SALT AND LOW MOISTURE

S. aureus grows and produces toxin at the lowest water activity (0.85) of any food pathogen. And, like type *A bot* and *Listeria*, *Staph* is quite salt-tolerant and will produce toxin at 10%.

CONTROLS: HEATING, PROPER EMPLOYEE HYGIENE, PREVENTION OF TEMPERATURE ABUSE

Foods which require considerable handling during preparation and which are kept at slightly elevated temperatures after preparation are frequently involved in staphylococcal food poisoning. And, while *S. aureus* does not compete well with the bacteria normally found in raw foods, it will grow both in cooked products and in salted products where the salt inhibits spoilage bacteria. Since Staph is a faculative anaerobe, reduced oxygen packaging can also give it a competitive advantage. The best way to control Staph is to ensure proper employee hygiene and to minimize exposure to uncontrolled temperatures. Remember that while the organism can be killed by heat, the toxin cannot be destroyed even by heating.

Vibrios

There are quite a few species of Vibrios, but only four will be covered.

Vibrio parahaemolyticus - The bacteria is naturally occurring in estuaries and other coastal waters. Illness is most commonly associated with fish and shellfish which are raw, undercooked or recontaminated after cooking.

Vibrio cholerae 01 - Epidemic cholera - Poor sanitation and contaminated water supplies will spread the disease; feces contaminated foods including seafood have also been associated with outbreaks.

Vibrio cholerae non-01 -The reservoir for this organism is estuarine water - illness is associated with raw oysters, but the bacteria has also been found in crabs.

Vibrio vulnificus - This organism also occurs naturally in estuarine waters. So far only oysters from the Gulf of Mexico have been implicated in illness, but the organism itself has been found in both the Atlantic and Pacific Oceans.

GROWTH REQUIREMENTS
TEMPERATURE (F) . . . . . 41 – 111
MINIMUM WATER ACTIVITY . . . . . 0.94 - 0.97
PH . . . . . 4.8 - 11.0
MAXIMUMSALT (%) . . . . . 5 – 10
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . SALT TOLERANT; HEAT SENSITIVE

Vibrios are mesophilic and require relatively warm temperatures, high water activity and come neutral pH for growth, they also require some salt for growth, and are quite salt-tolerant. They are, however, easily eliminated by a mild heat treatment.

CONTROLS: COOKING, PREVENTION OF RECONTAMINATION, TIME/TEMPERATURE ABUSE, CONTROL PRODUCT SOURCE.

All the Vibrios can be controlled through cooking and the prevention of cross-contamination afterward. Proper refrigeration prevents proliferation, which is particularly important because of the short generation times for these species. To guard against cholerae, processors should know the source of the product and be cautious about importing from countries experiencing an epidemic.

Yersinia

Yersinia ssp: *Y. entercolitica*; Y. *pseudotuberculosis*; *Y. pestis* Of the 11 recognized species of *Yersinia*, three are known to be potentially pathogenic to humans:

enterocolitica, pseudotuberculosis and pestis. Only enterocolitica and pseudotuberculosis are recognized as foodborne pathogens. *Y. pestis*, the organism responsible for the black plague, is not transmitted by food.

Yersiniosos is often characterized by such symptoms as gastroenteritis with diarrhea and/or vomiting, but fever and abdominal pain are the hallmark symptoms. Yersinia infections mimic appendicitis, which has led to unnecessary operations.

RESERVOIR: LAKES, STREAMS, VEGETATION, SOIL, BIRDS, ANIMALS AND THEIR FECES

IMPLICATED FOODS: RAW VEGETABLES, MILK, ICE CREAM, CAKE, PORK, SOY, SALAD, SEAFOOD, CLAMS, SHRIMP

Yersinia can be found in raw vegetables, milk, ice cream, cakes, pork, soy products, salads, oysters, clams and shrimp. They are found in the environment, in such places as lakes, streams, soil and vegetation. They've been isolated from the feces of dogs, cats, goats, cattle, chincillas, mink, and primates; in the estuarine environment, many birds - among them, waterfowl and seagulls - may be carriers. The foodborne nature of Yersiniosis is well established, and numerous outbreaks have occurred worldwide.

GROWTH REQUIREMENTS

TEMPERATURE (F) . . . . . 30 - 108
MINIMUMWATERACTIVITY 0.95
PH . . . . . 4.2 - 10.0
MAXIMUM SALT (%) 7
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . WITHSTANDS FREEZING AND THAWING; SENSITIVE TO HEATING AND SANITIZERS

CONTROLS: SANITATION TO PREVENT RECONTAMINATION; COOKING; PASTEURIZATION; WATER TREATMENT; PROPER HOLDING TEMPERATURES

Key factors for controlling Yersinia include proper cooking or pasteurization, proper food handling to prevent recontamination, adequate water treatment, and care taken to ensure that products are not time or temperature abused. Proper use of sanitizers is also an effective control. Essentially, to control Yersinia, it is necessary to keep things clean and moving.

Sample Plans

The following represents a sample Food Safety Plan for a fictitious company. Recognizing that the HACCP plan is only part of the food safety plan, additional supporting information is included on GMP's and SOP'S.

The plan is composed of the following sections:

- ***Plan for Smokehouse operations including:***
  - Equipment list
  - Formulation/Recipe
  - Flow Diagram
  - Standard Operating Procedures including Critical Control Points, Critical Limits, Monitoring, and Corrective Actions

- ***Plan for Reduced Oxygen Packaging Operations including:***
  - Equipment List
  - Flow Diagram
  - Standard Operating Procedures including Critical Control Points, Critical Limits, Monitoring, and Corrective Actions

Plan for ....

Also included is General information that might apply for all HACCP plans which includes:

- Training Program
- Standard Operating Procedures for Person in Charge
- Labeling
- Cleaning and Sanitizing Procedures
- Good Manufacturing Practices - Employee Practices

SAMPLE

Retail Food Establishment
Food Safety Plan

Including:

HACCP PLAN

For: Smokehouse Operations

Reduced Oxygen Packaging

GMP's/SOP's

Employee Practices

Cleaning and Sanitizing Procedures

Verifications Procedures by *Person in Charge*

Labeling Requirements

Training Program

J's Market
505 Saratoga St.
Anytown, MN

JANUARY 13, 2000

Smokehouse Operations Equipment List

Walk-in Cooler – brand _____ size _____

Other products/operations supported _____
Grinder
Mixer
Stuffer

Smokehouse - brand _____
Smoke generator/liquid smoke

Digital Thermometer
Assorted measuring containers, hand utensils, lugs, totes, etc.

Smokehouse Operations Formulation/Recipe

RING BOLOGNA

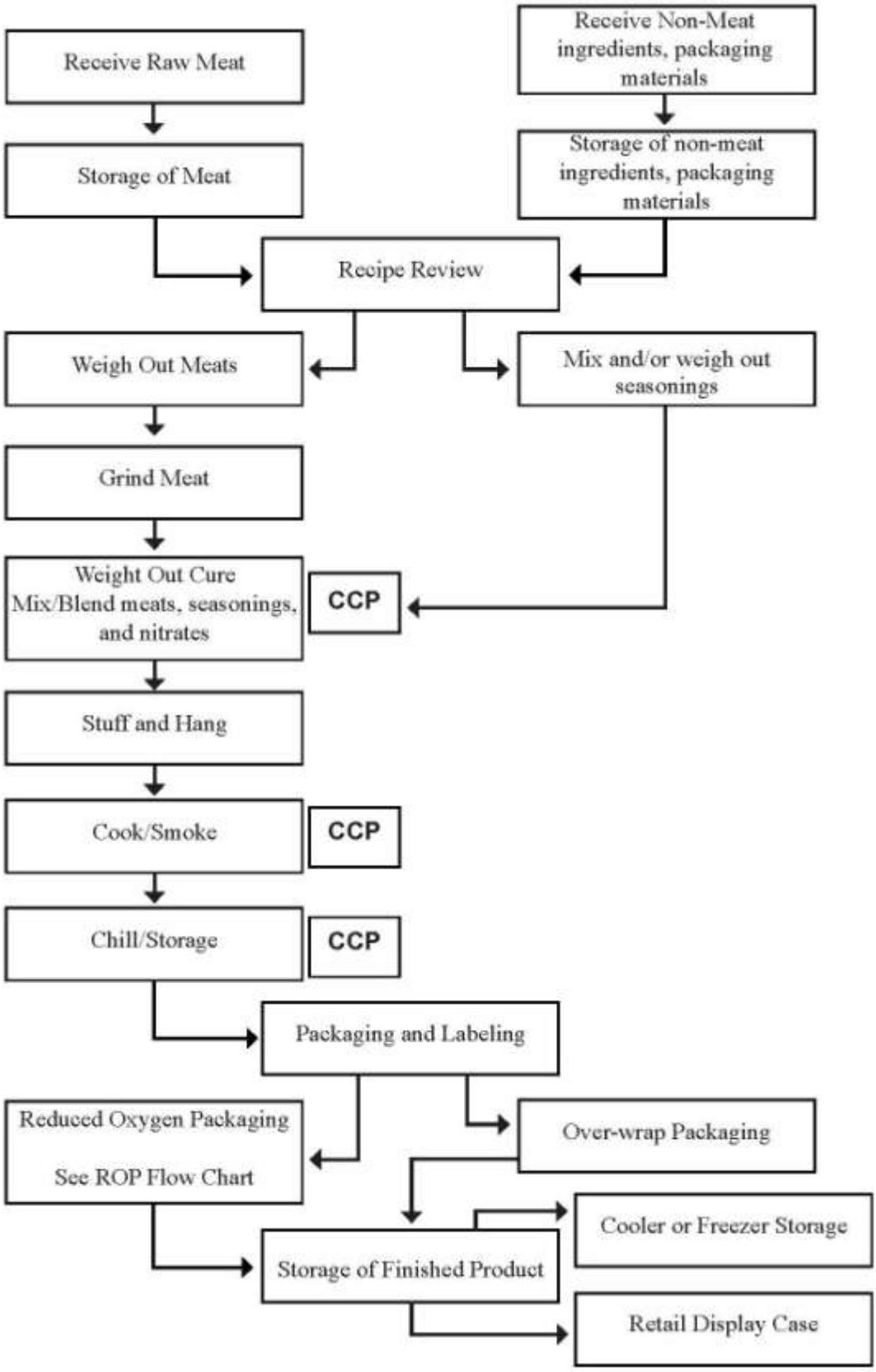
Full batch
- 50 pounds pork trim
- 50 pounds beef trim 6.5 (1 full packet) pounds of XYZ brand Bologna Seasoning
- 4 oz (1 full packet) of Quick Cure 10 pounds water

- Casings - Natural beef casing

Also include procedures for producing the product that show who food safety concerns are controlled.

Recipes to be included for every product

Smokehouse Operations Flow Diagram


Receive Raw Meat
Receive Non-Meat ingredients, packaging materials
Storage of Meat
Storage of non-meat ingredients, packaging materials
Recipe Review
Weigh Out Meats
Mix and/or weigh out seasonings
Grind Meat
Weight Out Cure Mix/Blend meats, seasonings, and nitrates
CCP
Stuff and Hang
Cook/Smoke
CCP
Chill/Storage
CCP
Packaging and Labeling
Reduced Oxygen Packaging
See ROP Flow Chart
Over-wrap Packaging
Cooler or Freezer Storage
Storage of Finished Product
Retail Display Case

Smokehouse Operations Standard Operating Procedures

CURED-SMOKED/COOKED SAUSAGE

1. Receiving/Storage of meat products, seasonings, fillers, cure agents, packaging materials, sawdust. Check the temperature of meat products on receipt. These products must be received at 41°F or less- products at higher temperatures should be rejected. Perishable products must be stored in refrigeration at 41°F or less or frozen at 0°F or less - Ensure that all products are stored under sanitary conditions to prevent contamination.

2. Ensure that facilities are clean and sanitary and in good condition and that equipment is clean and sanitary and is working properly and safely. Ensure that sawdust is in the smoke generator and install a temperature recording chart on the smokehouse.

3. Ensure that food handlers are in compliance with Employee Practices requirements in the Good Manufacturing Practices.

4. Review the recipe to confirm that all required ingredients, are on hand and assemble spices, fillers, cure agents, casings, packaging materials, etc in the work area.

5. Establish the size of the batch to be made. Almost all pre-mix units come packaged for 100 pounds of meat.

Example:

100.00	Lbs.	Meat	
6.50	Lbs.	Seasoning and filler (one bag)	
.25	Lb.	Cure (separate packet)	RESTRICTED INGREDIENT
10.00	Lbs.	Water	
116.75	Lbs.	Gross weight	

If less than a full batch is to be made, calculations must be made to reduce all ingredients by the same amount.

Examples of reduced batches are:

1/2 batch

50.00	Lbs.	Meat	
3.25	Lbs.	Seasoning and filler	
.125	Lb.	Cure	RESTRICTED INGREDIENT
5.00	Lbs.	Water	
58.375	Lbs.	Gross weight	

1/4 batch

25.00	Lbs.	Meat	
1.625	Lbs.	Seasoning and filler	
.0625	Lb.	Cure	RESTRICTED INGREDIENT
2.5	Lbs.	Water	

29.1875 Lbs. Gross weight

Weigh out meat, seasonings and fillers, and water. Do not necessarily assume that containers/pails/lugs/scoops of ingredients always weigh the same. Record entries for these ingredients on the batch record.

6. Grind the meat.

7. ***Critical Control Point* -** Weigh out cure and premix with at least 1 pint of water to provide better distribution with the other ingredients. Pre-mix seasonings with part of the remaining water. In the automatic mixer, mix meat with seasoning/water blend, fillers, remaining water, and cure /water blend.

   ***Critical Limit* -** For full batches (100 pounds), net weight of cure is .25 lbs; for 1/2 batch/50 pounds net weight of cure is .125 pounds; for 1/4 batch (25 pounds) net weight of cure is .0625 pounds. Because of the small amounts of cure required batches, weighing of cure ingredients must be done on a certified digital scale. Thoroughly mix ingredients, especially the cure mixture to ensure even distribution throughout the batch.

   Monitoring - Observe the mixing process to ensure complete distribution. Complete entries on the batch record. Attach seasoning and cure bag to batch record.

   Corrective Action - If errors are noticed before any further steps are completed, take the following steps:
   - If insufficient cure has been added, additional amounts up to the amount required in the recipe can be added and the batch re-mixed
   - If too much cure was added, additional meat and seasonings can be added to extend the batch and remixed. If errors are noted after the cook step, nothing can be done to save the batch and the entire batch must be discarded.

8. Stuff the mixed product into the appropriate size and type of casing for the product being made. Use only clean, fresh casings that have been stored properly to prevent contamination. Hang to product onto rods and into smokehouse. Insert temperature probe into product into sausage.

9. ***Critical Control Point* -** Smoke and Cook. Set smokehouse computer to the appropriate cycle for the product being produced. The smokehouse will automatically shut down when the programmed temperature is reached.

   Critical Limit - Minimum internal temperature of product are: Beef and Pork - 155°F for 15 seconds Poultry - 165°F for 15 seconds.

   Monitoring - Inspect temperature chart to ensure that the highest attained temperature has been met. Record the highest attained temperature on the Batch Record.

   Corrective Action - If minimum temperature has not been met, reset the smokehouse and re-cook until the minimum time and temperature have been met.

10. ***Critical Control Point* -** Cooling. The product must be rapidly cooled. This may be part of the smokehouse cycle if the unit has an internal shower. Showering with water will assist in bringing the temperature down. Next, the product must be removed from the smokehouse and placed in the cooler (which is at 41°F or less). This should happen immediately after the smokehouse cycle is completed as it is important that the cooling process begins right away.

When cooked product is placed into the cooler, ensure that it is placed so that it is protected from cross contamination by raw meat.

Critical Limit - Products must be cooled from 140°F to 70°F within 2 hours and from 70° to 41°F within another 4 hours.

Monitoring - Check internal temperature at 1 hour and 45 minutes, at 2 hours, and again at 6 hours. Record internal temperature on batch record.

Corrective Action - If the temperature taken at 1 hour 45 minutes is at 75° For greater, notify the Person in Charge and take immediate action to reduce the temperature. This can be accomplished by showering with cold water or if a greater temperature reduction is necessary, product could go into a water bath. If product does not meet the critical limits at 2 and 6 hours, it must be discarded.

1. **Packaging/Labeling** - if product is packaged by a Reduced Oxygen packaging method, refer to Standard Operating Procedures for ROP. If product is packaged by over-wrapping, ensure that packaging materials (trays, wrap) are in a sanitary condition and do not subject the food to cross contamination. Food employees must limit direct hand contact with exposed ready to eat food. Products be labeled with mandatory labeling requirements.
2. **Storage/Display** - Place packaged food into refrigerated storage, either retail display cases or cooler storage at 41°F or less.

Smokehouse Operations

J's Market
505 Saratoga St. W
Anytown MN 55555

Batch Record

Required to be completed for each product made as official record of monitoring critical control points.

PRODUCT _____ PRODUCTION DATE _____ CODE/LOT ID _____

FORMULATION:

Beef: _____ LBS Water: _____ LBS
Pork: _____ LBS Other: _____
Turkey: _____ LBS _____
Veal: _____ LBS _____

Seasonings: *Contents and Weight* _____

_____

_____

CURING AGENT: Critical Control Point

Type _____ Weight _____ Signature _____
How incorporated (mix, injected, soak, etc.) _____
Cure Lot Number _____
Other Processing _____

_____

_____

SMOKE/COOK: Critical Control Point

Temperature Checks: _____
FINAL INTERNAL TEMPERATURE* _____ *°F *Minimum cook temperature of 155°F (165°F for poultry)*
Signature _____

COOLING: Critical Control Point

Temperature Checks _____
Temp at 2 Hours* _____ **Must be 70°F or less*
Signature _____
Temp at 6 Hours* _____ *Must be 41°F or less
Signature _____

All CCP's Met? ❑ Yes ❑ No

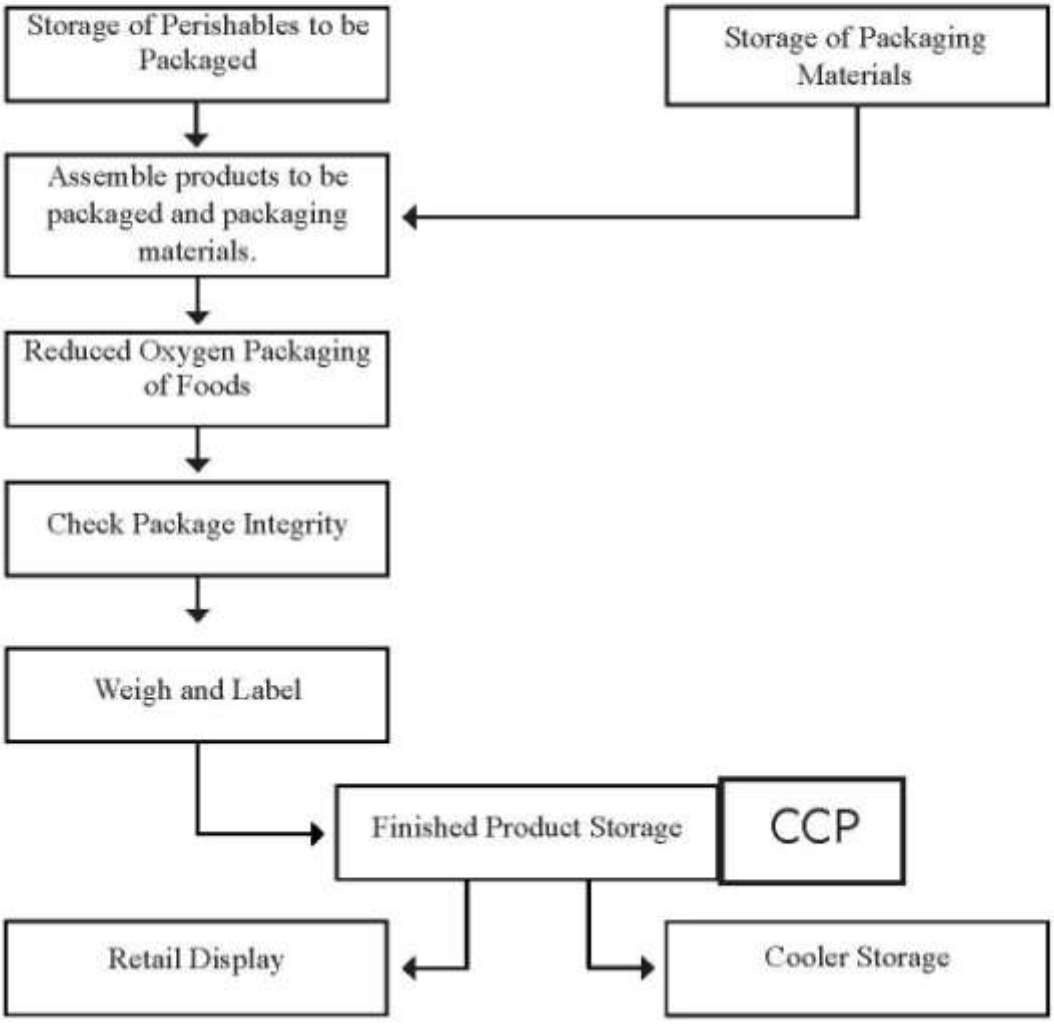
Signature _____

Reduced Oxygen Packaging

Equipment List

- Slicer - brand _____
- Vacuum Packaging Machine - _____
- Digital Thermometer
- Assorted knives, tongs, trays, lugs/totes, hand utensils

Flow Diagram



Reduced Oxygen Packaging Standard Operating Procedures

Only food handlers that are trained in the use of the reduced oxygen packaging equipment and process of reduced oxygen packaging and have a thorough understanding of the HACCP plan shall operate or conduct ROP operations.

1. Ensure that facilities in the area where ROP operations are to be conducted are clean and sanitary and are in good physical condition. ROP operations must only be conducted in the designated area in the meat department. No packaging of ready to eat foods can be conducted while raw foods are present or are being processed in the same room. Only properly cleaned and sanitized equipment is to be used in the operation.

2. Ensure that all equipment is operating properly and safely. Ensure that equipment involved in the ROP process has been properly cleaned and sanitized according to regulation and store policy. This equipment includes (but not limited to): tables, cutting boards, slicer, knives, tongs, trays,

3. Ensure that food handlers are in compliance with Employee Practices requirements in the Good Manufacturing Practices. This includes employee hygiene, handwashing, clean clothing, etc.

4. Assemble packaging materials, labels, etc. necessary to the operation.

5. Assemble products that are to be packaged.
   - Products to be ROP shall remain at room temperature no longer than 30 minutes during the packaging process, therefore, only remove sufficient quantities so that this is managed.
   - Products that can be ROP are limited to list provided.

6. Place foods in the packaging materials. Food Employees must limit direct hand contact with exposed, ready-to-eat food when deli tissues, spatulas, tongs, dispensing equipment, or other utensils can be used.

7. Place bags in vacuum machine ensuring that adequate space is provided around each package. Ensure that machine settings are appropriate for product being packaged. It is important that a full vacuum is provided or if using gas displacement, that the equipment is working properly. Start the machine and wait for the lid to open indicating that the process is complete

8. Remove packages from the machine. Visually check the seal to ensure that it is tight and that there are no food materials in the seal. Make a note of any indicators of a faulty seal such as wrinkles or an incomplete seal. Packages with a faulty seal should be re-packaged. Trim excess packaging as required.

9. Weigh and label each package. Ensure that all required information is provided on the label. Ensure that the shelf life is no longer than 14 days.

10. ***Critical Control Point *** Place packaged food into refrigerated storage, either retail display cases or cooler storage.

    Critical Limit -Temperature in storage must be 41°F or less. Products will be considered to be temperature abused if they are exposed to temperatures above 41°F for more than 4 hours.

    Monitoring - The designated employees of the meat department will check and record the actual temperature in both the walk-in cooler and retail case that contains in-store packaged products at intervals not to exceed 4 hours. If temperatures are out of range, notify the Person in Charge and move products to other approved

storage location that does meet temperature requirements. Record temperature on cold storage log.

Corrective Action -Discard temperature abused products. Make necessary adjustments or repairs to cooler or case prior to restocking. Document any corrective actions on the log.

11. Visually check ROP products on a daily basis in the retail case or as products in reserve storage are brought out to the retail case and check the package integrity (faulty seals, 'puffy' packages, holes, tears, or packages that may have otherwise lost their 'vacuum') and contents of the package (slime, mold, discoloration). Packages that do not meet the requirements should be destroyed. Also check for products that have passed their 'use by' date.

Cold Storage Log

Store Name _____

Store Address _____

Month/Year _____ Cooler/Location _____

DATE	TIME	TEMP.	S	TIME	TIME	S	DATE	TIME	TEMP.	S TEMP. TEMP.	S
1							17				
2							18				
3							19				
4							20				
5							21				
6							22				
7							23				
8							24				
9							25				
10							26				
11							27				
12							28				
13							29				
14							30				
15							31				
16											

S= signature of person taking/recording temperature

If air temp is more than 45°, check product temperature;
If product temp is more than 41° but less than ___°, move product to another cooler, cool to 41 ° within 4 hours and make necessary repairs to case;
If product temperature is higher than ___°, discard product and make necessary repairs to the case
Any record noted above 41°F, must have explanation/corrective action noted below:

For example:
5/4 – temp at 45° – case on defrost – product temp - 39° - OK or
5/5 – temp at 50° – product temp 50° – 100 pounds of sausage product destroyed

Records Reviewed by: _____ Date: _____
Comments:

Labeling

Mandatory Labeling Information

1. Name of Product
2. Name, address including zip code of store
3. Net weight statement
4. Complete and detailed ingredients statement
5. On fresh/raw meat products, the Safe Handling Statement must be included
6. Nutrition facts may be required, contact the Minnesota Department of Agriculture

In addition, Reduced Oxygen packaged food labels must also include:

1. The Statement: **Keep Refrigerated or Frozen**
2. Instructions to discard the food if within 14 days of its packaging if it is not consumed
3. The shelf life must not be longer than 14 days from packaging to consumption or the original manufacturers "sell by"' or "use by" date, whichever occurs first.

Shelf life for various products will be as follows:

All in-store smokehouse products	XX days
Sliced cold cuts (ham, smoked turkey, salami, etc.)	XX days
Cheese (block or sliced)	XX days
Raw meats or poultry	XX days

Sample Label

Training Program - For Food Handlers Conducting Reduced Oxygen Packaging

Understanding the potential hazards associated with reduced oxygen packaging

While the process of packaging foods using a reduced oxygen method extends the shelf life, it also can pose a serious public health threat.

Generally, bacteria survive under conditions where there is oxygen is present - aerobic conditions - or where oxygen is not present anaerobic conditions. Some bacteria have the ability to adapt to either condition. Under traditional packaging conditions (aerobic conditions), spoilage bacteria would normally thrive and the product would spoil before the more hazardous types of bacteria might become a problem. During the process of 'vacuum packaging' or 'reduced oxygen packaging', the air inside the package (which is approximately 21 % oxygen) is eliminated, creating anaerobic conditions and thereby changing the types of bacteria that can survive in the package. Spoilage organisms are eliminated, but several types of pathogenic bacteria survive and actually thrive under these conditions. The pathogen of greatest concern is Clostridium botulinum. While botulism bacteria will normally be killed in a cooking step, spores of the bacteria may survive and could grow and produce toxin if the conditions are right. These conditions are similar to those that occur in a vacuum/reduced oxygen package. Other pathogens of concern may be Listeria monocytogenes, Yersinia enterocolitica, Campylobacter jejuni, and Clostridium perfringens.

Concepts Required for a Safe Operation

A thorough understanding of the of the HACCP plan, the use of the reduced oxygen packaging equipment, and the standard operating procedures are critical to a safe operation. Areas to focus on include: products that can be packaged, temperature control, prevention of cross contamination, and health and personal hygiene of food handlers.

Products that can be packaged by ROP

State regulations limit the types of foods that can be packaged. This store's HACCP plan defines the foods that can be packaged using reduced oxygen packaging. **Only specific products on this list can be reduced oxygen packaged**. Any addition to the above list must first have the approval of the PERSON IN CHARGE. Changes must be noted in the HACCP PLAN. Foods to be reduced oxygen packaged at the retail level must be limited to one that does not support the growth of Clostridium botulinum because of one of the following requirements:

1. has a water activity of 0.91 or less
2. has a pH of 4.6 or less
3. is a food with a high level of competing organisms, including raw meat, raw poultry, or a naturally cultured standardized cheese
4. is a meat or poultry product that was cured at a USDA meat plant and received in an intact package or cured using approved substances (nitrates/nitrites).

By limiting the types of food that can be ROP to those on the list, an additional barrier to the growth of Clostridium botulinum is provided and thereby helps to ensure a safe product.

In addition, except for fish that is frozen before, during, and after packaging, a food establishment shall not package fish using a reduced oxygen packaging method.

Following are examples of foods that do not meet the above requirements and therefore may NOT be reduced oxygen packaged: Cooked turkey (including whole or sliced turkey breast), cooked roast beef, sandwich spread (including ham salad, chicken salad, etc.), cooked fresh sausage (not cured/smoked such as bratwurst), fresh salads.

Temperature Control

Temperature control is a very important factor in keeping all potentially hazardous foods safe. But the extended shelf life and decreased oxygen concentration allows certain pathogens to multiply in reduced oxygen conditions. To reduce the potential for growth of these pathogens, products (packaged and unpackaged) must be stored at cooler temperatures of 41^{o} F or less. Employees must monitor the cooler temperatures at least every 4 hours to ensure that foods are not allowed to be out of the temperature requirements for extended periods of time.

Preventing Cross Contamination

Raw foods should be handled separately from cooked and ready to eat foods to avoid cross contamination. Utensils, equipment and work surfaces used for raw foods should be thoroughly cleaned and sanitized prior to using for cooked or ready-to-eat foods. In addition, ensure that ready-to-eat foods are stored so that blood or juices from raw products cannot drip or otherwise come into contact with them. Food handlers can also be a source of cross contamination through improper handwashing, or soiled clothing or aprons.

Employee Health and Hygiene

The health and personal hygiene of food handlers can also play a critical role in producing a safe ROP food. It is vital that employees working in this operation follow the Employee Practices guidelines in the Good Manufacturing Practices. (See Page xx). Particular attention should be paid to #1 - Handwashing procedures, #6 Clean Outer

Garments, and #1 0 - Food handling.

Cleaning and Sanitizing Procedures - Equipment Food Contact Surfaces

Properly cleaned and sanitized food contact surfaces are critical to ensuring a safe, sanitary operation. Use of approved cleaners and sanitizers will reduce levels of pathogenic organisms to prevent cross contamination of the product. Detergent cleaners suspend and help remove various food soils. Chemical sanitizers (chlorine, iodine, acid, or quaternary ammonia types) reduce the numbers of pathogens and other microorganism to insignificant levels.

The clean up process must be completed in accordance with the following procedures.

- **Pre-cleaning** - Equipment and utensils shall be pre-flushed, pre-soaked, or scraped as necessary to eliminate excessive food debris.

- **Washing** - Equipment and utensils shall be effectively washed to remove or completely loosen soils using manual or mechanical means. Only approved chemicals are to be used in this process. Approved chemicals for WASHING are: _____

- **Rinsing** - Washed utensils and equipment shall be rinsed to remove abrasives and to remove or dilute cleaning chemicals with water.

- **Sanitizing** - After being washed and rinsed, equipment and utensils must be sanitized with an approved chemical by immersion, manual swabbing, brushing, or pressure spraying methods. Exposure time is important to ensure effectiveness of the chemical. Approved chemicals and exposure times for SANITIZING are:
  _____
  _____

Ensure that an appropriate chemical test kit is available and routinely used to ensure that accurate concentrations of the sanitizing solutions are being used.

Frequency of Cleaning

Equipment, food contact surfaces and utensils shall be cleaned in a time frame as follows:

1. Before each use with a different type of raw animal food, including beef, fish, lamb, pork, or poultry;
2. Each time there is a change from working with raw foods to working with ready to eat foods;
3. Between uses with raw fruits or vegetables and with potentially hazardous foods;
4. At any time during the operation when contamination may have occurred.
5. If used with potentially hazardous foods, throughout the day at least once every four hours
6. Utensils and equipment that are used to prepare food in a refrigerated room that maintains the utensils, equipment, and food under preparation at 41°F or less and are cleaned at least once every 24 hours
7. Before using or storing a food thermometer.
8. For equipment used for storage of packaged or un-packaged food, including coolers, and the equipment is cleaned at a frequency necessary to eliminate soil residue.
9. For ice bins, at a frequency necessary to preclude accumulation of soil or mold.
10. Food contact surfaces of cooking equipment shall be cleaned at least once every 24 hours.

Non-food-contact surfaces of equipment shall be cleaned at a frequency necessary to prevent accumulation of soil residues.

Good Manufacturing Practices - Employee Practices

1. Hands are to be thoroughly washed in a designated hand sink with soap and water, paying particular attention to the areas underneath the fingernails and between the fingers by scrubbing thoroughly with a using a fingernail brush. Dry with single use towels. Handwashing is to be done at the following times:

    - after using the toilet, in the toilet room
    - after coughing, sneezing, using a tissue, using tobacco, eating, or drinking
    - after handling soiled equipment or utensils
    - immediately before engaging in food preparation activities
    - during food preparation as necessary to remove soil and prevent cross contamination
    - when switching between raw and ready-to-eat foods
    - other times as needed to maintain good sanitation

2. Fingernails must be kept trimmed, filed, free of nail polish, and maintained so the edges are cleanable and not rough.

3. Eating and drinking is prohibited in areas where contamination of exposed food, clean equipment, utensils, unwrapped single service and single use articles could occur. A food employee may drink from a closed beverage container in a food prep area as long as it is handled to prevent contamination.

4. Effective hair restraints must be worn in processing areas.

5. Smoking and other uses of tobacco are prohibited.

6. Clean outer clothing must be worn each day and changed as often as necessary throughout the day (when moving from a raw food operation to a ready-to-eat food operation).

7. Frocks and aprons used by employees are to be hung in a designated area when not in use. They are not to be worn in the toilet area, eating areas and locker rooms.

8. Foot wear is to be kept clean.

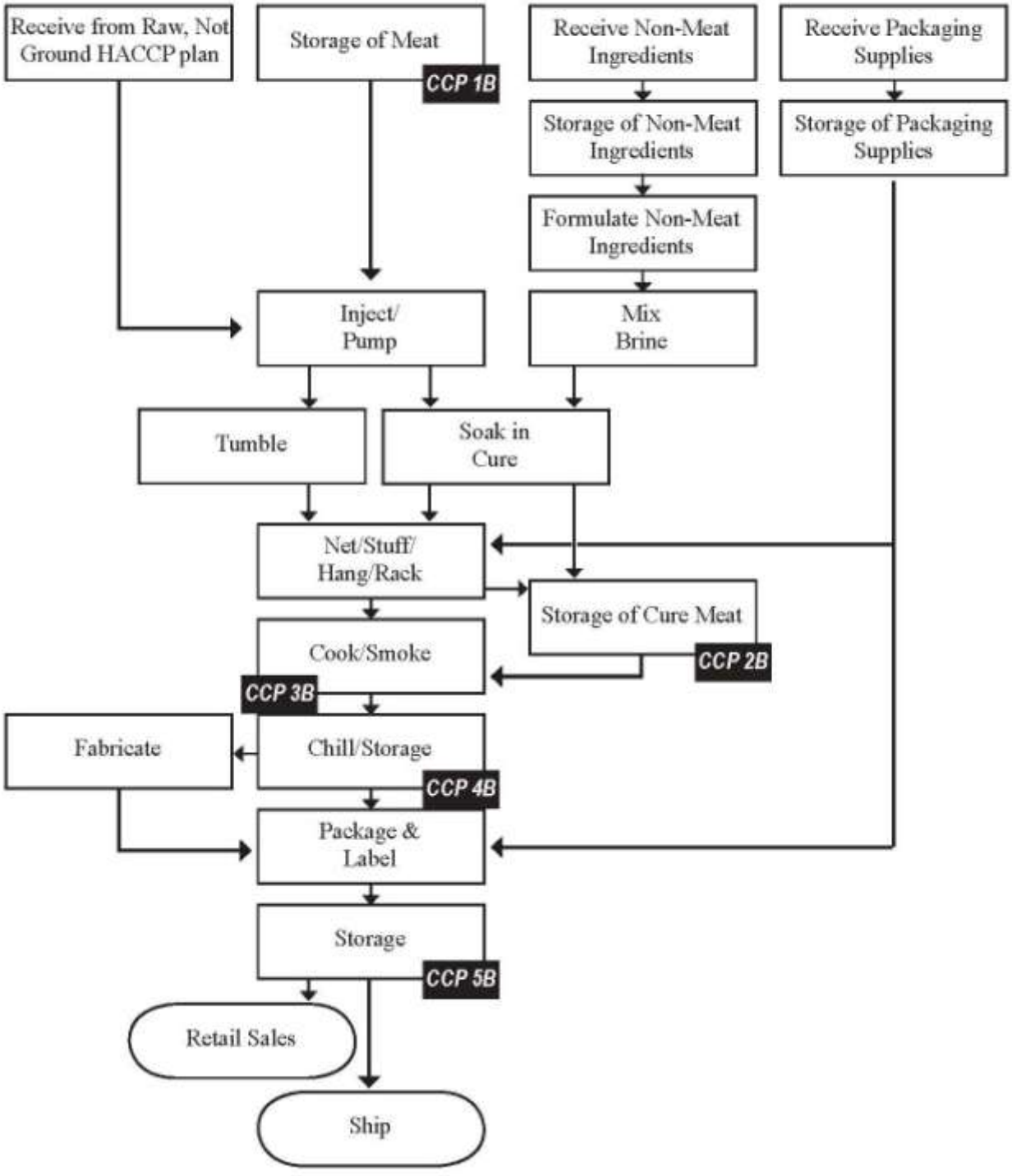
9. No jewelry (except a wedding band or other plain ring) is allowed during handling of food.

10. Food Employees shall report to the Person in Charge when they have a symptom caused by illness, infection, or other source that is:
    - associated with diarrhea, vomiting or other acute gastrointestinal illness
    - jaundice
    - a boil, infected wound or other lesion containing pus that is open or draining unless if on the hands or wrists, unless a finger cot or other impermeable cover protects the lesion and a single use glove is worn if on exposed portions of the arms, the lesion is protected by an impermeable cover.

The Person in Charge shall impose the proper restrictions and exclusions according to rule.

Flow Diagram for HACCP Category: Fully Cooked, Not Shelf Stable Whole Muscle Products

Example Product(s): Hickory Smoked Bacon, Hickory Smoked Boneless Ham



m a i
- e t n

Flow Diagram for Smoked Sausage

	POTENTIAL HAZARDS	CCP/CP	CRITICAL LIMITS	POTENTIAL HAZARDS	CORRECTIVE ACTIONS
RECEIVING	Rapid bacterial growth, spoilage, cross- contamination, foreign objects.	CP	Frozen items must be kept frozen. Chilled items must be kept at 40°F or below. No cross-contamination, foreign objects or spoilage.	Visual inspection. Use a digital thermometer.	Reject thawed frozen items. Reject chilled items above 40°F. Reject product with foreign objects.
STORAGE	Rapid bacterial growth, spoilage, cross- contamination, foreign objects.	CP	Temperature at 40°F or below. Any product stored above 70°F or a four-hour period must be discarded.	Record temperature every four hours. After normal working hours, the cooler will be on automatic alarm system.	Adjust cooler temperature. Discard any product that exceeds 70°F for more than four hours.
GRINDING	Rapid bacterial growth and cross- contamination.	CP	Utensils and equipment must be clean. Employees must meet personal sanitary standards.	Visual inspection.	Stop production and modify procedure.
MIXING	Insufficient mixing or amounts may result in poor distribution of cure.	CCP	Cure must be properly distributed, following uniform formulation mix.	Observe batch make slip, date and weight of product. Attach seasoning and cure bag.	Modify and re-blend, following uniform formulation mix.
STUFFING AND HANDLING	Cross- contamination between personnel and equipment.	CP	Utensils and equipment must be clean. Employees must meet personal sanitary standards.	Visual inspection.	Stop production and rework product.
COOKING AND SMOKING	Pathogens and bacterial spores may survive if product is not properly cooked.	CCP	Internal temperatures must be: Beef and Pork: 155°F Poultry: 165°F	Inspect temperature chart. Verify that the minimum time and temperature have been met.	Re-cook product until the minimum time and temperature have been met.
CHILLING	Surviving bacterial spores may germinate to vegetative cells if chilling is to slow.	CCP	Products must be cooled to 70°F within two hours, and to 40°F and below within another 4 hours.	Record internal temperature on batch make slip at two hours and six hours.	Discard any product not cooled to 40°F or below within six hours.
PACKAGING AND LABELING	Products may be incorrectly labeled. Outdated product may not be safe. Economic fraud. Cross-contamination.	CP	Overwrap product to prevent bacteria growth. Policies for rotation, disposal, and proper labeling must be followed. Follow good manufacturing practices.	Record the lot code and refrigeration statement. Follow proper procedures for coding and dating. Follow good manufacturing practices.	Reject or discard improper packaging. Discard outdated products.
DISPLAY	Improper temperature may result in rapid and progressive growth of pathogens.	CCP	Temperature must be maintained at 40°F or below. Products will be considered temperature-abused if they are exposed to temperatures above 40°F for more than six hours.	Check and record display case temperature every four hours.	Lower the thermostat. Discard any temperature-abused products.

PROCESS STEP	FOOD SAFETY HAZARD	REASONABLY LIKELY TO OCCUR	JUSTIFICATION FOR DECISION	IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level?	IS THE STEP A CRITICAL CONTROL POINT (CCP)?
Receive meat form raw, not ground HACCP Plan	B — None	B: — No			
	C — None	C: — No			
	P— None	P: — No			
Storage of meat	B — Pathogen Growth	B — Yes	Proper storage temperature suffiecient to prevent pathogen growth.	Temperature control to reduce a potential risk of pathogenic growth.	Yes (CCP 1B Holding Cooler)
	C — None	C — No			
	P — Foreign Materials (ex. overhead contamination)	P — None	Preventive maintenance and sanitation SOP's to prevent contamination.		
Receiving from chill	B — Pathogen Growth	B — No	Proper storage temperature sufficient to prevent pathogen growth.		
	C — Pathogen Growth	C — No			
	P — Foreign Materials (ex. overhead contamination)	P — No	Preventive maintenance and sanitation SOP's to prevent contamination		
Receive packaging supplies	B — Microbial Spores	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
	C — None				
	P — Foreign Materials	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
Receive non-meat ingredients	B — Microbial Spores	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
	C — None				
	P — Foreign Materials	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
Storage of packaging supplies	B — Microbial Spores	B — No	Letters of guarantee are on file for all packaging supplies and ingredients		
	C — None	C — No	Letters of guarantee are on file for all packaging supplies and ingredients. GMP's, routine samition, visual observation for container integrity.		
	P — Foreign Materials	P — No			
Receive non-meat ingredients	B — Microbial Spores	No	Letters of guarantee are on file for all packaging supplies and ingredients		
	C — None				
	P — Foreign Materials	No	Letters of guarantee are on file for all packaging supplies and ingredients		

PROCESS STEP	FOOD SAFETY HAZARD	RESEASONABLY LIKELY TO OCCUR	JUSTIFICATION FOR DECISION	IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level?	IS THE STEP A CRITICAL CONTROL POINT (CCP)?
Storage of non-meat ingredients	B — Micobial Spores	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
	C — None				
	P— None	No	Letters of guarantee are on file for all packaging supplies and ingredients.		
Formulate non-meat ingredients	B — Pathogen Introduction	B — No	Responsible employee prepares according to formulation.		
	C — None	C — No			
	P — Foreign Materials (ex. metal)	P — No	Plant history indicated that metal contamination is not likely to occur.		
Mix brine	B — Pathogen Introduction	B — No	Sanitation SOP's to prevent cross-contamination.		
	C — Nitrate	C — No	Responsible employee prepares according to formulation.		
	P — Foreign Materials (ex. overhead contamination)	P — No	Plant history indicated that metal contamination is not likely to occur.		
Inject/pump	B — Pathogen Introduction	No	Sanitation SOP's to prevent cross-contamination.		
	C — Excessive Nitrate		Proper pump % for appropriate formulation.		
	P — None	No			
Tumble	B — Microbial Spores	No	Sanitation SOP's to prevent cross-contamination.		
	C — None				
	P — None	No			
Net/stuff/ hangrack	B — Microbial Spores	B — No	Sanitation SOP's to prevent cross-contamination.		
	C — None	C — No			
	P — None	P — No			
Storage of meat cure	B — Pathogen Growth	B — Yes	Proper storage temperature sufficient to prevent pathogen growth.	Temperature control to reduce a potential risk of pathogenic growth.	Yes (CCP 2B cured meat cooler)
	C — None	C — No			
	P — None	P — No			
Cook/smoke	B — Pathogen Reduction	Yes	Potential survivor and/or growth of pathogens with improper cooking.		Yes (CCP 3B)
	C — None				
	P — None				

PROCESS STEP	FOOD SAFETY HAZARD	REASONABLY LIKELY TO OCCUR	JUSTIFICATION FOR DECISION	IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level?	IS THE STEP A CRITICAL CONTROL POINT (CCP)?
Chill/storage	B — Pathogen Growth	B — Yes	Potential survival and/or growth of pathogens with improper chilling. Improper storage temperature can provide ambient temperature for both spoilage and pathogenic growth.	Temperature control to reduce a potential risk of pathogenic growth.	Yes (CCP 4B smoked meats cooler)
	C — None	C — No			
	P— Foreign Materials	P — No	Container integrity.		No
Fabricate	B — Pathogen Contamination (*Listeria monocytogenes*)	No	Potential contamination form envimmental sources. Pre-operational and operation sanitation can reduce the risk of contamination from the environment and cross-contamination between products.		No
	C — None	C — No			
	P — None	P — No			
Package and label	B — Pathogen Contamination	B — No	Sanitation Standard Operating Procedures are in place to prevent contamination.	.	No
	C — Nitrate	C — No			
	P — None	P — No			
Storage of finished product	B — Pathogen Growth	B — No	Improper storage temperature can provide ambient temperature for both pathogenic growth.	Temperature control to reduce a potential risk of pathogenic growth.	Yes (CCP 5B holding cooler)
	C — None	C — No			
	P — Foreign Materials	P — No	Container integrity.		No
Ship	B — Pathogen Growth	B — No	Low risk, temperature abuse is unlikely to occur, since truck temperatures are sufficient to prevent pathogen growth.		No
	C — None	C — No			
	P — Foreign Materials	P — No	Container integrity.		

CCP	CRITICAL LIMITS	MONITORING PROCEDURES & FREQUENCIES	MONITORING RECORDS	CORRECTIVE ACTIONS	VERIFICATION PROCEDURES & FREQUENCIES	VERIFICATION RECORDS
CCP 1B Holding Cooler Hazard: Pathogen Growth	The cooler temperature is not to exceed 40°F except for periods of defrost.	The temperature of the raw meat storage areas will be taken continuously by a computerized data recorder with an alarm.	Bi-weekly or as necessary a printout of the plant temperatures. Non-compliance Log	See the Corrective Action Report for the specific actions taken to bring the CCP under control. Corrective actions may include but are not limited to; Plant management will immediately notify maintenance personnel to repair the cooler. The temperature of the cooler will be brought into compliance as soon as possible. If the increased temperature effects product temperature, the product will be temporarily relocated in another cooler or freezer, a hold may be placed on the cooler to prevent cold air from escaping.	Thermometers. Alarms will be checked and if necessary calibrated on a monthly basis.	Thermometer Calibration Log Monthly Verification Log
CCP 2B Cured Meat Cooler	Same as CCP1B	The temperature of the cured meat storage areas will be taken continuously by a computerized data recorder with an alarm.	Same as CCP1B	Same as CCP1B	Same as CCP1B	Same as CCP1B
CCP 3B Internal Product Temperature	The minimal internal temperature must reach 148°F.	At the end of the cooking, the oven operator or designee will take and record the internal temperature per each product in the oven. The temperature will be taken with a calibrated thermometer.	Smokehouse Log Non-compliance Report	Specific corrective actions will be recorded for each deviation from the critical limit. Corrective actions may include but are not limited to: holding in the oven until the temperature is reached, recooking the product, reworking the product, or disposing of the product.	Thermometers will be calibrated on a monthly basis or as necessary. Daily review of production records by management Visual Observations of procedures will be conducted on a monthly basis or as necessary. Findings will be recorded on the Monthly Verification Log.	Thermometer Calibration Log Monthly Verification Log
CCP 4B Smoked Meat Cooler	Same as CCP1B	The temperature of the smoked meat storage areas will be taken continuously by a computerized data recorder with an alarm.	Same as CCP1B	Same as CCP1B	Same as CCP1B	Same as CCP1B
CCP 4B Holding Cooler	Same as CCP1B	The temperature of the finished and packaged product areas will be taken continuously by a computerized data recorder with an alarm.	Same as CCP1B	Same as CCP1B	Same as CCP1B	Same as CCP1B

Conference for Food Protection
2012 Issue Form

Internal Number: 119
Issue: 2012 I-014

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Beef Grinding Log Template for Retail Establishments

Issue you would like the Conference to consider:
The Food Safety and Inspection Service (FSIS) recommends that a CFP Committee be created to review the FSIS grinding log template and provide feedback to FSIS on its use at retail. The draft grinding log template will become the basis of the FSIS compliance guidelines that accompanies the planned proposed rule, "Records to be Kept by Official Establishments and Retail Stores That Grind or Chop Raw Beef Products". The FSIS proposed rule is expected to require establishments and retail stores to keep records that disclose the identity of the supplier of all source materials that they use in the preparation of raw ground or chopped product. FSIS is seeking feedback on the grinding log template and any additional comments on developing the log for use at retail.
In the interim, FSIS also recommends an update to the supporting documents for retail grinding logs in the Food Code Annex 2 (Page 305) so that retail establishments will have more detailed information on how to maintain grinding logs and understand its importance during recalls and outbreak investigations. Recently over the past few years, FSIS has been unable to determine the source suppliers of contaminated ground beef product because of inadequate retail grinding logs. FSIS developed and published a grinding log template and example on the FSIS website entitled "Sanitation Guidance for Beef Grinders" http://www.fsis.usda.gov/PDF/Sanitation_Guidance_Beef_Grinders.pdf. FSIS will consider the feedback from CFP for incorporation into a future FSIS compliance guideline that will accompany the FSIS rule.

Public Health Significance:
Ground beef contaminated with pathogens such as *Escherichia coli* O157:H7 or *Salmonella* is a known source of illness. During outbreak investigations, traceback of contaminated beef to the producing facility is often unsuccessful because of inadequate recordkeeping at retail establishments that grind beef products. FSIS enforcement strategy relies heavily on being able to identify the source material and the producing facility.
FSIS has reviewed foodborne investigations in which FSIS investigators found that retail facility grinding logs were a limiting factor for the Agency's ability to pursue public health investigations. FSIS conducted a retrospective review of 16 investigations (2006 through 2008) in which beef products were ground or reground at retail stores. In only 5 of 16 (30%)

of investigations, were records kept by the retail stores present and adequate to enable traceback to the official establishment supplying the beef. FSIS results are supported by Gould et al [Gould LH, Seys S, Everstine K, Norton D, Ripley D, Reimann D, et al. J Food Prot. 2011;74(6):1022-4] in a review of retail grinding records. Of 125 stores surveyed, 60(49%) kept grinding records. In those stores keeping grinding records, 22% of 176 records were judged complete (JFP 2011; 74:1022-1024). Schneider et al also reported a multistate outbreak with 42 illnesses. Investigators used shopper card information for 12 stores, but were unable to identify the identity of the source (JFP 2011, 74:1315-1319).
Additonal References:

- "Marler Clark calls on Hannaford to Release Meat Grinding Logs and Identify All Suppliers Linked to Salmonella Outbreak" 12/23/2011 - http://www.foodpoisonjournal.com/foodborne-illness-outbreaks/marler-clark-calls-on-hannaford-to-release-meat-grinding-logs-and-identify-all-suppliers-linked-to-s/
- Beef Grinding Logs Study: Restaurant Policies and Practices and Food Worker Practices/Behavior (CDC)http://www.cdc.gov/nceh/ehs/ehsnet/Restaurant_Policies_Practices.htm

Recommended Solution: The Conference recommends...:

1.) That a CFP Committee be created to:

a. review the FSIS grinding log template

b. Create a new committee to review the FSIS grinding log template and provide feedback to FSIS for consideration into the future FSIS compliance guide on retail grinding logs and on its use at retail

c. report back to the 2014 Biennial Meeting.

2.) That a letter be sent to the FDA to request amending the 2009 Food Code (as modified by the supplement issued in 2011) Annex 2 - Supporting Documents, References under Part 3, K Supplemental Documents (Page 305), using strike through to remove language and underline format to add language to read as follows:

K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

This document may be found at the web site for "Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7" http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf On October 7, 2002, USDA/FSIS published a Federal Register Notice (67 FR 62332) entitled, *E. coli* O157:H7 Contamination of Beef Products, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf in which the Agency discussed its views on the application of the Hazard Analysis and Critical Control Point (HACCP) system regulations with respect to *Escherichia coli (E. coli)* O157:H7 contamination.

USDA/FSIS announced <u>in 2002 </u>that there is sufficient new scientific data on the increased prevalence of *E. coli* O157:H7 in live cattle coming to slaughter and on its impact on public health to require that all establishments producing raw beef products reassess their HACCP plans, in light of these data.

Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback ~~*E. coli* O157:H7~~ contaminated product that is in commerce to its source and to remove it from

commerce. In Spring ~~March~~ 2004, FSIS began conducting sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities, as well as at import facilities. ~~the agency issued "FSIS Directive 10,010.1; revision 1, Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components" available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf. In this Directive, the Agency stated that, effective May 17, 2004, it would conduct sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities, as well as at import facilities.~~ Some of the products most likely to be sampled and tested at retail facilities are:

- Ground beef products produced from retail steaks and roasts.
- Manufacturing trimmings derived at retail.
- Ground beef that is formulated at retail by co-mingling in-store trim and trim from federally inspected establishments.
- Irradiated ground beef co-mingled with non-irradiated meat or poultry.

Additionally, ground beef products have been implicated as a transmission vehicle in foodborne outbreaks of infection with pathogens such as *Escherichia coli* O157:H7 and Salmonella. To facilitate product traceback and to meet regulatory requirements, USDA/FSIS expects retail facilities as well as federally inspected establishments to maintain and provide FSIS with access to all applicable records associated with the source material used for ground beef products. In cases where USDA/FSIS identifies adulterated ground beef, ~~*E. coli* O157:H7 ground beef in a product,~~ and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

FSIS recently published "Sanitation Guidance for Beef Grinders" which contains an example of a fresh ground beef production log. The guidance is located at the following website: http://www.fsis.usda.gov/PDF/Sanitation_Guidance_Beef_Grinders.pdf

The following information would be used to facilitate traceback of contaminated ground beef products:

- *The manufacturer name of source material used for product produced*
- *The type of product or description of the purchased or received article(s).*
- *The establishment information from the label of source product used such as the name, address, and establishment number.*
- *The supplier lot numbers, product code or production or pack date of source materials used.*
- *Any other information that would be useful in the quick removal of adulterated product from the market or commerce such as time of grind, grinder sanitation records, and amount (in pounds) and lot/batch numbers, production codes, name and package size of products produced.*

In addition to the references cited above, the following references also provide information:

1. Federal Meat Inspection Act (21 USC Sec. 642).
2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.
3. Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products
4. Best Practices for Raw Ground Products

5. FSIS Sanitation Performance Standards Compliance Guide:
6. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program and Other Verification Activities For *Escherichia coli* O157:H7 http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf

~~The following information would be adequate for meeting federal transaction requirements:~~

- ~~The name or description of the purchased or received article(s).~~
- ~~The name, address, and establishment number of the seller of the articles purchased or received.~~
- ~~The supplier lot numbers and production dates of the articles purchased or received.~~
- ~~Any other information that would be useful in the quick removal of adulterated product from the market or commerce.~~

~~In addition to the references cited above, the following references also provide information:~~

~~1. Federal Meat Inspection Act (21 USC Sec. 642).~~

~~2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.~~

~~1. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program and Other Verification Activities For *Escherchia coli* O157:H7 http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010 1/ecolio157h7dirguid4-13-04.pdf~~.

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Attachments:

- "FSIS Sanitation Guidance for Beef Grinders"
- "Canadian Beef Good Retail Practices Ground Meat Management (Example Log)"
- "Multistate Outbreak of Multidrug-Resistant Salmonella Newport"
- "Recordkeeping Practices of Beef Grinding Activities Retail Establishments"
- "BIFSCO Best Practices For Retailer Operations Producing Raw Ground Beef"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Sanitation Guidance for Beef Grinders

1. Good sanitation prevents the introduction of new bacterial hazards to controlled ingredients.

The objective of a beef grinder is to maintain the clean condition of the carcass, primal, subprimal, or coarse ground beef starting material.

a) The grinder should develop sanitation standard operating procedures (SOPs) that address, at a minimum, the cleaning of food contact surfaces, equipment, utensils, implements, and the processing areas. The SOPs should indicate the frequency with which these items will be cleaned and how the grinder will verify their cleanliness.

b) Systematic sanitizing of belts and implements is recommended, as it will break the chain of any contamination that slips through. Thus, rather than the contaminant being spread throughout the lot, it will be stopped or at least diminished.

c) Employees are in continuous contact with the product. Therefore, sanitation training and education, as well as supervision, are crucial. Keeping the processing areas clean and in good repair and keeping employee areas clean and in good repair set a personal tone for the operation. These are management choices, but can indirectly affect the product.

d) Desirable practices to instill in employees are:
   1) Removing outer clothing when leaving the processing area.
   2) Practicing personal hygiene, such as proper handwashing after using the toilet or before entering the processing area.

2. Sanitation procedures should prevent cross-contamination from equipment, personnel, traffic, air flow, tables, and floors to product.

3. Additional resources:

Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products:
Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products

Best Practices for Raw Ground Products:
http://www.fsis.usda.gov/PDF/Best_Practices_Raw_Ground_Products_08.pdf

FSIS Sanitation Performance Standards Compliance Guide:
http://www.fsis.usda.gov/Regulations_&_Policies/Sanitation_Performance_Standards/index.asp

Store Name: _____
Store Address: _____
_____

FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee Name: _____ Today's Date: _____

Time of Grind	Lot/ Batch Number (lot = same source material)	Exact Name/ Type of Product Produced	Package Size of Product Produced	Amount (in pounds) of Product Produced	Production Code of Product Produced	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot Numbers, Product Code and/or Pack Date of Source Material Used	Establishment Information from label of Source Product Used (Est. #, ph #, contact info)	Establishment Information from label of Source Product Used (Est. #, ph #, contact info)	Grinder Cleaned and Sanitized? If Y, Date and Time	Comments

_____ _____
Signature of Store Management Reviewer Date

NEW WAVE STORE
123 Main Street
Anytown, USA, Zip Code

FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee name: John Williams

Today's Date: 12/14/11

Time of Grind	Lot/ Batch Number (lot = same source material)	Exact Name/ Type of Product Produced	Package Size of Product Produced	Amount (in pounds) of Product Produced	Production Code of Product Produced	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot Numbers, Product Code and/or Pack Date of Source Material Used	Establishment Information from label of Source Product Used (Est. #, ph #, contact info)	Comments
0700-1000 AM	Lot 001	91/9 New Wave Ground Chuck	Catch-weight retail trays	1,250 lbs total of 91/9 Ground Chuck	121511-01 NWGB; Sell-by 12/20/11	Boneless Chuck, twenty-one 60 lb boxes from USA Beef Company	BB120311USA Packed on 12/03/11; BB120411USA Packed on 12/04/11	Est. 00321 M, (202)-123-4567, 898 Dodge St, Omaha, NE, 68104	Cleaned and sanitized grinder after Lot 001
1030-1130 AM	Lot 002 **From store-generated bench trim**	70/30 New Wave Ground Beef	2 lb. Trays	50/2 lb. trays	121511-03 NWGB; sell-by date 12/20/11	USA Company	BB120511USA Packed on 12/05/11 BB120711USA Packed on 12/07/11;	Est. 00321 M, (402)-123-4567, 898 Dodge St, Omaha, NE, 68104	Used trim from two different production lots from USA
	same	same	same	same	same	National Brand Beef	NBB120111, Packed on 12/01/11	Est. 15555 M, (903) 999-5454, 220 Locust St, Denton, TX 76201	Used trim from only one production lot of NBB product

Appendix II: Grinding Log

Ground Meat Production Log photocopy template on page 30.

How to Use the Grinding Log

1 Grinding Time & Date

Record the time and date when in-store grinding was initiated for the batch.

2 Ingredient Source and Supplier

Internal

In this column simply place a check mark if the trim was generated in-store during fabrication of cuts or if rework from the display case was used to create ground meats. If trim or ground meats was purchased from external suppliers, leave blank.

Supplier

If coarse ground meats or trim is purchased from an external supplier, record the name of the supplier in the space indicated.

3 Species

Record the species ground using the first letter of its name. Use **P** for pork and **B** for Beef.

4 Ingredient Production Date

Rework

If rework is utilized, record the original "packaged on date" of the product which was reworked.

Internal Trim

Record the "produced on date" for the trim was generated during in-store fabrication of cuts.

External

Record the production date from the box or chub.

Note: If ingredients have a different production date always start a new line on the grinding log.

5. Fresh or Frozen Storage

Record if ingredients were stored Fresh with an **F** or with a **Z** if ingredients were Frozen.

6. Date Acceptable

If ingredients were frozen and packaged to prevent freezer burn, they may be used 12 months after the production date. Place a check mark if criteria is met.

Observe store guidelines for fresh coarse ground meat and trim – ingredients stored at 0°C may be used longer than those stored at 4°C.

7. Quality Check

When opening ingredients verify that no off-odour is present and that visually ingredients appear satisfactory for ground meat production. Place a check mark if criteria is met.

Ground Meat Production Log

Retail I

1 Grinding Time and Date		2 Ingredient Source		3 Species	4 Ingredient Production Date	5 Fresh or Frozen Storage	6 Date Acceptable
Year: 2005 Month: July Time	Day	✓ = Internal	If ingredients are externally sourced indicate supplier name	**B** = Beef **P** = Pork		**F** = Fresh **Z** = Frozen	✓ = Good
9 am	11	✓		B	July 8	Z	✓
10 am	12		Packer A	P	July 11	F	✓

14 Grinder Sanitation Check Each day the grinder is used, before the start of production perform
the day. Remember that the grinder should also be completely cleaned between species. If the grind
increases in shelf life and product safety may also be gained by cleaning the grinder during the day.

Grinder Sanitation Check (Please Check and Initial): ☑ Mon. MK | ☑ Tues.

8. Ingredient Quantity

Place a check mark to indicate if kilograms or pounds are used as the unit of measurement.

Place the value in kilograms or pounds under the correct column for the ingredient type utilized.

9. Lean %

Record the lean % of each ingredient or use the selected abbreviation.

10. Meat Temperature

Record the temperature of the ingredients before grinding using a probe thermometer which is periodically checked for accuracy.

Ground meat and trim should always be kept at 4°C or lower. Optimal shelf-life will be achieved at temperatures closer to 0°C. It is especially important for food safety reasons that ground meat and trim be kept under 5°C as at this temperature if any dangerous *E. coli* bacteria are present they will not grow. Remember that meat temperature will rise due to friction from grinding.

11. Clip Check

When removing clips from chubs ensure they are all properly disposed of and then place a check mark.

12. Additional Information

This space can be used to record any information that the retailer wishes to capture (such as temperature of product exiting the grinder).

13. Staff Initial

The individual who is performing the grinding process should initial indicating information recorded is accurate.

14. Grinder Sanitation Check

Each day the grinder is used, before the start of production, perform an inspection to ensure that grinder is visually clean and dry. If satisfactory record your initials by the day.

Remember that the grinder should also be completely cleaned between species. If the grinder is used in warm conditions where air temperature is significantly greater than 4°C substantial increases in shelf-life and product safety may also be gained by cleaning the grinder during the day.

Records Storage

Grinding logs should be filed and kept on the premises for a period of at least one month.

Items Requiring Corrective Action

If during the course of filling out the grinding log you find that ingredients are not satisfactory for use, place the suspect ingredients in a location where they will not be used and inform your supervisor or take action according to your store policy. Record the details on the back of the grinding log so you may refer to it at a later time.

Location: Store Name

7	8				9		10	11	12	13
Quality Check ✓= Good	**Ingredient Quantity** ☑ Kilograms ☐ Pounds				**Lean %** F = fat trim, EX = extra lean, L = lean, R = regular, M = medium		**Meat Temp.** ☑ °C ☐ °F	**Clip Check** ✓= Good	**Additional Information** Post grinding temp.	**Staff Initial**
	Rework	Trim	Ground Meat	Whole Muscle	Type	Percentage				
✓		56			M		0	✓	1°C	MK
✓		50				75%	2	✓	3°C	TL

an inspection to ensure that grinder is visually clean and dry. If satisfactory record your initials by
er is used in warm conditions where air temperature is significantly greater than 4°C, substantial

TL | ☐ Wed. ____ | ☐ Thurs. ____ | ☐ Fri. ____ | ☐ Sat. ____ | ☐ Sun. ____

Ground Meat Production Log

Retail Location:

Grinding Time and Date Year: Month: Time / Day	Ingredient Source ✓ = Internal If ingredients are externally sourced indicate supplier name	Species B = Beef P = Pork	Ingredient Production Date	Fresh or Frozen Storage F = Fresh Z = Frozen	Date Acceptable ✓ = Good	Quality Check ✓ = Good	Ingredient Quantity ☐ Kilograms ☐ Pounds Rework / Trim / Ground Meat / Whole Muscle	Lean % F = fat trim EX = extra lean L = lean R = regular M = medium Type / Percentage	Meat Temp. ☐ °C ☐ °F	Clip Check ✓ = Good	Additional Information	Staff Initial
EXAMPLE 9 am / 11	✓	B	July 8	Z	✓	✓	56	M / 75%	0	✓		MK

Grinder Sanitation Check Each day the grinder is used, before the start of production perform an inspection to ensure that grinder is visually clean and dry. If satisfactory record your initials by the day. Remember that the grinder should also be completely cleaned between species. If the grinder is used in warm conditions where air temperature is significantly greater than 4°C, substantial increases in shelf-life and product safety may also be gained by cleaning the grinder during the day.

Grinder Sanitation Check (Please Check and Initial): ☐ Mon. ____ | ☐ Tues. ____ | ☐ Wed. ____ | ☐ Thurs. ____ | ☐ Fri. ____ | ☐ Sat. ____ | ☐ Sun. ____

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Research Note

Multistate Outbreak of Multidrug-Resistant *Salmonella* Newport Infections Associated with Ground Beef, October to December 2007

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MS 11-046: Received 30 January 2011/Accepted 15 April 2011

ABSTRACT

In late October 2007, an outbreak of multidrug-resistant *Salmonella* Newport infections affected 42 case patients in California, Arizona, Idaho, and Nevada. A case-control study implicated ground beef from one chain store. Despite detailed ground beef purchase histories—including shopper card information for several case patients—traceback efforts by both the U.S. Department of Agriculture, Food Safety and Inspection Service and the California Department of Public Health were unable to identify the source of contamination. Case patients consumed multiple types of ground beef products purchased at numerous chain store A retail locations. These stores had received beef products for grinding from multiple beef slaughter–processing establishments. Detailed retail grinding logs and grinding policies that prevent cross-contamination between batches of ground beef products are crucial in the identification of contaminated beef products associated with foodborne illness.

In late October 2007, the California Department of Public Health (CDPH) noted an increase in *Salmonella* Newport isolates resistant to chloramphenicol, a marker for multidrug resistance. Historically in California, clusters of multidrug-resistant (MDR) *Salmonella* infections have predominantly occurred among the Hispanic population and have often been associated with consumption of raw milk and/or raw milk products *(2)*. Previous outbreaks of MDR *Salmonella* Newport in the United States have been associated with consumption of ground beef *(11)*. Among the six initial cases of this outbreak, all were non-Hispanic, and the isolates shared an extremely rare pulsed-field gel electrophoresis (PFGE) pattern; this PFGE pattern accounted for only 0.2% of all *Salmonella* Newport isolates posted to the national PulseNet database at that time. In all, 42 MDR *Salmonella* Newport isolates with indistinguishable PFGE patterns by two enzymes were identified in California, Arizona, Nevada, and Idaho, from October to December 2007. A case-control study was conducted by the CDPH, the Arizona Department of Health Services, the California Emerging Infections Program, and the Centers for Disease Control and Prevention. This report summarizes the results of the epidemiologic investigation that linked these MDR *Salmonella* Newport infections to consumption of contaminated ground beef purchased from several grocery stores of the same chain (chain store A).

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MATERIALS AND METHODS

Epidemiologic investigation. A case was defined as a culture-confirmed MDR *Salmonella* Newport infection in a U.S. resident, with symptom onset on or after 1 October 2007 and an isolate matching the outbreak PFGE patterns (*Xba*I JJPX01.0422–*Bln*I JJPA26.0196). The CDPH Microbial Diseases Laboratory conducted a national PulseNet search to identify isolates with the outbreak patterns.

Hypothesis-generating questionnaires were administered by phone to case patients in California and Arizona during the first 2 weeks of November. Foods consumed by more than 50% of the case patients were included on the case-control study questionnaire. Case-control study interviews were conducted during the last week of November and the first week of December. Controls were defined as persons without self-reported diarrhea in the 2 weeks prior to interview and were matched to cases by age (younger than 18 years, 18 to 64 years, and 65 years and older) and neighborhood, using reverse address lookup, with the case patient's address as the anchor. Case patients provided information about foods consumed during the 7 days prior to the onset of illness. Controls provided information about foods consumed during the month of October to match exposure period to that of the case patients. Case patients and controls were asked about

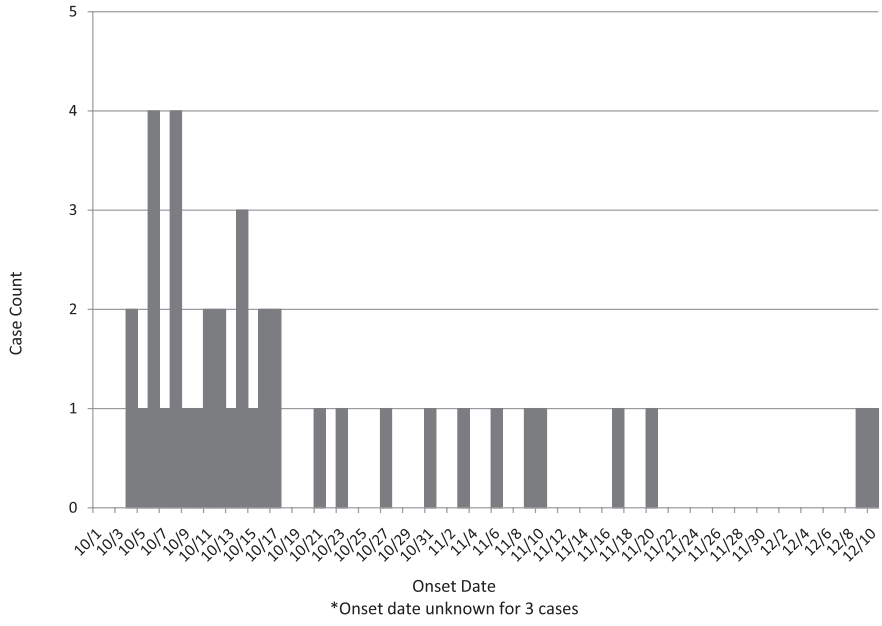

FIGURE 1. *Symptom onset date of MDR* Salmonella *Newport outbreak cases, October to December 2007, United States (*n = *39).**

consumption of ground beef, chicken, tomatoes, milk, cheese, eggs, bananas, and raw onions. Case patients were asked to provide grocery store shopper card information if available. Odds ratios and 95% confidence intervals were calculated with SAS 9.1 software (SAS Institute, Cary, NC). A two-tailed P value <0.05 was considered statistically significant.

Environmental investigation. Product isolates collected during the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) Pathogen Reduction–Hazard Analysis and Critical Control Point *Salmonella* Verification Testing Program are subject to PFGE and antimicrobial resistance testing at the U.S. Department of Agriculture, Agricultural Research Service *(6)*. Each *Salmonella* isolate is cut by a primary enzyme (*Xba*I) and, on request, by a secondary enzyme (*Bln*I). The PFGE patterns are uploaded to the VetNet database maintained by the Agricultural Research Service. A VetNet pattern search was conducted by the FSIS to match the unique PFGE *Xba*I pattern of the outbreak strain to isolates collected from meat and poultry establishments during FSIS *Salmonella* testing.

Grocery shopper card purchase information was sought from case patients. Using shopper card information, the FSIS and the CDPH conducted traceback investigations of case patients' ground beef purchases at multiple retail locations. Investigators met with store meat managers to review in-store grinding procedures and policies. Investigators reviewed grinding logs, and invoices for the day's ground beef purchased by case patients had been fabricated to identify specific beef suppliers of interest. Investigators conducted traceforward investigations at FSIS-regulated establishments where ground beef–positive *Salmonella* Newport isolates that exhibited the outbreak PFGE *Xba*I pattern were recovered in 2007.

RESULTS

Epidemiologic investigation. The CDPH Microbial Diseases Laboratory noted an increase in chloramphenicol-resistant *Salmonella* Newport isolates in late October 2007. A PulseNet search conducted on 31 October 2007 identified 10 isolates with the same pattern in the United States during the previous 60 days. In all, 42 isolates with a two-enzyme (*Xba*I and *Bln*I) PFGE match were identified between October 2007 and January 2008. Isolates from three California case patients were confirmed by the National Antimicrobial Resistance Monitoring System and met the System's definition of MDR *(1)*.

The 42 case patients were from California (22), Arizona (16), Nevada (3), and Idaho (1). Onset dates ranged from 4 October to 10 December 2007 (Fig. 1). The median age of case patients was 41 years (range, <1 to 94 years); 56% of the case patients were female. The majority (82%) of patients was non-Hispanic white. Twenty-five (74%) of 34 patients had bloody diarrhea. Seventeen (46%) of 37 patients were hospitalized; there were no deaths.

Fifteen case patients in California and Arizona completed the hypothesis-generating questionnaire. Twenty-one case patients and 36 controls were enrolled from the four states in the case-control study. In univariate analysis, no single food item was significantly associated with illness. There was a borderline-significant association with purchasing ground beef from chain store A (42% [8 of 19] of cases versus 18% [6 of 33] of controls, P value of 0.06) (Table 1). Case patients were more likely to have shopped for groceries at chain store A in the week prior to the onset of illness, as compared with controls during the month of October (81% of cases compared with 67% of controls, P value of 0.25), although the association was not statistically significant. Among case patients and controls who had shopped at chain store A, no single food item was associated with illness. However, among persons who consumed ground beef at home during the week prior to the onset of illness or in the month of October for controls, 80% of the case patients purchased their ground beef from chain store A compared with 26% of controls (odds ratio = 11.3, 95% confidence interval = 1.9 to 69.1, P value = 0.005). The investigation did not identify a link between any of the illnesses and ground beef purchased at other store chains. At

TABLE 1. *Food consumption and exposure history for cases and controls*

Exposure	No. (%) of cases	No. (%) of controls	Odds ratio	95% confidence interval	*P* value
Ground beef at home	12 (57)	28 (78)	0.38	0.1–1.2	0.1
Ground beef in restaurant	6 (40)	19 (56)	0.53	0.2–1.8	0.3
Ever cook ground beef	15 (79)	29 (81)	0.9	0.2–3.6	0.9
Chicken at home	12 (71)	31 (86)	0.39	0.1–1.6	0.18
Chicken at restaurant	12 (63)	22 (63)	10	0.3–3.2	1
Raw onion	7 (37)	22 (61)	0.37	0.1–1.2	0.09
Grocery shop at chain store A	17 (81)	24 (67)	2.1	0.6–7.7	0.25
Ground beef from chain store A	8 (42)	6 (18)	3.3	0.9–12	0.06

the time of the case-control study, none of the patients contacted for this investigation had leftover ground beef available for testing.

Traceback and traceforward investigations. FSIS investigators followed up on shopper card information collected from 11 case patients and visited nine Arizona, two California, and one Nevada chain store A locations. Based on the shopper card information, case patients had purchased multiple and various types (percent lean) of ground beef products prior to illness onset, but had not purchased ground beef patties. Seven establishments were identified that directly supplied beef products to chain store A locations in California, Arizona, and Nevada (Fig. 2). Four of the establishments (I, J, K, and L) provided primal cuts of beef to stores in all three states. Bench trim from the primal cuts was ground into 80% (80/20) lean ground beef at individual chain store A locations. Three establishments (B, C, and E) supplied ground beef products to chain store A locations. Establishment B, a grinding plant, supplied coarse ground beef for regrinding to stores in California, Arizona, and Nevada. Establishment C, a slaughter–processing establishment, supplied coarse ground beef to chain store A locations in Arizona for regrinding. Establishment E, a grinding plant, supplied preformed ground beef patties to chain store A locations in Arizona. Establishment A, a slaughter–processing plant, and establishment D, a processing plant, supplied both establishments B and E with boneless beef products for grinding. Establishment B also received boneless beef products from foreign establishment G (Fig. 2).

Chain store A locations did not regularly clean the grinder between batches of various blends of ground beef; it is likely that individual ground beef products were commingled with the subsequent batch of ground beef products. Additionally, the chain store locations did not record the sources of the bench trim on daily grinding logs, and information on the source of coarse ground beef was recorded incompletely or inaccurately at some stores. This made it difficult for the investigators to collect establishment and lot numbers for specific ground beef products purchased by case patients.

In September 2007 one *Salmonella* Newport ground beef isolate, indistinguishable (by *Xba*I) from the outbreak strain, was recovered during FSIS sampling at establishment E. Establishment E supplied ground beef patties to store chain A locations in Arizona and, as previously stated, no case patients reported consuming that type of ground beef. Establishment F, a small processing plant, was the source of a second 2007 FSIS ground beef isolate indistinguishable by two enzymes (*Xba*I and *Bln*I) from the outbreak strain.

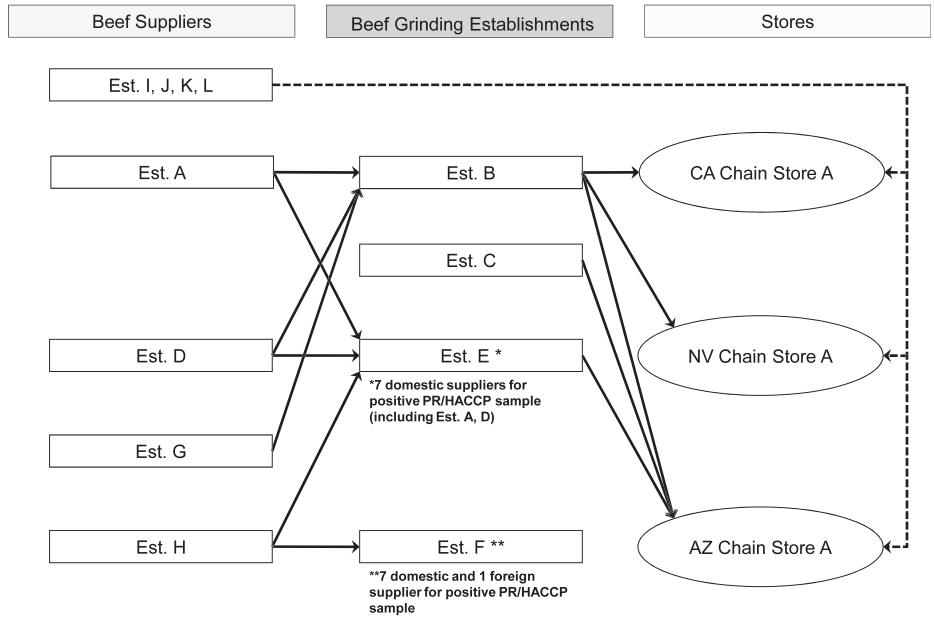

FIGURE 2. *Beef product suppliers for chain store A supermarkets.*

Time of Grind	Lot/ Batch Number (lot = same source material)	Type of Product Produced (e.g. 80/20, 93% lean)	Package size	Amount (in lbs.) of Product Produced	Production Code of Product Produced	Manufacturer Name -- Source Material Used for Product Produced	Product Code and/or Pack Date of Source Material	Establishment Number for Source Product	Comments	Initials
0700-0830 AM	Lot 001	91/9 Gold Standard Ground Chuck	Catch-weight retail trays	1,250 lbs total of 91/9 Ground Chuck	033109-01 GSGC; Sell-by 04/02/09	Boneless Chuck, twenty-one 60 lb boxes from USA Beef Company	BC031509 USA Packed on 03/15/09; BC031709 USA Packed on 03/17/09	Est. 00321 M	Cleaned and sanitized grinder after Lot 001; excess source material (approx. 10 lbs) made into RTE chili;switched source materials	John Doe ID # 222

FIGURE 3. *Ground beef production records at retail: information needed in grinding logs for traceback purposes.*

Establishment F could neither be linked to store chain A nor to establishments A, D, I, J, K, or L. Both establishments E and F did have a common foreign supplier of boneless beef, establishment H.

The FSIS issued a public health alert *(7)* on 20 December 2007, after an exhaustive FSIS investigation could not identify specific production lots that would be subject to a recall. The public health alert advised consumers not to consume ground beef that was ground and sold by chain store A locations between 19 September and 5 November 2007. The original alert was expanded on 15 February 2008 to include ground beef sold between 19 September and 25 November 2007, based on an additional case patient with illness onset of 10 December 2007, who reported a ground beef purchase at store chain A on 23 November 2007.

On 30 January 2008, a public health laboratory isolated *Salmonella* Newport from leftover frozen ground beef retrieved from a California case patient's freezer. The patient bought the ground beef from a chain store A location on 4 October 2007. On 8 February 2008, the CDPH confirmed that the isolate was MDR *Salmonella* Newport and matched the outbreak strain, with two enzymes by PFGE. The subsequent recovery of the outbreak strain from frozen ground beef confirmed the epidemiologic implication of ground beef from chain store A. Subsequent traceback activities by the FSIS confirmed that this product had been the first product ground at the chain store A location on 4 October 2007, and that establishment B was the sole source of that ground beef product.

DISCUSSION

Ground beef has been identified previously as the source for MDR *Salmonella* Newport and *Salmonella* Typhimurium infections *(4, 10)*. It is important to identify strategies to control MDR *Salmonella* from farm through processing. The judicious use of antibiotics in animal agriculture is important to decrease the emergence of resistant pathogens.

An outbreak of MDR *Salmonella* Newport occurred among residents of California, Arizona, Nevada, and Idaho in late 2007. The epidemiologic and laboratory evidence supported that this outbreak was due to consumption of ground beef purchased at chain store A. Because of chain store A's beef grinding policies, it is likely that individual ground beef products were routinely commingled with the next batch of ground beef, although incomplete grinding logs at some store locations hindered conclusive findings on this point.

Patients infected with MDR *Salmonella* have a greater risk of hospitalization and death compared with patients infected with drug-susceptible *Salmonella (5, 9)*. During this 2007 outbreak, almost half (46%) of all patients were hospitalized. State and national level surveillance systems for MDR *Salmonella* Newport need to be maintained to enhance detection of outbreaks. Once an outbreak is detected, epidemiologic studies and prompt collection of product (food) samples from case patients are the key to the identification of the source of the infections. Initiation of traceback activities early in an investigation enhances the identification of the source of the outbreak. Supermarket loyalty cards have proved an invaluable resource, providing detailed case patient purchase information. This information, combined with detailed and accurate retail recordkeeping, is crucial to the successful determination of the source of the contamination and the removal of potentially contaminated products from commerce *(8)*. Changes to retail supermarkets' ground beef policies and recordkeeping could aid investigations. When grinding beef in-store, retail supermarkets should consider separating batches of beef from different sources to prevent commingled product, which may result in the spread of contamination by pathogens, such as MDR *Salmonella* Newport or *E. coli* O157:H7. Retailers should maintain detailed records of grinding activities and logs (Fig. 3) that include documenting cleanup between grinds. Detailed grinding logs are essential for the successful traceback of contaminated beef when implicated in outbreaks and to allow focused, detailed, and prompt recalls to prevent additional infections *(3)*.

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Research Note

Recordkeeping Practices of Beef Grinding Activities at Retail Establishments

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ABSTRACT

Ground beef has been implicated as a transmission vehicle in foodborne outbreaks of infection with pathogens such as *Escherichia coli* O157:H7 and *Salmonella*. During outbreak investigations, traceback of contaminated beef to the producing facility is often unsuccessful because of inadequate recordkeeping at retail establishments that grind beef products. We conducted a survey in three states participating in the Environmental Health Specialists Network to describe beef grinding and recordkeeping practices at retail establishments. In each establishment that maintained grinding logs, three randomly selected records were reviewed to determine whether important data elements for traceback investigations were recorded. One hundred twenty-five stores were surveyed, of which 60 (49%) kept grinding logs, including 54 (74%) of 73 chain stores and 6 (12%) of 51 independent stores. One hundred seventy-six grinding records from 61 stores were reviewed. Seventy-three percent of the records included the establishment code of the source beef, 72% included the grind date and time, and 59% included the lot number of the source beef. Seventy-five percent of records noted whether trimmings were included in grinds, and 57% documented cleanup activities. Only 39 (22%) records had all of these variables completed. Of stores that did not keep grinding logs, 40% were unaware of their purpose. To facilitate effective and efficient traceback investigations by regulatory agencies, retail establishments should maintain records more detailed and complete of all grinding activities.

Consumption of beef, particularly ground beef, is a risk factor for infection with several foodborne pathogens, including *Escherichia coli* O157:H7 and *Salmonella (8, 10)*. Foodborne disease outbreaks with ground beef as a vehicle of infection are relatively common; in 2006, outbreaks caused by ground beef accounted for approximately 10% of outbreaks with a known food vehicle *(3)*. Contaminated ground beef ground at grocery stores or other retail establishments has been implicated in a number of outbreaks *(8)*. In some of these outbreaks, investigators found that although the retail establishment where the beef was ground or purchased could be identified, determining the source of the implicated beef supplied to the retail establishment was difficult or impossible. To identify the source of the contaminated product (traceback investigation), investigators must be able to determine what products were incorporated into each batch of ground beef, on what day, and whence these products originated. Additionally, records of beef grinding activities (grinding logs) can help investigators to identify other potentially contaminated batches of meat that might have originated at the same establishment, and other establishments that might have been affected by contaminated product (traceforward investigation). Difficulties in these investigations have been attributed to poor retail recordkeeping practices or to inadequate or incomplete grinding logs.

While establishments are required by both the Federal Meat Inspection Act (21 United States Code [U.S.C.] 642) and the Poultry Products Inspection Act [21 U.S.C. 460(b)] to keep records that will disclose fully and correctly all transactions involved in their business subject to the acts (including keeping bills of sales, invoices, bills of lading, and receiving and shipping papers), there are currently no U.S. Department of Agriculture (USDA) or state requirements to generate or maintain grinding logs. Because many USDA Food Safety and Inspection Service (FSIS) traceback activities have been impeded by lack of information, the FSIS and public health officials continue to encourage businesses to maintain production records such as grinding

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TABLE 1. *Summary of store characteristics and grinding activities in EHS-Net sites, by store type, 2008*

Characteristic	Store type:		
	All ($n = 125$)	Chain ($n = 74$)	Independent ($n = 51$)
Median no. (range) of grinds per week	7 (2–140)	10 (3–140)	7 (2–42)
Median no. (range) of kilograms per grind	18 (1–363)	23 (2–182)	14 (1–363)
Stores using trimmings for grinds (%)	78	91	61
Among stores using trimmings in grinds, those grinding separately (%)	78	90	52
Stores maintaining grinding logs (%)	49	74	12

logs that provide important information about how, when, and where product was prepared, shipped, received, stored, and handled.

The Environmental Health Specialists Network (EHS-Net) is a network of environmental health specialists and epidemiologists in nine states *(7)*. The network conducts special studies to evaluate food preparation and handling practices in restaurants and retail establishments. After a multistate outbreak of multidrug-resistant *Salmonella* Newport infections attributed to store-ground beef *(2, 6),* we initiated a study in EHS-Net sites to evaluate the prevalence of grinding logs in retail establishments. The primary objectives of this study were to describe how often retail establishments keep grinding logs and to determine the completeness of these grinding logs.

MATERIALS AND METHODS

Three EHS-Net sites (California, Minnesota, and Tennessee) participated in this survey. Each site surveyed a convenience sample of retail establishments that ground beef in their respective jurisdictions; the establishments were selected based on the site's schedule for routine facility inspections and a priori knowledge about whether each establishment ground beef in the facility. The survey was administered as part of routine facility inspections. The survey contained questions on the type and size of the store, the number of times beef was ground each week and the number of kilograms contained in each grind, and whether grinding logs were kept in the store. Each store that kept grinding logs was asked the reasons logs were kept (e.g., corporate requirement), for how long logs were kept, and where the logs were kept (e.g., in store, at corporate headquarters). Additionally, we asked if the establishment included trimmings (i.e., beef remnants typically produced during the cuttings of steaks and other cuts that are routinely incorporated into ground beef products) in beef grinds.

In each establishment that kept grinding logs, three records of individual grinds from the previous month were randomly selected and reviewed to determine whether data elements needed for traceback and traceforward investigations were completed. These data elements included the date and time the grind was performed, the type of product produced, the lot and establishment code of the source beef, whether cleanup was performed between grinds, and whether beef trimmings were included in the grind. Descriptive data analysis was performed with SAS, version 9.2, software (SAS Institute Inc., Cary, NC).

RESULTS

Of the 125 stores surveyed, 43 were in California, 33 in Minnesota, and 49 in Tennessee. Seventy-four (59%) stores were classified as chain stores, and 51 (41%) stores were classified as independent. Among the 70 chain stores for which ownership information was available, 58 were corporately owned or operated, and 12 were franchisee owned. Most of the stores (91 [73%]) were grocery stores, 14 (11%) were ethnic or international stores, 10 (8%) were butchers or meat markets, and 10 (8%) were another type of establishment.

Overall, the surveyed stores ground beef a median of seven times per week and ground a median of 18 kg per grind, but this differed between chain and independent stores (Table 1). Chain stores also ground more beef in each grind. Three-quarters of stores reported that they used beef trimmings in grinds, and this practice was more common in chain stores (91%) than it was in independent stores (61%). Among the 98 stores using trimmings in grinds, chain stores were also more likely than were independent stores to report grinding trimmings in batches separate from other beef grinds (90 versus 52%).

Overall, 61 (49%) stores kept grinding logs, including 55 (74%) chain stores, but only 6 (12%) independent stores. Among the stores that kept grinding logs, a number of reasons were cited for keeping them, including a corporate or franchise requirement (64%), for store records (23%), for state requirements (16%), for USDA requirements (11%), or another reason (21%). Most stores (39%) kept logs for 6 months to 1 year, 36% of stores kept logs for more than 1 year, 21% for 1 to 6 months, and 3% for less than 1 month.

Stores that did not keep logs were asked why not. The most common reason stated was that they did not know what logs were (35%). Other common reasons stated included because they were not required (21%), that they were supposed to keep them but did not (6%), and that they were too busy or it was too much paperwork to keep logs (5%).

We reviewed 179 grinding log records in the 61 stores that kept grinding logs. Overall, 22% of records included information for all of the data elements that are needed for a traceback or traceforward investigation. The remaining records were either only partially completed or the grinding logs did not record all of the necessary data elements; we did not distinguish between the two. Most records (164 [92%]) indicated the type of product (e.g., 90% lean) produced during that grind, whether trimmings were included in the grind (135 [75%]), the grind date and time (131 [73%]), the establishment code of the source beef (129 [72%]), and the production date of the source beef (120 [67%]). About half of records included the lot number of the source beef (106 [59%]) and whether cleanup was

performed after that grind or on that day (104 [58%]). Fewer records (69 [39%]) contained the ''use-by'' date of the source beef.

DISCUSSION

Accurate recordkeeping by retail establishments that grind beef is essential for complete and effective investigations during foodborne outbreaks associated with ground beef. In a survey of retail establishments in three states, we found that only half of stores kept grinding logs to document their beef grinding activities, and that grinding logs were more common in chain than they were in independent establishments. Among stores that kept logs, only a quarter maintained complete records needed to conduct a traceback investigation.

The FSIS relies heavily on records maintained by retailers to aid in traceback and traceforward investigations of products associated with illness and other food safety incidents, to determine quickly and effectively the source product, and to ensure that appropriate controls are implemented, because contaminated product can be widely distributed among retailers. With effective traceback and traceforward, contaminated products can be removed from the market in a fashion timelier and more complete, helping to prevent further cases of illness. When traceback and traceforward investigations cannot be completed because of incomplete information, illnesses could continue to occur *(4),* and recurrent outbreaks associated with the same source might occur *(1, 4).*

Our findings from this survey are consistent with those reported from recent investigations of outbreaks associated with beef products ground at retail establishments. In 2007 and 2008, the FSIS conducted 16 such investigations involving retail operations *(9).* Nine (56%) establishments kept grinding logs that contained sufficient information for traceback and traceforward activities; five of these nine investigations resulted in recall actions.

Meat grinding is an important source of cross-contamination in retail establishments *(5).* In the current study, just over half of the stores we surveyed documented cleanup after grinding beef in their grinding logs. We did not document or review the procedures used by each store for cleanup between grinds, and could not assess whether cleaning activities were sufficient to prevent cross contamination; similarly, we did not assess cleanup procedures in stores that did not keep grinding logs. If cleaning is not documented properly, it might be impossible for investigators to determine the source of a contaminated lot of beef.

Most stores that kept grinding logs cited keeping them to meet a corporate–franchise, state, or USDA requirement, although neither the USDA nor any of the states included in this study had regulations that required retail establishments to keep grinding logs. While it is heartening that many corporate chains and franchises do require their stores to keep records of grinding activities, only half of the establishments we surveyed even maintained records, and in particular, independent stores kept records of grinding activities less frequently. More work is needed to ensure that retail establishments maintain grinding logs that contain sufficient information for traceback and traceforward investigations.

This study had several limitations. First, we surveyed a limited number of stores, and stores were selected based on convenience rather than a sample more systematic or random. We included more than one store from some chains in the analysis, possibly biasing our findings to reflect the practices of selected corporations or company policies. While our findings were similar across all three participating sites, it is possible that the findings are not representative of other states or of other jurisdictions in the states included in this study. Last, although evidence from outbreak investigations supports the utility of grinding logs, the study was not designed to evaluate any establishment's safety benefits because of keeping grinding logs.

While proper recordkeeping will aid in more efficient and effective traceback and traceforward investigations, and might help to reduce the scope and duration of outbreaks, grinding logs are only one part of a range of activities that are essential to limit foodborne infections. Other interventions are needed to reduce the prevalence of pathogens such as *E. coli* O157 on beef products *(5),* and consumers should continue to be vigilant about preparation of ground beef products and prevention of cross-contamination in the home.

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Best Practices For Retailer Operations Producing Raw Ground Beef

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Best Practices for Retail Operations Producing Raw Ground Beef

Introduction:

Producers of raw ground, including ground beef, products recognize that these products have an inherent food safety risk due to the nature of the process and the lack of a sufficient "kill" step for biological hazards in the process. Therefore, it is extremely important that retail operations producing raw ground beef implement Best Practices to produce the safest products possible by increasing total process control throughout the process. This document focuses on retail operations that are grinding beef in the store, not the handling of ground product that is purchased in the final packaged form. For detailed information on developing a total food safety program the Food Marketing Institute (FMI) has developed a document entitled, "A Total Food Safety Management Guide: A Model Program for Category: Raw, Sold Ready to Cook Product: Ground Beef."

This document provides guidelines for grinding and can be used by retail operations to develop store specific programs. The guidelines are designed to provide a recommended set of practices and procedures that retail operations may want to adopt in their entirety or part to ensure optimal quality and food safety. It also addresses the issues of designing an effective lotting system and reprocessing ground products. These recommendations focus solely on the production of raw ground beef.

It should be noted that the following items are not fully addressed in this document, but they should be covered by existing retail operating procedures and/or other store-specific processing programs.

- Personnel — disease control, hygiene, clothing, training, etc.
- Retail Facility — construction and design, product flow, drainage, etc.
- Sanitary operations — general maintenance, cleaning and sanitizing, pest control, etc.
- Sanitary facilities and controls — water supply, plumbing, sewage disposal, rubbish and offal disposal, etc.
- Freezer and coolers — monitored and maintained to ensure temperature control, recording devices, alarms, etc.
- Equipment maintenance and calibration — adequate frequency for thermometers, recording devices, compressed air equipment, etc.

A training document (Attachment 1) developed by Costco is included in this document as an example, but it is recommended that each store develop store-specific information. Many of the items listed above are also addressed in 21 CFR Part 110 – Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food (Attachment 2) – which was developed by the Food and Drug Administration and can be used as a resource if more information on any of these areas is needed.

LOTTING

All retail grinding operations should have a lotting mechanism for coding and recording finished ground products to allow for tracing the product back through the system for tracing the product forward through the chain to determine when it was sold and how much was sold vs. disposed of at the store. Some retail operations may develop computerized bar codes or tracking systems that are very elaborate and detailed, and others may have simple handwritten documentation and box/package codes. Lotting is usually driven by some time factor (i.e., hour, shift, day, etc.) or by raw materials (i.e., sirloin, chuck, etc.) and is given a specific identification code. Creating smaller lots or utilizing a sub-lotting system for tracking information may help demonstrate/document process control and could possibly help minimize the economic impact of a recall from product that is ground in the store.

Regardless of the mechanism each store should have a record keeping system, and the following items may be considered for each identified lot/sub-lot.

- Raw material source(s) by vendor, including vendor lot identification, time used
- Data collected during process (product and/or storage temperatures, microbial data, etc.)
- Metal detector records, if used
- Equipment evaluation records (i.e., grinder checks)
- Bone collection records, if applicable
- Date placed in the case/date removed from the case and disposed of at the store, if applicable

If any abnormal condition(s) (odor, off color, etc.) are found during the grinding process then it is recommended that the product be segregated, that the grinder and all other equipment be cleaned and sanitized prior to reinitiating grinding process, and that a new lot /sub-lot is started when product begins. It is best if information can be documented to show what the problem was, the product(s) that were involved, how the product was handled, and that the equipment was cleaned and sanitized appropriately.

While retail operations may grind small or limited amounts of beef in the store, it is still important that retailers fully understand the importance of product identification and lotting. The concept of lotting systems in ground beef productions is a complex and detailed issue. The existing USDA definition for a lot, when there is a positive result for *E. coli* O157:H7, is “from full sanitation to full sanitation.” In most federally established commercial grinding operations this definition may impact a full day’s production of ground beef. However, proper documentation and controls (including product testing) may allow finished products to be sub-lotted under this definition to minimize the amount of affected products.

A retail operation may also consider sub-lotting under the context of the definition described above. If so, then the following types of documentation are useful:

- Batching records — These records should identify the types of raw materials used by its tracking codes; the amount used in each batch of formulated product, the time it was used and the grinder that it was ground in, if there is more than one grinder.
- Packaged product tracking systems — The finished products should be coded with the actual times they are packaged and placed in the retail case.
- Microbiological testing and tracking — If a retail store is sampling and testing finished formulated raw materials from each batch for potential microbial adulterants, then it should include the batch number samples, the time of the sample and a protocol tracking form for submission to the laboratory used for analysis. It is extremely important that a retail store clearly identifies what lots/sub-lots are represented by the sample being tested.
- Finished Product "Test and Hold" Programs — If a retail store is testing finished ground product for potential microbial adulterants, then it should place all of the product on hold until the laboratory testing is completed and the results are available.

Utilizing the guidelines provided above will allow retailers to better identify and document the amount of suspect or affected product. For example, if one composite sample for formulated products tested positive for *E. coli* O157:H7 during a day's production where all other composites tested negative, then the information discussed above may provide added assurance that sufficient controls were in place to minimize the amount of product affected and the impact of a recall.

Sub-lotting can also be used for other potential contamination such as a physical contaminant. Sub-lotting for physical contamination will require the following:
Batching records — These records should identify the types of raw materials used by its tracking codes, the amount used in each batch of formulated product, grinder head, the time the batch was formulated, the cleaning and inspections by authorized representatives.
In-process Control Records — These records should identify the types of control checks performed on metal detectors and other control instruments, the time checks were performed and the line and/or product code information.

REPROCESSED PRODUCT

Retail store grinding operations must address the use of reprocessed product and should not reintroduce product from one's day's production to the next. For the purpose of the best practices, a lot was defined as the finished product and a batch was defined as material that is in-process. The following categories are recommended to help distinguish between the types of raw materials being reintroduced and the points of entry into the grinding operation.

1. Distressed/Returned product — Retailers should dispose of all product that is returned by a customer or has been distressed at the store-level.

2. Out-of-date product — Out dated products should be discarded and should not be introduced into ground product. Use of products that are nearing the expiration date (i.e., round) will need to be properly identified and may impact the shelf-life of the ground product.

The recommendations provided above should help a retailer make decisions relating to the reprocessing of products. Each store will need to carefully consider the options and determine which one works best within their process based on amount of production, opportunities for further processing, etc. Each retailer is encouraged to develop written procedures for how it will handle and document these issues. Retailers should note that any time product is being reprocessed food safety considerations must come first.

BEST PRACTICES

The following guidelines for developing best practices for retail store that are grinding beef are recommended for voluntary consideration and use in developing store-specific procedures. These are not designed to control specific food safety hazards, but are intended to provide useful information to help stores produce safe and wholesome products. For detailed information on developing a total food safety program the Food Marketing Institute has developed a document entitled, "A Total Food Safety Management Guide: A Model Program for Category: Raw, Sold Ready to Cook Product: Ground Beef."

Raw Material Source:

Retail stores should encourage/support further actions at all sectors of the industry (from animal production to consumer) to reduce microbial contamination and foodborne illness. This is especially important for ground beef and the control of *E. coli* O157:H7. The responsibility for safe food depends upon all sectors working together to produce the safest food possible for consumers. Stores that produce ground beef are responsible for outlining the requirements for raw material suppliers and for establishing a procedure to verifying that all of the requirements are implemented and working as designed. From a retail store's perspective, there are three basic points that could be considered in selecting suppliers for raw materials for ground product(s).

A. Process Interventions and/or Controls for Food Safety
   1. HACCP
      Ensure that the supplier has a HACCP program that meets all regulatory requirements and has been validated to control the food safety hazards identified as reasonably likely to occur. Retail operations may want to verify that these programs are in place and implemented appropriately.
   2. For Beef, the following items are specific to *E. coli* O157:H7

a. Suppliers of beef should have validated process interventions and/or validated Critical Control Points (CCPs) in place to prevent, eliminate or reduce *E. coli* O157:H7 to a non-detectable level. Validation may include scientific literature and/or store specific validation using indicator organisms, and it should be specific to the process(es) being applied at the store. This can be incorporated into the retail store's purchase specifications or other store programs to ensure that all raw materials are produced using validated CCPs or process interventions. If a retailer is requiring testing for E. coli O157:H7, the specifications and testing protocol could be included in the purchase specifications. This is true for both domestic and imported suppliers of raw beef to be used in ground product(s).

B. Foreign Material Contamination:

Retail stores should track unacceptable inclusions, indigenous and foreign materials, found in raw materials to help identify trends in suppliers. These findings should be shared with the supplier to help them improve their process, and may be a factor in supplier selection for future orders. This should be included in specifications to the supplier outlining items that are not acceptable in the raw materials.

C. Testing / Prescreening Requirements:

1. Sampling and testing for *E. coli* O157:H7 (by supplier or retail store)
   There should be a written protocol for sample collection, lab analysis and proficiency testing, as well as the procedures for reporting the results. It is very important that the supplier and the customer fully understand what the sample represents (i.e., a single combo, a composite of 5 combos, an entire trailer load, etc.), and the steps to be taken in the event of a positive. Communication is extremely important for reporting the test results if the product is being transported to the customer while the test is pending to ensure that all positive product is handled according to the store's written protocol.
2. Other microbiological Testing (Salmonella, APC, TPC, coliforms, etc.)
   As above, there should be a written protocol for sample collection, lab analysis and proficiency testing, as well as the procedures for reporting the results. It is important to establish how the results will be used before data are collected. Most of these microbiological tests are used for tracking supplier trends over time; however, each store must clearly define how they are going to use the information and the consequences of failing to meet the testing requirements.
3. In-store microbiological testing
   If a retail store elects to conduct its own testing of raw materials and/or finished product, then it should notify the supplier because the results may impact the supplier's production and distribution of product.

Supplier Evaluations:

Raw material suppliers are critical to both food safety and quality aspects of producing ground products. Therefore, it is important that each new supplier is approved prior to using their products, and that there is a procedure for evaluating on-going suppliers. The following guidelines can be utilized to help design a system for evaluating suppliers.

A. New Supplier Approval:
   1. Each new supplier should provide written acknowledgement of the retailer's purchase specifications and willingness to comply.
   2. Each supplier should meet the guidelines outlined in the purchase specifications for microbial testing and profiling. For new suppliers a retail grinder may want to establish an intensified sampling program to determine if the supplier can consistently meet the specifications.
   3. Each store should have a supplier audit conducted on a specified frequency to ensure compliance with the purchase specifications and other programs. The audits may be conducted by the retail grinder or by a third-party auditor. The audit requirements should be provided to the supplier as part of the purchase specifications.
   4. Retailers should conduct quality inspections of incoming materials to ensure that they are acceptable. For new suppliers a retailer may want to intensify the sampling frequency to ensure consistency in meeting the requirements.

B. Ongoing Suppliers:
   1. Retail grinding operations should periodically provide an update of the purchase specifications to each supplier and request on updated acknowledgement of receipt of the specifications and a willingness to comply.
   2. Data should be collected and tracked on the following items to identify supplier trends and help make purchasing decisions:
      a. Microbial profile data — may include, but not limited to: *Salmonella*, *E. coli* O157:H7, generic *E. coli*, Total Plate Count (TPC), Aerobic Plate Count (APC), and coliforms.
      b. Retailers may want to include periodic verification of results with a third party analysis.
      c. Foreign object contamination
      d. Defect(s) (unacceptable indigenous inclusions)
      e. Store Audits Results
      f. Age of Product at receipt
      g. Temperature of Product at receipt
      h. On-time Delivery
      i. Other store specific requirements

Pre-Receipt of Raw Material(s) Verification:

Based on all of the purchase requirements and store specifications, it is important that a system of checks and balances are put in place to verify that the supplier is conducting their program as planned. This verification process will help minimize problems and increase the integrity of the entire supplier purchasing program.

A. Negative Pre-Screen for *E. coli* O157:H7

The best practice is to have a negative *E. coli* O157:H7 test result from the laboratory or the supplier prior to opening the trailer or receiving the product. This should include all documents related to product identification, written notification of the test results, bill of lading, seal number on load, if applicable, and other identification and tracking information.

If the product must be removed from the trailer prior to receiving the written negative test result, the retailer should have written and documented procedures for off-loading, tagging and holding all of the product to ensure that it is not used prior to receiving the negative test result for *E. coli* O157:H7. This will require good tracking documentation procedures and sufficient training of all employees involved in both receiving and production to prevent the use of the product. The retail store should refuse receipt of any raw materials that test positive for *E. coli* O157:H7.

B. Seal integrity (security)
The optimal process is to seal the truck and have one delivery stop; however, this is not always possible. If the delivery will include multiple stops, then there should be a procedure for re-sealing the load and a tracking system for each seal placed on the truck. This process will help maintain product integrity and security.

Receipt of Raw Material(s):

Receiving Meat

Incoming raw meat materials should be evaluated to ensure that they meet the store-established purchase specifications. Trucks, containers and carriers of raw materials should be evaluated upon receipt to ensure that the conditions meet store requirements for transporting meat. All containers/cartons should be intact. All incoming meat should be coded/identified for store use and for the in-store tracking system. Retailer should verify that the received product is identified on invoice and the product identified on microbiological test results, if applicable.

Specific items to consider:

1. Designated employee(s) should verify that the raw material is from a store approved supplier. Each retailer should set supplier requirements and maintain a list of approved suppliers.

2. Designated employee(s) should evaluate and document on a product receiving log the condition of the trailer, shipping container(s), and carriers of raw materials upon arrival, and should document the time the inspection was conducted. Items for evaluation may include:

   • Retailers should ensure that chemicals or other compounds that may contaminate the raw materials are not being transported on the trailer.
   - Cleanliness of trailer — no foreign materials, dirt, free of debris, free of off odors

• Temperature of trailer —temperature of the trailer must be acceptable to maintain product temperature. Retailer may set a specific temperature for the product and/or the trailer as part of the purchasing specifications. If specific temperatures are set, then there should be a written procedure that defines the action(s) that will be taken if the temperature does not meet the specification.
• General trailer condition — void of cracks, insulation in good condition, trailer door is sealed properly, paper on floors for carcass carriers, etc.

3. If the truck condition is acceptable, the designated employee should verify that the incoming material matches the store purchase specifications and/or required documentation is provided with the load. The following items may be included:

   • Species identity and/or origin
   • Domestic vs. foreign supply source
   • Boning date/ slaughter date
   • No foreign objects
   • Verification of intended use — verify product and box/combo identification matches the product ordered and the bill of lading, including the proper match for product and test results.
   • Supplier microbiological testing results, if required. If the supplier is required to test for *E. coli* O157:H7, then the material should not be used until the test results are received. Raw materials should be refused if it test positive for *E. coli* O157:H7. If the supplier is testing for generic *E. coli*, coliforms, TPC or other microorganisms that can be used to establish supplier trend data, then the product does not have to be held until the results are received. However, if specific accept/reject levels are set for any specific microorganism then the product should not be accepted until test results are received.
   • Packaging/pallet requirements — i.e., no metal fasteners or bands, pallets in good usable condition, slip sheets, covers on combos, plastic pallets, etc. It is important that package integrity is maintained and documented.
   • Age of raw material — recommend fresh products be used within $\leq$5days from fabrication; and frozen meat no more than 6 months from fabrication.

4. If the product meets the purchase specifications, then the designated employee should evaluate the actual condition of the raw materials. The following items are recommended for evaluation:

   • Temperature of raw materials (i.e., frozen $\leq$10°F; fresh $\leq$41°F or less). Each retailer should have a separate procedure for taking the temperature of incoming product and calibrating thermometers. Recommend both core and surface temperatures of the product.
   • Organoleptic evaluation of raw material for off odor, discoloration, improper appearance.
   • Material must have supplier code information and proper lot/load identification on materials.

5. If incoming raw materials pass the receiving inspection, then all raw materials should be placed into inventory and receive any retailer specific tracking/coding information prior to entering the storage area or being used in the grinder.

Use of Trimming Generated In-Store:

Some retail stores may decide to not use trimmings generated in the retail store in the production of ground beef. However, if trimmings are going to be used in the production of ground beef, then the retailer should develop and implement a tracking system to properly identify the source of the trimmings. It is recommended that in-store trimmings be ground within 24 hours, and should be stored under ≤41°F.

Non-meat Ingredients

Retailers will also need to make sure that all non-meat items ingredients, such as seasonings/spices, etc. meet the store-established specifications. After the retailer accepts the non-meat ingredients, then these items should be stored, handled and used in a manner that will maintain the integrity of the items.

Storage of Raw Material(s):

Raw materials should be used on a First-In/First Out (FIFO) basis or according to a store specified product rotation/inventory control schedule. Raw materials should be stored at temperatures that maintain proper product condition – temperature, integrity, etc. Frozen materials should be kept frozen, unless tempering or thawing is required prior to use. The packaging/pallet integrity must be maintained throughout the storage period to maintain the condition of the raw materials. Product identity in storage should allow for proper in-store tracking system.

Specific items to consider:

1. For shelf-life purposes place fresh raw materials into cold storage (i.e., ≤41°F or less) and frozen product into freezers (i.e., ≤10°F or less).

2. Develop retailer specific storage records or product identification, so product will be used on a FIFO basis or according to store product rotation/inventory control schedule.

3. Store raw materials to maintain package/pallet integrity. Boxed product should remained in closed box and combo bins should be covered during storage to prevent contamination.

4. Storage conditions should be maintained according to pre-requisite program requirements to ensure product integrity during storage.

5. Individual store security should address raw material and finished product storage areas.

Raw Material Processing:

Tempering/Thawing of Frozen Materials

If tempering or thawing is required prior to use, then it should be done in a time/temperature controlled manner that is adequately monitored and documented and verified. The product package integrity is important during this process. The product's traceability should be maintained throughout the tempering/thawing process. It is advisable to have a written program that outlines specific guidelines or procedures.

Specific items to consider:

1. Place frozen product in a tempering room that is ≤41°F and allow product to reach desired level of tempering or thawed state; actual time will vary depending on amount of product and type of packaging. (If the room temperature is higher than 41°F then one must evaluate the time/temperature relationship to reduce the risk of potential microbial growth on the surface of the product.) You may want to consider air temperature and velocity to ensure proper thawing.
2. The product should be monitored on a scheduled basis to prevent degradation of the package integrity and minimize product drip.
3. The product temperature should be monitored on a scheduled basis to ensure that the desired end temperature is not exceeded.
4. All of the products should maintain the store-specific tracking/coding information to ensure proper traceability of product from receiving through to final end products.

Grinding/Processing Records

Grinders should cleaned and sanitized between lots and should be document on the grinding logs. The grinding logs should include weighing, mixing, blending, coarse and final grinds, forming, packaging, and labeling and other specific aspects of the process. Throughout all of these steps the temperature of the product should be maintained. Steps should be taken to prevent species cross-contamination and proper labeling to maintain end-product identity. Procedures for ensuring proper endproduct characteristics (i.e., weights, size, shape, quantity, etc.) should be in place. The in-store tracking mechanism should allow for batch identification and time of batch production.

Specific items to consider for grinding:

1. Prior to initiating the grinding process, retailers should ensure that negative *E. coli* O157:H7 results have been received, if the raw material was subjected to testing.

2. Formulation of the product should utilize a grinding logs to document product identification and includes raw materials used, specific weights and amounts, fat

percent, etc. The formulation documentation should address quality characteristics, product specifications, and traceability both forward and backward in the production system.

3. Temperature monitoring of the backroom and the product to ensure integrity. The room temperature should be controlled and the actual time of processing should maintain product integrity, including maintaining the temperature below 41°F during production. A target of ≤50°F for the room is most often used and records of actual room temperatures should be maintained.

4. Defect inspection and elimination systems should be used when possible for bones, metal, etc.

5. Appropriate identification and tracking for traceability purposes should be maintained for all reprocessed product.

6. Retail employees should complete an evaluation of the equipment (grinders – plates and blades, defect eliminators, metal detectors, etc.) on a scheduled basis and the time of each evaluation should be recorded. It is important that this is performed during the production of ground beef, and that this information is reviewed prior to placing the packaged product in the retail display case. This will help minimize the risks associated with equipment malfunctions that can impact the product.

Packaging/Labeling:

It is important that the finished product is properly packaged and labeled to protect the integrity of the product and to provide appropriate handling and cooking instructions to the consumer.

Specific items to consider:

1. Package material must be approved for use with food.
2. Package materials must be stored in a manner to prevent contamination and the material must protect the finished product.
3. The product identification/tracking mechanism should identify specific processing lines used to produce this finished product. This may help narrow the product impacted if there is a problem with a particular processing line that does not impact the other lines.
4. Packaging and labeling employees are responsible for properly labeling end-products with product identity and proper code dates for example: expiration date, sell-by-date, use-by-date, production date and time, using a dating system according to the regulations for opening dating.
5. Packaging and labeling employees are responsible for including all safe handling and storage information according to each product's requirements, as well as specific cooking instructions. Safe handling labeling is required by USDA.

Storage of Finished Product and Products Displayed in Retail Case:

Finished products should be stored or placed in a retail case designated to maintain temperatures (≤41°F) over time to ensure product shelf-life and product safety. A FIFO or a store specified product rotation/inventory control schedule should be maintained for finished products. The package integrity should be maintained throughout the storage period to protect the condition of the finished product. Product identity in storage and during case display should allow for the in-store tracking system to be used for stock rotation and for recall and/or market withdrawal purposes.

Specific items to consider:

1. For shelf-life purposes place fresh product into cold storage and frozen product into freezers.
2. Utilize products in a specified time-period to maintain shelf-life requirements. Shelf-life of the product is dependent upon the type of product, type of package, temperature of storage, condition of incoming materials, etc. Therefore, each retailer should have specific guidelines for storing/displaying and utilizing finished products.
4. Storage/display conditions should be maintained according to pre-requisite program requirements to ensure product integrity during storage and display.

SYSTEM CHALLENGES TO MEASURE EFFECTIVENESS:

Recall Program and Mock stock recovery drills:

All retailers that grind beef should develop a recall program. The program should include mock recalls conducted on a periodic basis to ensure that the program works as planned. The recall program should include identification and tracking of raw materials, packaging, and finished products. The program must be able to cover all raw materials (meat, non-meat ingredients), packaging materials to the finished product. The program should identify all suppliers, customers, distributors and everyone involved in the process. The more details that are put in place prior to having a problem, the easier the recall or withdrawal will be if there is a problem. Retailers should have a tracking system to ensure that product that is pulled from the retail display case is documented (date pulled, amount, reason for pull, etc.).

Store Security:

Store security systems should address the security of the raw meat and the finished packaged product storage prior to being placed into the retail case. Access should be limited to designated employees only as part of the security program.

SANITATION:

Periodic sanitation practices must be followed to prevent the potential for product contamination. It is recommended that sanitation procedures should be a written schedule. Cleaning and sanitizing chemicals should be identified and stored separately from raw meat, grinding area and equipment, and finished products. It is recommended

that grinders and other equipment should be cleaned and sanitized between lots and documented on the grinder log.

HACCP IN A GRINDING OPERATION:

As we all know, HACCP is a process control system designed to prevent, eliminate or reduce to an acceptable level food safety hazards. The retailer should consider biological, physical, and chemical food safety hazards. This a raw process that has no scientific CCP for preventing, eliminating or reducing to an acceptable level microbial food safety hazards, such as *E. coli* O157:H7. Therefore, retailers that grind must focus on what can realistically be applied during the process to minimize the potential for growth of pathogens, if present on the raw material. These steps often involve time and temperature controls (i.e., raw material and finished product temperature during processing cold storage or other steps) to minimize the potential for growth.

All retailers that grind beef should be able to support the decisions that are made in the HACCP program and to use the documentation generated from the program to demonstrate product safety. For detailed information on developing a total food safety program the Food Marketing Institute has developed a document entitled, "A Total Food Safety Management Guide: A Model Program for Category: Raw, Sold Ready to Cook Product: Ground Beef."

Conference for Food Protection
2012 Issue Form

Internal Number: 069
Issue: 2012 I-015

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Addition to Original Containers and Records Section in the FDA Food Code,

Issue you would like the Conference to consider:
The 2009 FDA Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some retailers may grind intact beef or beef trim to produce ground beef "in house". While this practice is lawful, it may present an increased risk of foodborne illness to consumers, because intact beef may not be subject to the same rigorous pathogen control as ground beef. In addition, mixing of product from various suppliers and lots can spread contamination among the resulting ground product. Failure to adequately separate lots, clean and sterilize grinding equipment can contribute to the risk.

Public Health Significance:
Grinding intact beef "in house" may spread pathogenic contamination from the exterior of an intact product throughout the resulting ground beef, or, may serve as a source of cross-contamination of grinding equipment. Mixing of lots from the same or varied suppliers can spread contamination among resulting product. Outbreaks resulting from these products may be more difficult to trace as a result of the mixed nature of the product. Adequate recordkeeping is thus essential to provide traceback data for public health officials investigating an outbreak.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-203.13 Recordkeeping, Ground Product.
(A) Every FOOD ESTABLISHMENT that performs grinding or packaging of MEAT on PREMISES shall maintain adequate records sufficient to assist public health officials with traceback or other relevant investigation.
(1) Adequate records shall include:
(a) Producing store name, address, city/state/zip
(b) Date of each lot of store ground product produced, where a lot is defined as all identically labeled product produced from full equipment clean-up to clean-up
(c) Exact name/type of store ground product

(d) Amount of each lot of store ground product
(e) Sell by/use by date and/or production code of each lot of store ground product
(f) Other information used to identify store ground product
(g) Full name(s) and product code(s) of all source products used to formulate each lot of store ground product
(h) All Federal or State Establishment numbers of each source product contained in each lot of store ground product
(i) Each source product sell by, use by, or production date/code
(j) The source firm name, establishment number and use by/sell by/production date/code for all Shop trim/rework used in each lot of store ground product
(k) Bills of Sale (e.g. sales receipts) reflecting Item numbers for each ground beef product sold to consumers
(l) Invoice(s) and Bill(s) of lading for source product(s)

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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Conference for Food Protection
2012 Issue Form

Internal Number: 067
Issue: 2012 I-016

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Addition to Duties: Person in Charge Section 2-103.11 of FDA Food Code

Issue you would like the Conference to consider:
The FDA Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some food establishments-retailers as well as restaurants-may grind intact beef to produce ground beef "in house". While this practice is lawful, it may present an increased risk of foodborne illness to consumers, because intact beef may not be subject to the same rigorous pathogen control as ground beef.

Public Health Significance:
Grinding intact beef "in house" may spread pathogenic contamination from the exterior of an intact product throughout the resulting ground beef, or, may serve as a source of cross-contamination of grinding equipment. Further, consumers may mistakenly believe that ground beef produced "in house" in this way is fresher or safer, and thus may order such products undercooked (i.e., rare or medium rare), which is insufficient to kill pathogens.
It is thus imperative that those employees tasked with handling and grinding such meats (and those employees responsible for cleaning the grinding equipment, if different) are specially trained about the importance of rigorous cleaning for the prevention of foodborne illness, the logistics of cleaning, and the maintenance of appropriate records to assist in an outbreak investigation resulting from in house ground products.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting the addition of the underlined language to Section 2-103.11 of the FDA Food Code, *Duties: Person in Charge*:
2-103.11 Person in Charge.
(L) EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties; <u>with enhanced training for those employees who may be responsible for production and handling of "in house" ground beef, such as the grinding of MEAT, PRIMAL CUTS and WHOLE MUSCLE, INTACT BEEF;</u> and

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Conference for Food Protection
2012 Issue Form

Internal Number: 009
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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Use of Consumer Advisory for Non-Continuous Cooking

Issue you would like the Conference to consider:
Add a new section to Section 3-401.14 of the FDA Food Code to allow for the service of raw intact whole muscle beef cooked using a non-continuous cooking process, to be served undercooked with an adequate consumer advisory as described in 3-401.11 (D).

Public Health Significance:
Section 3-401.11 (D) allows for the service of raw or undercooked animal products with the use of an adequate consumer advisory. This important and balanced public health approach, currently not allowed under Section 3-401.14, provides the same level of protection and fair consumer choice for raw or undercooked, or non-continuous and undercooked animal products, such as when large catered events either cook to order or when they partially cook, cool and cook to order. As long as consumers are informed with an adequate consumer advisory as outlined in 3-603.11, the same level of public health protection is assured.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:
Add new language to Section 3-401.14 indicated in underlined language below
3-401.14 Non-Continuous Cooking of Raw Animal Foods.
Raw animal FOODS that are cooked using a NON-CONTINUOUS COOKING process shall be:
(A) Subject to an initial heating process that is no longer than sixty minutes in duration; P
(B) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked POTENTIALLY HAZARDOUS FOOD (TIME /TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.14(A); P
(C) After cooling, held frozen or cold, as specified for POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.16(A) (2); P
(D) Prior to sale or service, cooked using a process that heats all parts of the FOOD to a temperature of at least 74°C (165°F) for 15 seconds; P

(E) Cooled according to the time and temperature parameters specified for cooked POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.14(A) if not either hot held as specified under ¶3-501.16(A), served immediately, or held using time as a public health control as specified under §3-501.19 after complete cooking; P and

(F) Prepared and stored according to written procedures that:

(1) Have obtained prior APPROVAL from the REGULATORY AUTHORITY; Pf

(2) Are maintained in the FOOD ESTABLISHMENT and are available to the REGULATORY AUTHORITY upon request; Pf

(3) Describe how the requirements specified under ¶ (A)-(E) of this Section are to be monitored and documented by the PERMIT HOLDER and the corrective actions to be taken if the requirements are not met; Pf

(4) Describe how the FOODS, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as FOODS that must be cooked as specified under ¶ (D) of this section prior to being offered for sale or service; Pf and

(5) Describe how the FOODS, after initial heating but prior to cooking as specified under ¶ (D) of this section, are to be separated from READY-TO-EAT FOODS as specified under ¶ 3-302.11 (D).

(G) Allow for the service of raw intact whole-muscle beef cooked using a non-continuous cooking process to be served undercooked with an adequate consumer advisory.

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 090
Issue: 2012 I-018

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Report - Recall Evaluation Committee

Issue you would like the Conference to consider:
The Food Recall Evaluation Committee (REC) was tasked with the evaluation of current policy and practice of food recalls of the U.S. Food and Drug Administration and the U.S. Department of Agriculture, with the goal of providing feedback and recommendations that these agencies could consider in improving food recalls and recoveries.
The committee met via a series of webinars for the past 18 months. Membership included a diverse cross-structure of industry and regulators as well as academia and public interest representatives.
The committee believes we have reached consensus on the items included herein and detailed in the attached reports.

Public Health Significance:
Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process.
Consider:

- FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR
- Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA
- Firms affected by the recall throughout the complex food system (distributers, sub-producers, brokers) have no official FDA guidance
- There is no time limit for executing a Class I Recall, or any other Class
- There are no minimum requirements for the information required in a recall notice
- There is no consideration of cost to benefit
- Current Classification system is ambiguous and confusing

Recommended Solution: The Conference recommends...:

- acknowledgement of the Food Recall Evaluation Committee (REC) report and attachments,
- thanking the Committee members for their efforts, and
- disbanding the Committee as the charges are completed.

Submitter Information:

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Attachments:

- "Final Roster 1_6_12"
- "Recall Evaluation Committee Final Report"

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Committee Name: Recall Evaluation Committee

First Name	Last Name	Company /Employer Name	City	State	Role (Chair, Co-Chair, Vice Chair)
David	Abney	Sonic Drive In	Oklahoma City	OK	Member
Laura	Adam	FDA	College Park	MD	Member
Dare	Akingbade	USDA	Wash DC	DC	Member
David	Armatis	Safe Foods First	San Francisco	CA	Member
Patti	Bailey	Yum! Brands, Inc.	Dallas	TX	Member
James	Baldwin	Price Chopper Supermarkets	Schenectady	NY	Member
Rick	Barney	Delhaize America	Tampa	FL	Member
Angela	Benton	Jetro/Restaurant Depot	College Point	NY	Member
Teresa	Bullock	Arkansas Department of Health	Little Rock	AR	Member
Mary	Cartagena	FDA	College Park	MD	Member
Gary	Coleman	Underwriters Laboratories, Inc.	Research Triangle Park	NC	Member
Drew	Falkenstein	Marler-Clark	Seattle	WA	Member
Kelli	Fall	NSF International	Ann Arbor	MI	Member
Laura	Fenton	Advance Food	Enid	OK	Member
Gary	Fleming	Cross Link Group			Member
Robert D.	Frappier	Ahold USA	Braintree	MA	Member
Liza	Frias	Supervalu	Fullerton	CA	Member
Joe	Graham	Washington State Department of Health	Olympia	WA	Member
John	Gurrisi	Darden Restaurants, Inc.	Orlando	FL	Member
Roger	Hancock	Recall Info Link	Boise	ID	Member
George	Hanssen	Nebraska Department of Agriculture	Lincoln	NE	Member
Craig K.	Harris	Michigan State University	Okemos	MI	Co-Chair
Jill	Hollingsworth	Food Marketing Institute	Arlington	VA	Member
Tim	Ihry	USDA	Omaha	NE	Member
Adam	Johnson	Wal-Mart	Bentonville	AR	Member
Larry	Kohl	Food Lion	Arlington	VA	Member
Don	Lane	The Kroger Co.	Cincinnati	OH	Member
Tressa	Madden	Oklahoma State Department of Health	Oklahoma City	OK	Member
Ernie	McCullough	ASI Food Safety Consultants	Cumming	GA	Member
Charles E.	McGuffey	7-Eleven, Inc.	Dallas	TX	Member
Sheri L.	Morris	PA Dept. of Agriculture/Food Safety & Laboratory Services	Harrisburg	PA	Member
Gina	Nicholson	The Kroger Company	Westerville	OH	Member
Kathleen	O'Donnell	Wegman's Food Markets			Member
Joel	Ortiz	Whole Foods Market	Austin	TX	Member

2012 Committee Lists for Program Booklet

Gregory	Pallaske	U.S. Foodservice	Rosemont	IL	Co-Chair
Richard	Parker	HEB	San Antonio	TX	Member
Angela	Paymard	N2N Global	Longwood	FL	Member
Larry	Payton	Tokyo Gardens Sushi	Houston	TX	Member
Stephen	Posey	Brinker International	Dallas	TX	Member
Terrance	Powell	Los Angeles County Dept. of Public Health	Baldwin Park	CA	Member
Gale	Prince	Your Food Safety Coach, LLC	Cincinnati	OH	Member
Ramona	Quintanilla	Proctor & Gamble	Cincinnati	OH	Member
John	Raulerson	Firehouse Restaurant Group	Jacksonville	FL	Member
David J.	Read	Minnesota Department of Agriculture	St. Paul	MN	Member
Karen	Reid	Walt Disney Parks and Resorts US	Lake Buena Vista	FL	Member
Robert	Reinhard	Sara Lee Corporation	Downers Grove	IL	Member
Kenneth	Rosenwinkel	Jewel-Osco/Supervalu	Itasca	IL	Member
Grant	Sherratt	Steton Technology	St. George	UT	Member
Mike	Sostrin	Walmart Stores Inc	Bentonville	AR	Member
Kristina	Stefanski	Ahold/The Stop & Shop Supermarket Company LLC	Quincy	MA	Member
Casimir M.	Tryba	Big Y Foods, Inc.	Springfield	MA	Member
Susan	Tyjewski	CKE Restaurants, Inc.	Ontario	CA	Member
Travis	Waller	Associated Food Stores, Inc.	Salt Lake City	UT	Member
Lisa	Weddig	Better Seafood Board	McLean	VA	Member
Tim	Westbrook	Publix Super Market	Orlando	FL	Member
Laurie	Williams	FDA	College Park	MD	Member
Sharon	Wood	H-E-B Grocery Company	San Antonio	TX	Member

Conference for Food Protection

Recall Evaluation Committee **Final report**

Council: **I**
Date: **01/31/2012**
Submitted by: **Greg Pallaske**

Committee Charges:

Clarify the system of classification for recalls established by USDA and FDA.

Create clarifying instructions and procedures that industry and consumers can easily understand and comply with.

Recommend enforceable and reasonable time frames for execution of recall communications and actions.

Clarify the information required to be included in supplier recall notifications.

Recommend expectations for the notification of end-users, including restaurant and retail customers as well as school and institutional food service.

Report back to the 2012 Biennial Meeting.

Committee Activities and Recommendations:

This document contains an overview of the discussions of the Recall Evaluation Committee of the past two years. Included are some suggestions and ideas that provide a background for the bullets provided in Committee Issue titled: Change in Definitions. These are not specific recommendations, but rather are intended to serve to provide a background into the concerns shared by many committee members.

Charge #1: Clarify the system of classification for recalls established by USDA and FDA.
For example, what is the difference between a "reasonable probability" (Class I) and a "remote probability" (Class II)? Many industry members believe the public does not distinguish between them; therefore, to the public, all recalls are "bad".

To address this issue, the committee felt that different terminology may be helpful. One set of terms under discussion was to use the word "recall" only for what is currently a Class I situation. Thus we defined "Food Recall" as *a health risk to the general public*, and generally agreed that a "food recall" should coincide with what the FDA generally defines as a "reportable food" or the USDA classifies as a Class I Recall.

The equivalent of what is currently a Class II recall was a bit more problematic

– many of us noted that historically, Class II's have been situations where a major allergen was not listed on the product label, and thought the term "Allergen Alert" would be appropriate. Other committee members felt the term was too narrow as not all Class II equivalents are caused by one of the big eight allergens. Their term of choice is "Food Alert". Either of these is defined as *a health risk to allergic/selected/sensitive populations*.

Finally, the term agreed upon for the equivalent of a Class III is "Food Notification", defined as *little or no health risk*.

A great deal of discussion centered on the difficulty on the part of industry and the public in distinguishing the differences between a Class I, II, and III Recall.

Regardless of the terminology used, the committee overwhelmingly agrees that recalls must be classified upon release. To better accomplish this goal, the committee recommends creation of a decision tree for classification of recalls, with the following stipulations:

- Tree should be transparent and readily available as a tool to industry and regulators
- The decision tree should be developed jointly with industry, regulators, and consumer representatives
- The tree is a guideline, not an absolute rule – regulators maintain final classification decision
- The same/ similar tree/ system should be followed by both FDA and USDA

Charge #2: Create clarifying instructions and procedures that industry and consumers can easily understand and comply with.

The committee's concern is that notifications do not clearly delineate the relative risks of the various categories of recalls. To correct this, the committee feels that:

- Recall announcements should clearly instruct public of severity of risk and tell them how to react accordingly
- Instructions should be different for each classification but standardized (public should always get same instructions for Class I, different for Class II, etc.)
- Affected, or potentially affected, industry sectors should be notified at the same time (or before) information is provided to the general public and media
- Announcements should be consistent and more specific consumer messages (for example, explaining the difference between recalls for pathogens that present a risk to the general public versus a recall for an allergen that only impacts a select portion of the population).

Furthermore:

- Guidelines established by the FDA and USDA, working jointly with

industry, should standardize industry best practices on what to do, and when, upon receiving notice of a recall.

- Expectations should differ by classification
- Expectations should be tailored to major industry segments – production, retail, foodservice – as each of these segments bears different responsibilities and reactions

Charge #3: Recommend enforceable and reasonable time frames for execution of recall communications and actions.

Currently, the recall initiating firm is the only entity in the distribution chain with written guidelines for recall actions. Our thoughts:

- Industry best practices should be established by the FDA/USDA and in place for secondary suppliers and distributors
- Expectations should be established for tracing one step forward and back within a defined time frame
- The government agency overseeing the recall should require that originating firm issues classified recall notice and contacts direct receivers
- FDA/USDA should establish expectations for timeliness in notifying next link in food chain
- Receivers should react immediately (defined as within 24 hours maximum – 4 hours for high-risk; or as defined by the FDA and USDA)
- Customers should be contacted/ notices posted as soon as possible (24 hours max- 4 hours for high-risk product recall) following the Food Safety Modernization Act (FSMA) guidelines
- Reports to Agency (product remaining, customers affected) should be submitted in a timely fashion

Note that the issue of retailers notifying consumers has already been addressed by FDA and the Food Marketing Institute (FMI) and therefore was not discussed here.

Charge #4: Clarify the information required to be included in supplier recall notifications.

- Identify the format of the communications downstream- start with existing models (USDA/FDA)
- All Recall Notices should follow the same format
- Identify minimum required information to properly identify the product - note that existing models exist with both government agencies but industry is not required to use them as a template
- Identify minimum best practices for notification, including times
- Classification of the recall should be determined by FDA/USDA and included upon release of the recall notification
- Standardized plain language assessment of risk should be included in the recall notice
- The recalling firm, including contact information, should be included
- Describe the recalled product in adequate detail so that it can be clearly identified and rapidly followed through distribution to the end user. This should

include:

- The product description or some surrogate—manufacturer and product name
- Producing establishment identification /plant numbers
- Brands/ sizes/ packaging/identifying information such as lot codes, manufacturing codes, "sell by" or "best by" dating, retail product UPC, shipping case UPC, etc.

- Provide instructions on how to return, destroy, get credit, or avoid a potential hazard
- Include the Distribution channel (retail, foodservice, etc.) including geographic information – this is especially important because firms and individuals want to know if they are NOT included in a recall.

Charge #5: Recommend expectations for the notification of end-users, including restaurant and retail customers as well as school and institutional food service.

- A Properly Classified recall notice should be publicized on FDA or USDA web site as well as the supplier web site – including instructions how to avoid or minimize harm
- All downstream recipients in the supply chain of a recall (including consumers when required) must be notified by verified phone, fax, or email (note that retail consumer notification is covered under a FSMA committee)
- Federal Agencies are urged to review best methods of communicating recalls to the general public, including use of modern technology.

Requested Action:

The Committee will submit three (3) Issues to the Conference.

1) To acknowledge the Committee report, thank the members, and disband the committee.

2) Requesting that a letter be sent to the FDA and USDA recommending the following

a. Change in definitions:

i. Replace Class I Recall with "Food Recall" defined as *a health risk to the general public*, and should coincide with what the FDA generally defines as a "reportable food" or the USDA Class I Recall

ii. Replace Class II Recall with "Allergen Alert" or "Food Alert" defined as *a health risk to allergic/selected/sensitive populations*.

iii. Replace Class III Recall with "Food Notification" defined as *little or no health risk.*

b. Creation of a decision tree for classification of recalls, with the following stipulations:

i. Tree should be transparent and readily available as a tool to

industry and regulators

ii. The decision tree should be developed jointly with industry, regulators, and consumer representatives

iii. The tree is a guideline, not an absolute rule – regulators maintain final classification decision

iv. The same/ similar tree/ system should be followed by both FDA and USDA

3) Requesting that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing a uniform food recall system. Examples of what should be considered in this initiative include:

- A mechanism for working with industry and other stakeholders to further identify the specific changes needed to enhance the current recall system
- A uniform recall process be used by all federal food regulatory agencies
- A revised classification system that is prompt, transparent and meaningful to industry, regulatory, and the general public using consistent definitions for recall classifications
- Consistent information provided with every recall, especially a decision on the classification
- Clarifying instructions and procedures for industry and the public
- A mechanism for engaging relevant private-sector expertise in recall investigations and recall decisions
- Reasonable "best practice" time frames for execution of recall communications and actions including verification of notification
- Clear and consistent information in recall notifications to each segment of the supply chain including information that clearly identifies the product being recalled in sufficient detail
- Consistent protocol for audits and/or effectiveness checks
- Consistent and more specific consumer messages (for example, explaining the difference between recalls for pathogens that present a risk to the general public versus a recall for an allergen that impacts a select portion of the population)
- A single website and database for all food recalls with a consumer-friendly format

Roster: (see attached)

Conference for Food Protection
2012 Issue Form

Internal Number: 092
Issue: 2012 I-019

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Uniform Food Recall System

Issue you would like the Conference to consider:
The Recall Evaluation Committee requests that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing a uniform food recall system that is easier to understand and contains guidelines and best practices that will make the process faster and more efficient.

Public Health Significance:
Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process.
Consider:

- FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR
- Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA
- Firms affected by the recall throughout the complex food system (distributers, sub-producers, brokers) have no official FDA guidance
- There is no time limit for executing a Class I Recall, or any other Class
- There are no minimum requirements for the information required in a recall notice
- There is no consideration of cost to benefit
- Current Classification system is ambiguous and confusing

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA and the USDA requesting that they work together in collaboration with industry stakeholders on developing a uniform food recall system.
Examples of what should be considered in this initiative are:

- A mechanism for working with industry and other stakeholders to further identify the specific changes needed to enhance the current recall system
- A uniform recall process be used by all federal food regulatory agencies

- A revised classification system that is prompt, transparent and meaningful to industry, regulatory, and the general public using consistent definitions for recall classifications
- Consistent information provided with every recall, especially a decision on the classification
- Clarifying instructions and procedures for industry and the public
- A mechanism for engaging relevant private-sector expertise in recall investigations and recall decisions
- Reasonable "best practice" time frames for execution of recall communications and actions including verification of notification
- Clear and consistent information in recall notifications to each segment of the supply chain including information that clearly identifies the product being recalled in sufficient detail
- Consistent protocol for audits and/or effectiveness checks
- Consistent and more specific consumer messages (for example, explaining the difference between recalls for pathogens that present a risk to the general public versus a recall for an allergen that impacts a select portion of the population)
- A single website and database for all food recalls with a consumer- friendly format

Submitter Information:

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Conference for Food Protection
2012 Issue Form

Internal Number: 018
Issue: 2012 I-020

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Recall Definitions and Decision Tree

Issue you would like the Conference to consider:
The Recall Evaluation Committee requests that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing new terminology for Class I, II, and III recalls that is easier for industry, regulators, and the public to understand. Additionally, that a decision tree be developed that creates more transparency into how a recall should be classified.

Public Health Significance:
Food recalls are the last line of defense when a dangerous or violative food product has entered the marketplace. When a firm is unable to determine proper classification, the process slows down, causing potentially dangerous delays in public notification and distribution chain removal of the product from the marketplace.

Additionally, many suppliers and the general public do not understand the difference in the significance and danger associated with the various classes of recalls. The result is either apathy, where the public pays little attention because of the sheer volume of "noise", or they over-react and needlessly throw out and stop buying perfectly good products. The net result is an unnecessary loss of public confidence in our food supply, as well as a tremendous waste of food.

A great deal of discussion within the Committee centered on the difficulty on the part of industry and the public in distinguishing the differences between a Class I, II, and III Recall. For example, what is the difference between a "reasonable probability" (Class I) and a "remote probability" (Class II)? Many industry members believe the public does not distinguish between them; therefore, to the public, all recalls are "bad."

To address this issue, the Committee felt that different terminology may be helpful. One set of terms under discussion was to use the word "recall" only for what is currently a Class I situation. Thus we defined "Food Recall" as *a health risk to the general public*, and generally agreed that a "food recall" should coincide with what the FDA generally defines as a "reportable food" or the USDA equivalent thereof.

The equivalent of what is currently a Class II recall was a bit more problematic - many Committee members noted that historically, Class II's have been situations where a major allergen was not listed on the product label, and thought the term "Allergen Alert" would be

appropriate. Other committee members felt the term was too narrow as not all Class II equivalents are caused by one of the big eight allergens. Their term of choice is "Food Alert". Either of these is defined as *a health risk to allergic, selected, sensitive populations*. Finally, the term agreed upon for the equivalent of a Class III is "Food Notification", defined as *little or no health risk*.

Regardless of the terminology used, the Committee overwhelmingly agrees that recalls must be classified upon release. To better accomplish this goal, the committee recommends creation of a decision tree for classification of recalls, with the following stipulations:

• Decision tree should be transparent and readily available as a tool to industry and regulators.

• Decision tree should be developed jointly with industry, regulators, and consumer representatives.

• Decision tree is a guideline, not an absolute rule - regulators maintain final classification decision.

• The same/ similar tree/ system should be followed by both FDA and USDA.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA and USDA recommending the following:

a. Change in definitions:

- Replace Class I Recall with "Food Recall" defined as *a health* ***risk to the general public***, and should coincide with what the FDA generally defines as a "reportable food" or the USDA equivalent thereof
- Replace Class II Recall with "Allergen Alert" or "Food Alert" defined as *a health risk to* ***allergic/selected/sensitive populations***.
- Replace Class III Recall with "Food Notification" defined as *little or no health risk.*

b. Creation of a decision tree for classification of recalls, with the following stipulations:

- Decision tree should be transparent and readily available as a tool to industry and regulators.
- Decision tree should be developed jointly with industry, regulators, and consumer representatives.
- Decision tree is a guideline, not an absolute rule - regulators maintain final classification decision.
- The same/ similar decision tree/ system should be followed by both FDA and USDA.

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Conference for Food Protection
2012 Issue Form

Internal Number: 065
Issue: 2012 I-021

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
New Recall Notification Section of the FDA Food Code (Section 3-603.12)

Issue you would like the Conference to consider:
The 2009 FDA Food Code recognizes that consumers may not receive adequate, timely information in the event of a food safety recall, and that retailers play an important role in disseminating critical public health information. Records kept by retailers in the ordinary course of business for marketing or promotional purposes can be extremely useful for notifying consumers and curtailing the spread of an outbreak. Grocery stores and vendors should, when otherwise maintaining customer purchasing data, make every reasonable effort to notify consumers in the event of a Class I Recall.

Public Health Significance:
Removal of contaminated foods is vital to minimizing the adverse impact on consumers and public health, including reducing the size of associated foodborne illness outbreaks. While retailers' actions are essential for rapid removal of recalled foods from shelves, this does not address products that have already been sold. A proposed Food Code amendment offers a solution to better inform consumers about outbreak-associated and recalled products.
Where retailers routinely collect consumer purchasing data, that information can be useful in identifying consumers who may have recalled product still in their homes. Retailers should access purchasing data and the associated consumer contact information to alert consumers to their previous purchases of products that are later associated with a Class I Recall. Such personalized notice will help consumers identify recalled product at home, and will establish the retailer as a source of important public health information.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-603.12 Recall Notification.
(A) Every FOOD ESTABLISHMENT that offers PACKAGED FOOD for purchase by consumers, and that collects data on the purchasing of that food (through customer loyalty cards or other data collection methods), shall, in the event of a Class I Recall of any FDA or USDA product sold by the FOOD ESTABLISHMENT, contact those consumers for which

data is available to indicate the purchase of a product, within the previous 60 days, that is now subject to a recall. Consumers may be contacted via email, text message, telephone, or regular mail, and contact must be initiated within a reasonable time from when the FOOD ESTABLISHMENT receives notice that the FOOD ESTABLISHMENT sold recalled product, not to exceed 2 days from that notice.

Submitter Information:
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Conference for Food Protection
2012 Issue Form

Internal Number: 066
Issue: 2012 I-022

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
New Recordkeeping Section of the FDA Food Code (Section 3-603.13)

Issue you would like the Conference to consider:
The 2009 FDA Food Code recognizes that records kept by retailers in the ordinary course of business for marketing or promotional purposes can be extremely useful for public health officials investigating a foodborne illness outbreak and attempting traceback and attribution. Retailers should make every reasonable effort to give public health officials timely access to such records to assist in an outbreak investigation or for other such lawful and reasonable public health purposes.

Public Health Significance:
Where retailers routinely collect consumer purchasing data, that information is critical to identifying consumers who may have purchased products that are later implicated in an outbreak. That data has also proven to be of great importance to public health officials in performing traceback investigations and food attribution during and after an outbreak. Rapid identification of at-risk consumers (those who have purchased recalled product) is essential to curtailing the size and impact of an ongoing outbreak from contaminated products. Retailers should provide public health officials with customer purchasing data that may be helpful in the course of an outbreak investigation, in an effort to assist with attribution and containment of foodborne illness.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-603.13 Recordkeeping, Public Health Significance.
(A) Every FOOD ESTABLISHMENT that offers PACKAGED FOOD for purchase by consumers, and collects data on the purchasing of that food (through customer loyalty cards or other data collection methods), shall, provide public health officials upon request with timely access to customer purchasing data to assist in a public health investigation or for other such lawful purposes.

Submitter Information:
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Conference for Food Protection
2012 Issue Form

Internal Number: 095
Issue: 2012 I-023

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Shellstock Record Keeping

Issue you would like the Conference to consider:
Modification of the 2009 FDA Food Code to add language that addresses the use of shellstock being simultaneously used from different sources or growing areas. The facility's record-keeping system must be able to distinguish the shellstock that was served to each customer.

Public Health Significance:
The Interstate Shellfish Sanitation Conference (ISSC) continues to address illnesses associated with consumption of raw molluscan shellfish. Our primary focus is to improve our response time associated with illness outbreaks and to evaluate the effectiveness of control programs associated with pathogens which may result in illnesses.
These activities utilize illness investigation information from retail establishments. In recent years there has been improvement and the suggested change is intended to further improve the ability of illness investigators to accurately identify shellstock sources and growing areas. The ISSC and the Conference for Food Protection (CFP) have jointly worked to enhance record keeping at the retail level. In an effort to provide more accurate information which could be used for illness response and program evaluation, the need for this improvement was demonstrated in recent illness data reported by the Centers for Disease Control (CDC).

Recommended Solution: The Conference recommends...:
1. that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language underlined and deleted language shown with strikethrough):

Section 3-203.12, Shellstock, Maintaining Identification

(C) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under ¶ B of this section, by: [Pf]

(1) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under ¶ B of this section; [Pf] and

(2) If shellstock are being used from different sources or growing areas simultaneously that the system can distinguish the source and growing area of the shellstock that was served to each customer; [Pf] and

(~~2~~3) If shellstock are removed from its tagged or labeled container

and

2. that the Conference for Food Protection (CFP) *and* the Interstate Shellfish Sanitation Conference (ISSC) jointly write a letter to State retail food programs requesting that retailers be advised of shellstock identification record requirements for the purpose of improving compliance.

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Conference for Food Protection
2012 Issue Form

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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Food Code Date Marking Provision(s) For Raw, Live In-shell SHELLSTOCK

Issue you would like the Conference to consider:
The 2009 FDA Food Code contains no clear guidance (or exception) regarding date marking of raw, live, in-shell MOLLUSCAN SHELLFISH (i.e., SHELLSTOCK) in a FOOD ESTABLISHMENT when the FOOD is served to the CONSUMER in a raw (i.e., not heated treated) form.
This issue submission seeks clarification from the Conference as to date marking of raw, live, in-shell SHELLSTOCK, received and cold held longer than 24 hours in a FOOD ESTABLISHMENT and served to the CONSUMER in a raw (non-heat treated) form.

Public Health Significance:
Per the 2009 FDA Food Code Section 1-201.10 Statement of Application and Listing of Terms, raw, live in-shell SHELLSTOCK served to the CONSUMER without cooking meets the definition of a commercially processed Ready-To-Eat (RTE) Potentially Hazardous [Time/Temperature Control for Safety Food] FOOD (PHF/TCS FOOD) which was previously harvested and subsequently PACKAGED by a FOOD PROCESSING PLANT before being received by a FOOD ESTABLISHMENT.
During the 2004 Conference for Food Protection (CFP) Biennial Meeting, the subject of Food Code date marking for RTE PHF/TCS FOOD was re-evaluated to focus the provision on "Very High" and "High Risk" foods while simultaneously exempting certain categories of FOOD from the date marking provision. The September 2003 document referenced by CFP, Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-To-Eat Foods, concluded raw seafood to be categorized as "Risk Designation Low" along with other FOOD such as preserved fish products. This designation suggests date marking of raw seafood (including raw, live in-shell SHELLSTOCK) would not be necessary, however neither the 2005 nor the 2009 Food Codes specifically exempt raw, live in-shell SHELLSTOCK from date marking [Section 3-501.17(F)(1-7) Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Date Marking] and no elaborative explanation is offered in Annex 3, 3-501.17 (pages 414-419) regarding raw, live in-shell SHELLSTOCK.
The only guidance in the Food Code is located in Annex 3, 3-201.15 Molluscan Shellfish (pages 374-375) which specifically identifies *Listeria monocytogenes* (and others) as a

pathogen of concern at harvest, a position that is elaborated on in recently published research (Moustafa A. et. al *Listeria spp.* in the coastal environment of the Aqaba Gulf; Suez Gulf and the Red Sea. Epidemiol. Infect. 2006; 134; 752-757) (Colburn KG et. al. *Listeria monocytogenes* in California coast estuarine environment. Applied Environ Microbiol 1990; 56; 2007-2011).

Regarding FOOD excluded from date marking, the 2009 FDA Food Code currently lists only the following commercially produced RTE PHF/TCS FOOD categories: deli salads prepared and packaged in a FOOD PROCESSING PLANT; hard and semi-soft cheeses; cultured dairy products; preserved fish products (with exceptions); shelf stable dry fermented sausages not labeled "Keep Refrigerated"; and shelf stable salt-cured products not labeled "Keep Refrigerated".

Once received by a FOOD ESTABLISHMENT, raw live in-shell SHELLSTOCK are typically cold held longer than 24 hours due to the quantity received. And while the Food Code does not specify the number of days raw, live in-shell SHELLSTOCK can be cold held, Annex 3 estimates a shelf-life up to fourteen (14) days [Section 3-203.12 Shellstock, Maintaining Identification; page 382]. This presents a serious potential challenge to REGULATORY AUTHORITIES that adopt and enforce date marking as recommended in the Food Code since date marking for commercially processed RTE PHF/TCS FOOD limits shelf-life to seven (7) days [Section 3-501.17 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Date Marking; and Section 3-501.18 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Disposition].

SHELLSTOCK served in a raw, live in-shell form to the CONSUMER are currently subject to a CONSUMER ADVISORY [Section 3-603.11 Consumption of Animal Foods that are Raw, Undercooked or Not Otherwise processed to Eliminate Pathogens; pages 97-98] and have been identified by FDA as a potential source of pathogen contamination, including *Listeria monocytogenes* [Annex 3; Section 3.201.15 Molluscan Shellfish; page 375].

Further, raw, live in-shell SHELLSTOCK can be harvested, transported and delivered to the FOOD ESTABLISHMENT at temperatures above 41° F [Section 3-202.11 Temperature; page 54] which can encourage the growth of pathogens such as *Listeria monocytogenes*.

Further, SHELLSTOCK are PACKAGED and shipped in netted bags or other non-reusable shipping containers, none of which are air-tight. Some of the non-reusable containers are opened at receiving to allow the FOOD ESTABLISHMENT to verify the condition and temperature of the raw, live in-shell SHELLSTOCK and the porous nature of the shipped non-reusable bags/containers does not discourage or prevent possible further contamination of the SHELLSTOCK under refrigerated storage in the FOOD ESTABLISHMENT.

In the FOOD ESTABLISHMENT, raw, live in-shell SHELLSTOCK are frequently removed from their original shipping container(s) to be: (1) displayed on ice; or (2) held in refrigerated drawers, cold-rails, walk-in-coolers or reach-in-coolers. These refrigerated environments are subject to splash, dust, condensation drips and other filth that may be contaminated with pathogens, including *Listeria monocytogenes*. These refrigeration units can also simultaneously hold other raw animal FOODS and/or other RTE PHF/TCS FOODS. And these refrigeration units can be subject to temperature variation above 41° F as documented in FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant and Retail Food Store Facility Types (2009) (see attached).

Recommended Solution: The Conference recommends...:

...the language of the 2009 FDA Food Code (as modified by the Supplement issued in 2011) be changed to clearly reflect that date marking provisions apply to raw, live in-shell SHELLSTOCK served to CONSUMERS upon request without cooking or other treatment. *(new language is in underline format; language to be deleted in strike-thru format)*

3-501.17(B) Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.

(B) Except as specified in ¶¶ (D)-(F) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT and if the FOOD is held for more than 24 hours, to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded, based on the temperature and time combinations specified in ¶ (A) of this section and:[PF]

(1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1;[Pf] ~~and~~

(a) Except for containers of raw, live in-shell SHELLSTOCK, Day 1 shall be the date or day the SHELLSTOCK are receiving in the FOOD ESTABLISHMENT if the SHELLSTOCK will be served upon CONSUMER request in a raw, RTE PHF/TCS form; [Pf] and

(2) The day or date marking by the FOOD ESTABLISHMENT may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on FOOD safety.[Pf]

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Attachments:

- "Listeria monocytogenes Risk Assessment"
- "FDA Report on the Occurrence of Foodborne Illness Risk Factors"
- "Listeria spp. in the coastal environment of the Aqaba Gulf, Suez Gulf and.."
- "Listeria Species in a California Coast Estuarine Environment"

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Listeria monocytogenes Risk Assessment: Executive Summary

FDA/Center for Food Safety and Applied Nutrition
USDA/Food Safety and Inspection Service
September 2003

Background

The U.S. Department of Health and Human Service, Food and Drug Administration's Center for Food Safety and Applied Nutrition (DHHS/FDA/CFSAN) conducted this risk assessment in collaboration with the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) and in consultation with the DHHS Centers for Disease Control and Prevention (CDC). The purpose of the assessment is to examine systematically the available scientific data and information to estimate the relative risks of serious illness and death associated with consumption of different types of ready-to-eat (RTE) foods that may be contaminated with *Listeria monocytogenes*. This examination of the current science and the models developed from it are among the tools that food safety regulatory agencies will consider when evaluating the effectiveness of current and future policies, programs, and regulatory practices to minimize the public health impact of this pathogen.

The Healthy People 2010 goals for national health promotion and disease prevention called on federal food safety agencies to reduce foodborne listeriosis by 50% by the end of the year 2005. Preliminary FoodNet data on the incidence of foodborne illnesses for the United States in 2001 indicated that the incidence of infection from *Listeria monocytogenes* decreased between 1996 and 2001 from 0.5 to 0.3 cases per 100,000 people per year. The level then reached a plateau. In order to reduce further the incidence to a level of 0.25 cases per 100,000 people by the end of 2005, it became evident that additional targeted measures were needed. The *Listeria monocytogenes* risk assessment was initiated as an evaluation tool in support of this goal.

Listeria monocytogenes is a bacterium that occurs widely in both agricultural (soil, plants and water) and food processing environments. Ingestion of *Listeria monocytogenes* can cause listeriosis, which can be a life-threatening human illness. In 2000, the CDC reported that of all the foodborne pathogens tracked by CDC, *Listeria monocytogenes* had the second highest case fatality rate (21%) and the highest hospitalization rate (90.5%). Serious illness almost always occurs in people considered to be at higher risk, such as the elderly and those who have a pre-existing illness that reduces the effectiveness of their immune system. Perinatal listeriosis results from foodborne exposure of the pregnant mother leading to *in utero* exposure of the fetus, resulting in fetal infection that leads to fetal death, premature birth, or neonatal illness and death. *Listeria monocytogenes* also causes listerial gastroenteritis, a syndrome typically associated with mild gastrointestinal symptoms in healthy individuals. This risk assessment focuses on the severe public health consequences.

Scope and General Approach

This risk assessment provides analyses and models that (1) estimate the potential level of exposure of three age-based population groups and the total United States population to *Listeria monocytogenes* contaminated foods for 23 food categories and (2) relate this exposure to public health consequences. The food categories consist of foods with a documented history of *Listeria monocytogenes* contamination. The models provide a means of predicting the likelihood that severe illness or death will result from consuming foods contaminated with this pathogen. These

predictions are interpreted and used to estimate the relative risks among the food categories. The foods considered in this risk assessment are ready-to-eat foods that are eaten without being cooked or reheated just prior to consumption. One food, frankfurters, may or may not be reheated prior to consumption and was considered as two separate food categories. The working assumption is that all the cases of listeriosis are attributed to the foods in 23 categories, so that the risk assessment could be 'anchored' to the United States public health statistics. However, it is recognized that additional foods or cross-contamination from raw foods before cooking to other RTE foods may also contribute to additional cases.

The published scientific literature, government food intake surveys, health statistics, epidemiological information, unpublished food product surveys acquired from state and federal public health officials and trade associations, and surveys specifically designed to augment the data available for the risk assessment are the primary sources of data used in this document. Expert advice on scientific assumptions was actively sought from leading scientists from academia, industry, and government. This included two formal reviews of the underlying model structure and assumptions by the United States National Advisory Committee on Microbiological Criteria for Foods. In addition, the risk assessment was initially published in draft form and public comments sought for six months.

While the risk assessment purposely did not look into the pathways for the manufacture of individual foods, the risk assessment model developed can be used to estimate the likely impact of control strategies by changing one or more input parameters and measuring the change in the model outputs. This process, referred to as conducting 'what-if' scenarios, can be used to explore how the components of a complex model interact. Several 'what-if' scenarios are detailed within the risk assessment to evaluate the impact of refrigerator temperature, storage times, and reduction of the number of organisms in foods at before it is sold, and reduction in the contamination levels in foods that support growth.

Results

The relative risk rankings, along with the corresponding risk estimates expressed in terms of both the predicted number of cases per serving and per annum, are provided in Summary Table 1. Both measures are important in understanding and interpreting the risks associated with foodborne listeriosis. The per serving value can be considered the inherent risk associated with the manufacturing, distribution, marketing, and use of the food category, and is reflective of the degree of *Listeria monocytogenes* control achieved. Examples of factors that influence the 'per serving' risk include the frequency of contamination, the extent of that contamination, the ability of the food category to support the growth of *Listeria monocytogenes*, the duration and temperature of refrigerated storage, and the size of the serving. The predicted relative risk per serving can be viewed as the relative risk faced by individual consumers when he/she consume a single serving of the various foods considered in this risk assessment. The 'per serving' risk is typically the value upon which risk management decisions related to a specific product are based.

Summary Table 4. Relative Risk Ranking and Predicted Median Cases of Listeriosis for the Total United States Population on a per Serving and per Annum Basis

Relative Risk	Predicted Median Cases of Listeriosis for 23 Food Categories	
	Per Serving	Per Annum Basis[b]

Ranking	Basis[a]					
	Food	Cases	Food	Cases		
1	**High Risk**	Deli Meats	$7.7x10^{-8}$	**Very High**	Deli Meats	1598.7
2		Frankfurters, not reheated	$6.5x10^{-8}$	**High Risk**	Pasteurized Fluid Milk	90.8
3		Pâté and Meat Spreads	$3.2x10^{-8}$		High Fat and Other Dairy Products	56.4
4		Unpasteurized Fluid Milk	$7.1x10^{-9}$		Frankfurters, not reheated	30.5
5		Smoked Seafood	$6.2x10^{-9}$	**Moderate Risk**	Soft Unripened Cheese	7.7
6		Cooked Ready-to-Eat Crustaceans	$5.1x10^{-9}$		Pâté and Meat Spreads	3.8
7	**Moderate Risk**	High Fat and Other Dairy Products	$2.7x10^{-9}$		Unpasteurized Fluid Milk	3.1
8		Soft Unripened Cheese	$1.8x10^{-9}$		Cooked Ready-to-Eat Crustaceans	2.8
9		Pasteurized Fluid Milk	$1.0x10^{-9}$		Smoked Seafood	1.3
10	**Low Risk**	Fresh Soft Cheese	$1.7x10^{-10}$	**Low Risk**	Fruits	0.9
11		Frankfurters, reheated	$6.3x10^{-11}$		Frankfurters, reheated	0.4
12		Preserved Fish	$2.3x10^{-11}$		Vegetables	0.2
13		Raw Seafood	$2.0x10^{-11}$		Dry/Semi-dry Fermented Sausages	<0.1
14		Fruits	$1.9x10^{-11}$		Fresh Soft Cheese	<0.1
15		Dry/Semi-dry Fermented Sausages	$1.7x10^{-11}$		Semi-Sof t Cheese	<0.1

16		Semi-soft Cheese	$6.5x10^{-12}$		Soft Ripened Cheese	<0.1
17		Soft Ripened Cheese	$5.1x10^{-12}$		Deli-type Salads	<0.1
18		Vegetables	$2.8x10^{-12}$		Raw Seafood	<0.1
19		Deli-type Salads	$5.6x10^{-13}$		Preserved Fish	<0.1
20		Ice Cream and Other Frozen Dairy Products	$4.9x10^{-14}$		Ice Cream and Other Frozen Dairy Products	<0.1
21		Processed Cheese	$4.2x10^{-14}$		Processed Cheese	<0.1
22		Cultured Milk Products	$3.2x10^{-14}$		Cultured Milk Products	<0.1
23		Hard Cheese	$4.5x10^{-15}$		Hard Cheese	<0.1

[a] Food categories were classified as high risk (>5 cases per billion servings), moderate risk (≤5 but ≥1 case per billion servings), and low risk (<1 case per billion servings).
[b] Food categories were classified as very high risk (>100 cases per annum), high risk (>10 to 100 cases per annum), moderate risk (≥1 to 10 cases per annum), and low risk (<1 cases per annum).

The second measure, the 'per annum risk,' is the predicted number of fatal infections per year in the United States for each food category. This value takes into account the number of servings of the food category that are consumed. The predicted per annum risk of serious illnesses for each food category can be thought of as the predicted relative total public health impact for each food category. Since the 'per annum' risk is derived from the 'per serving' risk, there is generally a higher degree of uncertainty associated with the former. The predicted per serving and per annum relative risks are used to develop risk rankings to compare the various food categories. In addition to presenting the 'most likely' relative risk rankings for the different population groups and food categories, the risk assessment provides the inherent variability and the uncertainty associated with these rankings.

Evaluation and Interpretation

The overall interpretation of the risk assessment requires more than just a simple consideration of the relative risk rankings associated with the various food categories. First, the interpretation of the results requires an appreciation of the fact that the values being compared are the median values of distributions that may be highly skewed (i.e., not evenly distributed). The use of median values was selected as being the appropriate method for comparing the overall relative risks among the different food categories. The quantitative results must be considered in relation to the associated variability and uncertainty (i.e., the confidence intervals surrounding the median) and interpreted in the context of both the epidemiologic record and how the food categories are manufactured, marketed, and consumed. A detailed consideration of the

quantitative and qualitative findings for each food category is provided in the risk assessment and its appendices.

A number of methods for objectively grouping the results were evaluated, and are discussed in detail within the risk assessment. One approach is cluster analysis. When performed at the 90% confidence level, this analysis groups the per serving rankings into four clusters and the per annum rankings into five. These clusters are used, in turn, to develop a two-dimensional matrix of per serving vs. per annum rankings of the food categories (Summary Figure 1). In this approach, the 'per serving' clusters are arrayed against the 'per annum' clusters. The matrix is then used to depict five risk designations: Very High, High, Moderate, Low, and Very Low.

The risk characterization combines the exposure and dose-response models to predict the relative risk of illness attributable to each food category. While the risk characterization must be interpreted in light of both the inherent variability and uncertainty associated with the extent of contamination of ready-to-eat foods with *Listeria monocytogenes* and the ability of the microorganism to cause disease, the results provide a means of comparing the relative risks among the different food categories and population groups considered in the assessment and should prove to be a useful tool in focusing control strategies and ultimately improving public health through effective risk management. As described above, cluster analysis techniques are employed as a means of discussing the food categories within a risk analysis framework. The food categories are divided into five overall risk designations (see Summary Figure 1), which are likely to require different approaches to controlling foodborne listeriosis.

	Decreased Risk per Annum ⟶			
	Clusters A and B	**Clusters C and D**	**Cluster E**	
Decreased Risk per Serving ↓	**Cluster 1**	**Very High Risk (Clusters 1-A, 1-B)** Deli Meats Frankfurters (not reheated)	**High Risk (Clusters 1-C, 1-D)** Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	**Moderate Risk (Cluster 1-E)** No food categories
	Cluster 2	**High Risk (Clusters 2-A, 2-B)** High Fat and Other Dairy Products Pasteurized Fluid	**Moderate Risk (Clusters 2-C, 2-D)** Cooked RTE Crustaceans	**Moderate Risk (Cluster 2-E)** No food categories

		Milk Soft Unripened Cheese		
	Cluster 3	**Moderate Risk (Clusters 3-A, 3-B)** No food categories	**Moderate Risk (Clusters 3-C, 3-D)** Deli-type Salads Dry/Semi-dry Fermented Sausages Frankfurters (reheated) Fresh Soft Cheese Fruits Semi-soft Cheese Soft Ripened Cheese Vegetables	**Low Risk (Cluster 3-E)** Preserved Fish Raw Seafood
	Cluster 4	**Moderate Risk (Clusters 4-A, 4-B)** No food categories	**Low Risk (Clusters 4-C, 4-D)** No food categories	**Very Low Risk (Cluster 4-E)** Cultured Milk Products Hard Cheese Ice Cream and Other Frozen Dairy Products Processed Cheese

Summary Figure 1. Two-Dimensional Matrix of Food Categories Based on Cluster Analysis of Predicted per Serving and per Annum Relative Rankings

[The matrix was formed by the interception of the four per serving clusters vs. the per annum clusters A and B, C and D, and E. For example, Cluster 3-E (Low Risk) refers to the food categories that are in both Cluster level 3 for the risk per serving and Cluster level E for the risk per annum.]

Risk Designation Very High. This designation includes two food categories, Deli Meats and Frankfurters, Not Reheated. These are food categories that have high predicted relative risk rankings on both a per serving and per annum basis, reflecting the fact that they have relatively high rates of contamination, support the relatively rapid growth of *Listeria monocytogenes* under refrigerated storage, are stored for extended periods, and are consumed extensively. These products have also been directly linked to outbreaks of listeriosis. This risk designation is one that is consistent with the need for immediate attention in relation to the national goal for reducing the incidence of foodborne listeriosis. Likely activities include the development of new control strategies and/or consumer education programs suitable for these products.

Risk Designation High. This designation includes six food categories, High Fat and Other Dairy Products, Pasteurized Fluid Milk, Pâté and Meat Spreads, Soft Unripened Cheeses, Smoked Seafood, and Unpasteurized Fluid Milk. These food categories all have in common the ability to support the growth of *Listeria monocytogenes* during extended refrigerated storage. However, the foods within this risk designation appear to fall into two distinct groups based on their rates of contamination and frequencies of consumption.

- Pâté and Meat Spreads, Smoked Seafood, and Unpasteurized Fluid Milk have relatively high rates of contamination and thus high predicted per serving relative risks. However, these products are generally consumed only occasionally in small quantities and/or are eaten by a relatively small portion of the population, which lowers the per annum risk. All three products have been associated with outbreaks or sporadic cases, at least internationally.

  These foods appear to be priority candidates for new control measures (i.e., Smoked Seafood, Pâté and Meat Spreads) or continued avoidance (i.e., Unpasteurized Fluid Milk).
- High Fat and Other Dairy Products, Pasteurized Fluid Milk, and Soft Unripened Cheeses have low rates of contamination and corresponding relatively low predicted per serving relative risks. However, these products are consumed often by a large percentage of the population, resulting in elevated predicted per annum relative risks. In general, the predicted per annum risk is not matched with an equivalent United States epidemiologic record. However, the low frequency of recontamination of individual servings of these products in combination with their broad consumption makes it likely that these products are primarily associated with sporadic cases and normal case control studies would be unlikely to lead to the identification of an association between these products and cases of listeriosis.

  These products (High Fat and Other Dairy Products, Pasteurized Fluid Milk, and Soft Unripened Cheeses) appear to be priority candidates for advanced epidemiologic and scientific investigations to either confirm the predictions of the risk assessment or identify the factors not captured by the current models that would reduce the predicted relative risk.

Risk Designation Moderate. This risk designation includes nine food categories (Cooked Ready-to-Eat Crustaceans, Deli Salads, Fermented Sausages, Frankfurters-Reheated, Fresh Soft Cheese, Fruits, Semi-soft Cheese, Soft Ripened Cheese, and Vegetables) that encompass a range of contamination rates and consumption profiles. A number of these foods include effective bactericidal treatments in their manufacture or preparation (e.g., Cooked Ready-to-Eat Crustaceans, Frankfurters-Reheated, Semi-soft Cheese) or commonly employ conditions or compounds that inhibit the growth of *Listeria monocytogenes* (e.g., Deli Salads, Dry/Semi-dry Fermented Sausages). The risks associated with these products appear to be primarily associated with product recontamination, which in turn, is dependent on continued, vigilant application of proven control measures.

Risk Designation Low. This risk designation includes two food categories, Preserved Fish and Raw Seafood. Both products have moderate contamination rates but include conditions (e.g., acidification) or consumption characteristics (e.g., short shelf-life) that limit *Listeria monocytogenes* growth and thus limit predicted per serving risks. The products are generally consumed in small quantities by a small portion of the population on an infrequent basis, which results in low predicted per annum relative risks. Exposure data for these products are limited so

there is substantial uncertainty in the findings. However, the current results predict that these products, when manufactured consistent with current good manufacturing practices, are not likely to be a major source of foodborne listeriosis.

Risk Designation Very Low. This risk designation includes four food categories, Cultured Milk Products, Hard Cheese, Ice Cream and Other Frozen Dairy Products, and Processed Cheese. These products all have in common the characteristics of being subjected to a bactericidal treatment, having very low contamination rates, and possessing an inherent characteristic that either inactivates *Listeria monocytogenes* (e.g., Cultured Milk Products, Hard Cheese) or prevents its growth (e.g., Ice Cream and Other Frozen Dairy Products, Processed Cheese). This results in a very low predicted per serving relative risks. The predicted per annum relative risks are also low despite the fact that these products are among the more commonly consumed ready-to-eat products considered by the risk assessment. The results of the risk assessment predict that unless there was a gross error in their manufacture, these products are highly unlikely to be a significant source of foodborne listeriosis.

Conclusions

The following conclusions are provided as an integration of the results derived from the models, the evaluation of the variability and uncertainty underlying the results, and the impact that the various qualitative factors identified in the hazard identification, exposure assessment, and hazard characterization have on the interpretation of the risk assessment.

- The risk assessment reinforces past epidemiological conclusions that foodborne listeriosis is a moderately rare although severe disease. United States consumers are exposed to low to moderate levels of *Listeria monocytogenes* on a regular basis.
- The risk assessment supports the findings of epidemiological investigations of both sporadic illness and outbreaks of listeriosis that certain foods are more likely to be vehicles for *Listeria monocytogenes*.
- Three dose-response models were developed that relate the exposure to different levels of *Listeria monocytogenes* in three age-based subpopulations [i.e., perinatal (fetuses and newborns), elderly, and intermediate-age] with the predicted number of fatalities. These models were used to describe the relationship between levels of *Listeria monocytogenes* ingested and the incidence of listeriosis. The dose of *Listeria monocytogenes* necessary to cause listeriosis depends greatly upon the immune status of the individual.
    1. Susceptible subpopulations (such as the elderly and perinatal) are more likely to contract listeriosis than the general population.
    2. Within the intermediate-age subpopulation group, almost all cases of listeriosis are associated with specific subpopulation groups with increased susceptibility (e.g., individuals with chronic illnesses, individuals taking immunosuppressive medication).
    3. The strong association of foodborne listeriosis with specific population groups suggests that strategies targeted to these susceptible population groups, i.e., perinatal (pregnant women), elderly, and susceptible individuals within the intermediate-age group, would result in the greatest reduction in the public health impact of this pathogen.
- The dose-response models developed for this risk assessment considered, for the first time, the range of virulence observed among different isolates of *Listeria monocytogenes*.

The dose-response curves suggest that the relative risk of contracting listeriosis from low dose exposures could be less than previously estimated.>

- The exposure models and the accompanying 'what-if' scenarios identify five broad factors that affect consumer exposure to *Listeria monocytogenes* at the time of food consumption.
    1. Amounts and frequency of consumption of a ready-to-eat food
    2. Frequency and levels of *Listeria monocytogenes* in a ready-to-eat food
    3. Potential of the food to support growth of *Listeria monocytogenes* during refrigerated storage
    4. Refrigerated storage temperature
    5. Duration of refrigerated storage before consumption

Any of these factors can affect potential exposure to *Listeria monocytogenes* from a food category. These factors are 'additive' in the sense that foods where multiple factors favor high levels of *Listeria monocytogenes* at the time of consumption are typically more likely to be riskier than foods where a single factor is high. These factors also suggest several broad control strategies that could reduce the risk of foodborne listeriosis such as reformulation of products to reduce their ability to support the growth of *Listeria monocytogenes* or encouraging consumers to keep refrigerator temperatures at or below 40 °F and reduce refrigerated storage times. For example, the 'what-if' scenarios using Deli Meats predicts that consumer education and other strategies aimed at maintaining home refrigerator temperatures at 40 °F could substantially reduce the risks associated with this food category. Combining this with pre-retail treatments that decrease the contamination levels in Deli Meats would be expected to reduce the risk even further.

This risk assessment significantly advances our ability to describe our current state of knowledge about this important foodborne pathogen, while simultaneously providing a framework for integrating and evaluating the impact of new scientific knowledge on public health enhancement.

FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009)

EXECUTIVE SUMMARY

In 2008, the U.S. Food and Drug Administration's (FDA) National Retail Food Team conducted the third phase of a three-phase,10-year study to measure the occurrence of practices and behaviors commonly identified by the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks. Specifically, the study called for conducting data collection inspections of various types of foodservice and retail food establishments at five-year intervals to observe and document practices and behaviors that relate to the following CDC contributing factor categories associated with foodborne illness outbreaks within foodservice and retail food establishments, herein referred to as foodborne illness risk factors (risk factors):

- Food from Unsafe Sources
- Poor Personal Hygiene
- Inadequate Cooking
- Improper Holding/Time and Temperature
- Contaminated Equipment/Protection from Contamination

This 2009 report is the third report in a series and presents findings based on data collected in 2008. The first report in the study was issued in August 2000 and presented the findings from the first data collection effort in 1998. A second report was issued in 2004 and presented data collected in 2003. FDA intends to publish a report in 2010 that compares the results from the three data collection periods and examines what trends, if any, were observed.

The 2000 and 2004 reports called attention to the need for greater active managerial control of foodborne illness risk factors. They suggested that more innovative and effective strategies to improve food safety practices in retail and foodservice establishments were needed. The reports highlighted operational areas most in need of improvement including employee handwashing, cold holding of potentially hazardous foods (time/temperature control for safety foods), date marking of ready-to-eat foods, and cleaning and sanitizing of food contact surfaces.

In each phase of the study, FDA Regional Retail Food Specialists collected data during site visits of over 800 establishments representing nine distinct facility types. Direct observations, supplemented with information gained from discussions with management and food employees, were used to document the establishments' compliance status for 42 individual data items based on provisions in the *1997 FDA Food Code*. In each establishment, the compliance status for each data item was recorded in terms of IN Compliance, Out of Compliance, Not Observed (meaning the behavior or practice was applicable but not observed during the visit), or Not Applicable (meaning the behavior or practice did not apply to the establishment).

For each of the nine facility types, the percentage of observations recorded as Out of Compliance is presented for each risk factor and for the individual data items related to those risk factors most in need of priority attention. The percent Out of Compliance value for each risk factor was calculated by dividing the total number of Out of Compliance observations of data items in the

risk factor by the total number of observations (IN compliance and Out of Compliance) of data items in the risk factor. The percent Out of Compliance values for individual data items were calculated by dividing the total number of Out of Compliance observations for the individual data item by the total number of observations (IN and Out of Compliance) for the data item.

The data presented in this 2009 report indicate that some of the same risk factors and data items identified as problem areas in the 2000 and 2004 Reports remain in need of priority attention. This indicates that industry and regulatory efforts to promote active managerial control of these risk factors must be enhanced. The Out of Compliance percentages remained high for data items related to the following risk factors:

- Improper Holding/Time and Temperature
- Poor Personal Hygiene
- Contaminated Equipment/Protection from Contamination

For the improper holding/time and temperature risk factor, the high percent Out of Compliance values were most commonly associated with improper cold holding of potentially hazardous food (PHF)/time-temperature control for safety (TCS) food and inadequate date marking of refrigerated, ready-to-eat PHF/TCS Food.

Within the poor personal hygiene risk factor, the proper, adequate handwashing data item had the highest percent Out of Compliance value for every facility type. Percent Out of Compliance values for proper, adequate handwashing ranged from approximately 18% for meat departments to approximately 76% for full service restaurants.

Of the data items related to the contaminated equipment/protection from contamination risk factor, improper cleaning and sanitizing of food-contact surfaces before use was the item most commonly observed to be Out of Compliance in eight out of the nine facility types. Percent Out of Compliance values for this data item ranged from 18% in seafood departments to 64% in full service restaurants.

As in the 2004 Report, this 2009 report includes a comparison between the data collected from food establishments that had a Certified Food Protection Manager (CFPM) from a program recognized by the Conference for Food Protection and those that did not. The results of the study indicate that the presence of a Certified Food Protection Manager is positively correlated to the overall IN Compliance percentages in certain facility types, especially in delis, full service restaurants, seafood departments, and produce departments. Poor Personal Hygiene, Improper Holding/Time and Temperature, and Contaminated Equipment/Protection from Contamination appear to be the risk factors for which the presence of a certified manager had the most positive correlation.

The 2003 and 2008 data collection efforts included several supplemental data items that were not included in the 1998 data collection. While original 42 data items in the study remained the same from 1998 to 2008, the supplemental data items addressed changes made to the *FDA Food Code* since 1997. These items related to the cooking temperature for pork, the minimum hot holding temperatures, employee health, juice, eggs, and highly susceptible populations. Data gathered for the supplemental data items suggest that reducing the minimum hot holding temperature for PHF/TCS foods from 140ºF (60ºC) to 135ºF (57ºC) and reducing the minimum cooking temperature for pork from 155ºF (68ºC) to 145ºF (63ºC) had minimal effect on the industry's control of these risk factors.

Results from the 2008 data collection indicate that the recommendations made to foodservice and retail food operators and regulators in the 2000 and 2004 Reports need to be

reemphasized. Foodservice and retail food store operators must ensure that their management systems are designed to achieve active managerial control over the risk factors. Likewise, regulators must ensure that their inspection, education, and enforcement efforts are geared toward the control of the risk factors commonly found to be Out of Compliance.

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Listeria spp. in the coastal environment of the Aqaba Gulf, Suez Gulf and the Red Sea

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SUMMARY

Listeria monocytogenes is an important pathogen which causes an infection called listeriosis. Because of the high mortality rate (~30%) associated with listeriosis, and the widespread nature of the organism, it is a major concern for food and water microbiologists since it has been isolated from various types of foods, including seafood, as well as from the aqueous environment. To investigate the prevalence of this pathogen in the Aqaba Gulf (12 sites), Suez Gulf (14 sites) and Red Sea (14 sites), 200 water samples (collected during five sampling cruises in 2004), 40 fresh fish samples and 15 shellfish samples were analysed using the enrichment procedure and selective agar medium. All water samples were also examined for the presence *Listeria innocua* which was the most common of the *Listeria* spp. isolated, followed by *L. monocytogenes*, with a low incidence of the other species. During the whole year, the percentage of *Listeria* spp. and *L. monocytogenes* in 200 water samples was 20·5% (41 samples) and 13% (26 samples) respectively. In fresh fish (40 samples) it was 37% (15 samples) and 17·3% (7 samples) and in shellfish (15 samples) 53% (8 samples) and 33% (5 samples) respectively. In water samples, there was an association between the faecal contamination parameters and the presence of the pathogen; however, water salinity, temperature, dissolved oxygen and pH did not influence the occurrence of this bacterium. These results may help in the water-quality evaluation of the coastal environments of these regions.

INTRODUCTION

Listeria monocytogenes has been recognized as a human pathogen since 1929 [1] causing an infection called listeriosis which can be manifested through several different syndromes causing invasive illness. It can cause abortion during pregnancy, human meningitis, infection during the perinatal period, granulomatosis infantiseptica, sepsis, diarrhoea, pyelitis and 'flu-like' symptoms. The mortality rate of listeriosis is ~30% [2].

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In the early 1980s scientists recognized *Listeria* as a foodborne pathogen as human listerosis resulted from consuming food contaminated with this pathogen such as milk and dairy products, meat, poultry, vegetables, salads and seafood [3]. Moreover, *L. monocytogenes* has a saprophytic life and occurs widely in nature [4]. A variety of animals including domestic farm animals can carry the bacterium [5], and it can survive for long periods in a plant–soil environment [6]. *Listeria* spp. were isolated from the Mediterranean coast of Egypt, more specifically from the Eastern Harbour of Alexandria [7], while in the United States the bacterium was isolated from the California coast estuarine environment [6]. Scientists have proposed that the pathogen can survive for

a long time in a marine environment as it is a salt-tolerant organism [8–10].

In Egypt, the coastal water of Red Sea including the Suez Gulf and the Aqaba Gulf, may be contaminated by domestic and/or industrial sewage/wastes. Thus, the risk of the presence of such a pathogen in these contaminated areas is to be expected. *Listeria* spp. have been recovered from a variety of seafood [11–13]; in Egypt, they have been isolated from fresh fish [14] as well as from shellfish collected from the Eastern Harbour of Alexandria [7].

This work addresses the incidence of *Listeria* spp. as well as the faecal pollution bacteria indicators in the coastal marine water of the Aqaba Gulf, Suez Gulf and Red Sea. Testing of seafood, collected from the local markets along the investigated areas, for the presence of the pathogen was another goal of the study.

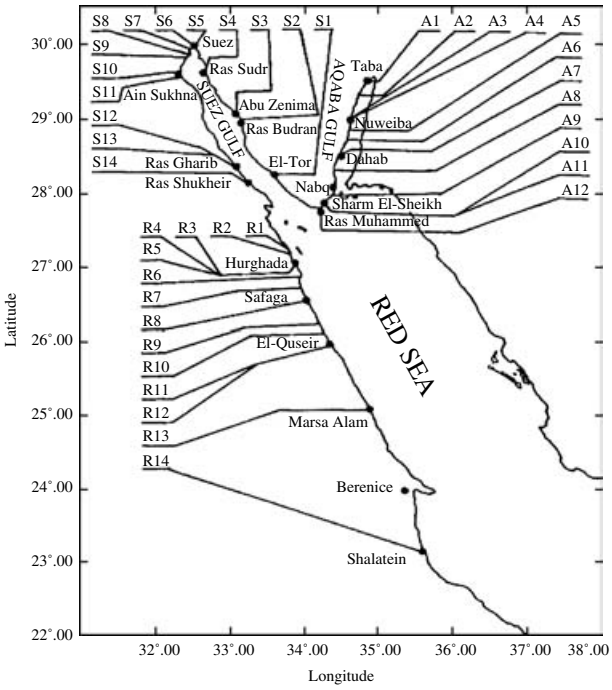

Fig. 1. Map showing names and codes of sampling locations at Aqaba Gulf (A), Suez Gulf (S) and Red Sea (R).

MATERIALS AND METHODS

Sampling sites

Coastal water samples were collected in five sampling cruises (bi-monthly intervals) during February to October 2004. The sampling sites along the Aqaba Gulf, Suez Gulf and Red Sea are shown in Figure 1. Water was sampled using 1-litre screw-cap bottles, with two sample bottles being taken at the same time/place from each site.

At each sampling cruise, one fresh fish sample, was purchased from the fish markets of the cities of Nuweiba, Sharm El-Sheikh, Suez, Ras Gharib, Hurghada, Safaga, El-Quseir and Shalatein; one shellfish sample was also purchased, but only from Nuwebia, Suez and Safaga.

All water samples were analysed immediately using an on-site mobile microbiological laboratory. At each sampling site, hydrographical parameters of the water samples including temperature (°C), salinity (‰), dissolved oxygen (mg/l and pH) were measured using CTD (YSI 6000, Yellow Springs, OH, USA). Fish and shellfish samples were collected in plastic bags and kept in the refrigerator of the mobile laboratory and were analysed within 6–12 h.

Bacteriological analysis

Water samples were examined for the presence of faecal pollution indicators of bacteria including total coliforms, *E. coli* and faecal streptococci using the membrane filtration technique (Gelman 0·45 μm membranes) as described by ISO 9308/1 [15], and ISO 7899/2 [16]. For detection of total coliforms, the membranes were fixed onto m-Endo-LES agar and incubated at 37 °C for 24 h; for detection of *E. coli*, m-FC agar was used followed by incubation at 44·5 °C for 24 h; however for faecal streptococci, m-Enterococcus agar was used and incubated at 37 °C for 48 h. The biochemical tests used for confirmation of the characteristic colonies as well as calculation of the final bacterial counts, per 100 ml of seawater, were done after the above-mentioned ISO examinations.

For detection of *Listeria* spp., the enrichment procedure based on the US Food and Drug Administration (FDA) technique [17] was used. One litre of each water sample was filtered. More than one membrane was used for each sample when needed. Then, the filter membrane(s) of each sample were scrubbed and manually crushed, using a sterile sharp glass rod, in a 500-ml volume sterile beaker containing 100 ml of *Listeria* enrichment broth base (LEB) (Oxoid CM 882 broth, Oxoid, Basingstoke, Hampshire, UK) supplemented with *Listeria* selective supplement (Oxoid SR 141). Membrane suspensions were transferred to sterilized conical flasks and kept at refrigerator temperature (4–8 °C) for 4 weeks.

Shellfish, after being scrubbed and rinsed with tap water, were opened aseptically and the flesh was collected. The flesh, or fish samples, were then blended in a sterile grinder to achieve homogenated slurries. Twenty-five grams of each representative slurry was directly suspended in 225 ml of LEB, and kept at refrigerator temperature (4–8 °C) for 4 weeks. The refrigerated enrichment cultures were then streaked onto Oxford formula selective agar medium (CM 856) plus *Listeria* selective supplement (SR 140) as described by Curtis et al. [18]. Plates were incubated at 35 °C for 48 h. Up to four colonies that were presumptively positive *Listeria*, with a black halo and a sunken centre, from each suspected positive plate were picked and purified onto trypticase soy agar (TSA) plates. For identification of the isolates a positive control of *L. monocytogenes* strain V7 (milk isolate) serotype 1 (obtained from the Department of Food Science, University of Wisconsin, Madison, WI, USA) served as a control in this work. This isolate was recovered by all media used in this study. Purified suspected isolates were viewed by the oblique light technique of Henry as described by the IDF [19]. Smears of suspected grey-blue colonies were Gram-stained and examined microscopically after streaking onto TSA plates and incubated at 35 °C for 18–24 h. Cultures displaying the correct morphology were tested for catalase, then stabbed into motility test medium (Difco, Detroit, MI, USA) and incubated at 25 °C to check for umbrella-shaped growth. Cultures that proved to be motile were tested for haemolysin using tryptose agar with 5% sheep blood. The isolates were streaked onto TSA slants, incubated at 35 °C for 18–24 h for further characterization to species using the criteria described by McLauchlin [2].

RESULTS AND DISCUSSION

Figure 2 shows the faecal pollution indicators represented as c.f.u./100 ml of the water samples examined during whole year, as well as the prevalence of *Listeria* spp. in the three studied areas.

In the Aqaba Gulf area *Listeria* spp. were detected in 10 out of 60 (17%) samples investigated during the whole year. Five of these contaminated samples (50%) were found to harbour *L. monocytogenes*. In the Suez Gulf area, 16 out of 70 (23%) samples investigated, proved to be contaminated by *Listeria* spp. Twelve (75%) of these contaminated samples were found to harbour *L. monocytogenes*. Along the coastal area of the Red Sea, only 15 out of 70 (21%) samples investigated were contaminated by *Listeria* spp., where nine (60%) of them harboured *L. monocytogenes*. These results indicated that Suez Gulf recorded the highest percentage for the presence of the bacterium. This may be due to the drainage of wastes and/or untreated sewage into the Gulf.

Generally, as illustrated in Table 1, *Listeria* spp. were detected in 21% ($n=41$) of the total examined water samples collected from all the investigated areas during the whole year ($n=200$). This percentage is lower than those reported at the Eastern harbour of Alexandria, where 9 out of 11 (82%), surface water samples were found to harbour *Listeria* spp. These results are similar to those reported in the United States where the percentage amounted to 33% of the examined marine waters collected from the California coast estuarine environment. Of these contaminated water samples ($n=41$), 63% ($n=26$) were found to harbour *L. monocytogenes*, however, *L. innocua* was the most predominant of the *Listeria* spp. since it was found in 80% ($n=33$) of the contaminated samples. At the same time a small percentage (5%) of other *Listeria* spp. was also detected ($n=2$).

In general, in the results obtained, *L. innocua* was more prevalent than *L. monocytogenes*, suggesting that it might be a very common organism in the coastal environment. Such an observation should, however, be made with care, since only a few colonies of the pathogen were picked up from the selective plates for identification. In this regard Seeliger [20] reported that *L. innocua* is a good indicator for *L. monocytogenes*, thus, when looking for sources of *Listeria*, the presence of both of these species is equally significant.

The present results indicated that there was an association between the faecal pollution indicators and the presence of the pathogen. As seen in Figure 2, the pathogen was detected in sites with high bacterial counts of the three faecal pollution indicators and never isolated from any site with low counts for these parameters. This association was to be expected since the bacterium is widely distributed in sewage [21] and the numbers of *Listeria* that are contributed to the environment by sewage and sewage sludge may be higher than those of *Salmonella* [22].

It should be noted that such an association between the presence of the pathogen and the faecal contamination indicators should not be considered as a general trend, since many factors/relations may interfere, e.g. distribution in water, sediments and biofilms,

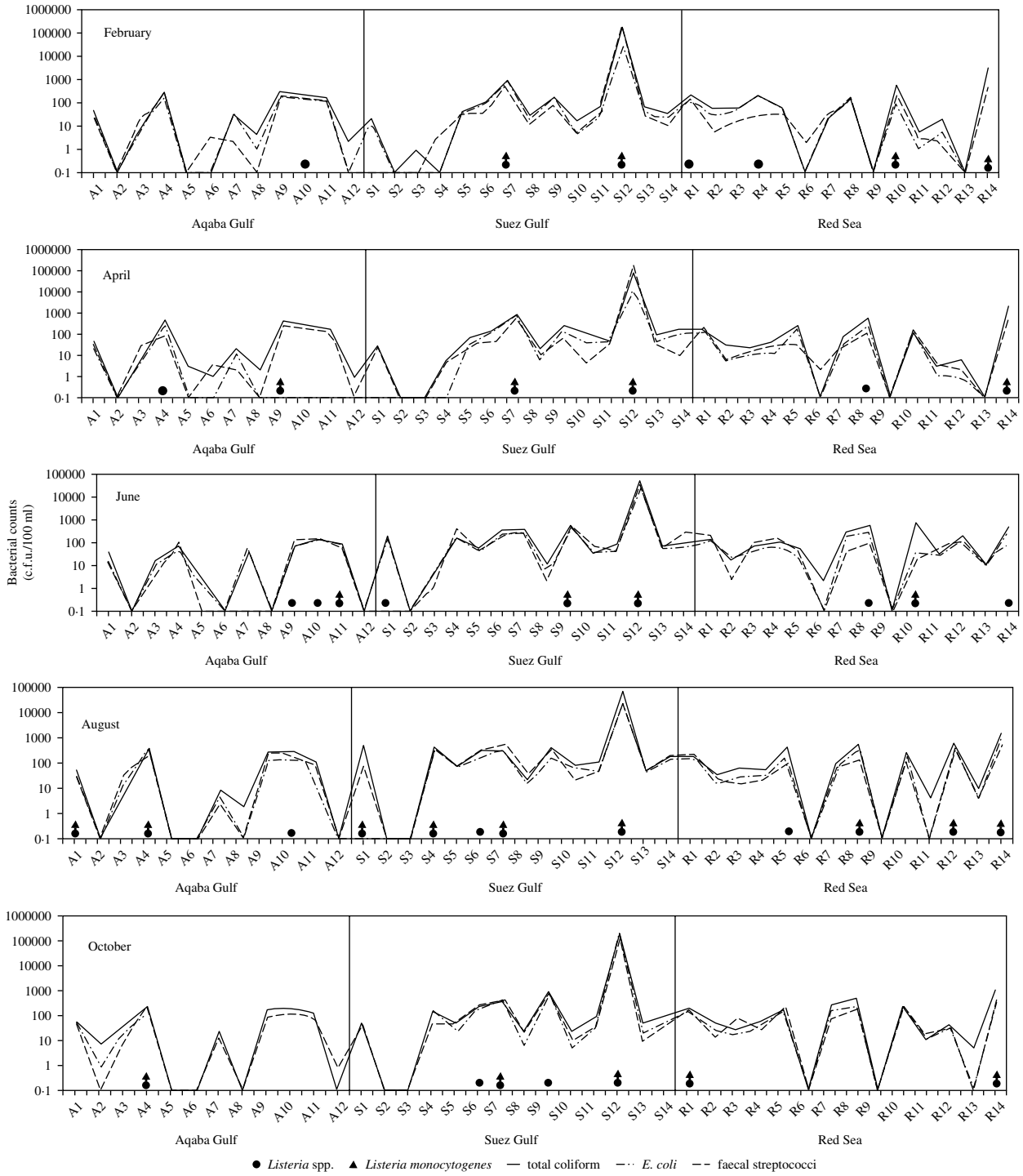

Fig. 2. Distribution of *Listeria* spp. and counts of faecal bacteria in coastal waters of Aqaba Gulf (A), Suez Gulf (S), and the Red Sea (R) during 2004.

seasonal variations, total bacterial load, relationship with indicators, etc. At least, our data give preliminary information on the behaviour of *Listeria* spp. in this coastal environment in an attempt to understand the epidemiology of this pathogen. At the same time, the recorded hydrographical parameters indicated that seasonal variation affected water temperature which ranged between 17·7 and 28·5 °C. A range of 39·2–42·6‰ for salinity was, however, recorded; the pH ranged from 7·8 to 8·5 and the dissolved oxygen

Table 1. *Number and percentage of water, fish and shellfish samples positive for* Listeria *spp.*

Sample	No. of examined samples	No. of positive samples				
		L. spp.	*L.m.*	*L.i.*	*L.m.* + *L.i.*	Other spp.
Water	200	41 (21%)	6 (3%)	13 (7%)	20 (10%)	2 (1%)
Fish	40	15 (38%)	3 (8%)	8 (20%)	4 (10%)	—
Shellfish	15	8 (53%)	1 (6%)	3 (20%)	4 (27%)	—

L. spp., *Listeria species*; *L.m.*, *Listeria monocytogenes*; *L.i.*, *Listeria innocua*; *L.m.* + *L.i.*, both species together.

Table 2. Listeria *spp. in fish and shellfish samples*

Location	Type	No. of samples	No. of samples positive for	
			Listeria spp.	*Listeria monocytogenes*
Fish				
Nuweiba	*Sigan*, *Hemiramphus*	5	2	1
Sharm El-Sheikh	*Lethrinus*, Shrimp	5	2	1
Suez	*Lethrinus*, *Sepia Hemiramphus*	5	3	2
Ras Garib	*Lethrinus*, *Mullus*	5	1	1
Hurghada	*Sigan*, squids, *Mullus*	5	1	—
Safaga	Shrimp, Sea bream	5	1	—
El-Quseir	*Lethrinus*, *Sigan*	5	2	1
Shalatein	*Lethrinus*, Sea bream	5	3	1
Total		40	15	7
Shellfish				
Nuweiba	*Lithophaga*, *Tridacna*	5	2	1
Suez	*Lambis*, caretshell Oyster	5	3	2
Safaga	*Lithophaga*, *Donax*	5	3	2
Total		15	8	5

between 6·3 and 9·5 mg/l. This variation in these hydrographical parameters, during the whole year, did not appear to affect the distribution of *Listeria* spp. and/or the bacteria of faecal pollution indicators in the investigated sites.

The incidence of *Listeria* spp. in the examined fish and shellfish samples is summarized in Table 2. As can be seen, *L. innocua* and *L. monocytogenes* were the only two species found in the investigated seafood samples. The incidence of *Listeria* spp. in the positive samples in relation to fish/shellfish type and the location where it was purchased is presented in Table 2.

In fish 38% ($n=15$) of the total examined samples ($n=40$) were found to be contaminated by *Listeria* spp. while 17·0% ($n=7$) were contaminated with *L. monocytogenes*. As observed in the coastal water samples, *L. innocua* was the most prevalent species since it was isolated from 30% ($n=12$) of the total samples examined (Table 1). These results are in accordance with reports by other authors [6] where the incidence of such a pathogen in fresh fish varied from very low to up to 50%, while a percentage ranging from 14·8 to 72·4% for the presence of *Listeria* spp. was also reported.

The highest frequency of *Listeria* spp. was recovered from shellfish where 53% ($n=8$) of the total examined samples ($n=15$) were contaminated with *Listeria* spp. and 33% ($n=5$) harboured *L. monocytogenes*. As was found in fish, *L. innocua* was the

most prevalent since it was isolated from 47% ($n=7$) of the total samples examined (Table 1). These results are a little higher than those reported by Colburn et al. [6] (they found a range from 12 to 44·4% for the presence of *Listeria* spp. and from 4·0 to 12·1% for *L. monocytogenes*). In general, the numbers of the samples examined, the pumping rate by shellfish which provokes the accumulation of microorganisms, the ability of *Listeria* spp. to survive in marine waters and the degree to which *Listeria* spp. are diluted are all different factors that may affect the uptake and retention of *Listeria* spp. by the shellfish; and consequently, the numbers of positive samples that might be affected. Moreover, the percentages of the pathogen in fish/shellfish could not be linked to the coastal environment only, this may also be linked to the market environment, although most fish markets in these areas are very close to the seashore.

In conclusion, faecal pollution bacteria as well as *Listeria* spp. were detected in some sites along the investigated areas. The polluted sites were located either in front of populated cities such as the Suez Gulf area or in front of the industrial/tourism activities in the other investigated areas. Consequently, the discharge of domestic raw/partially treated sewage onto the polluted sites should be taken into consideration. Our results may draw attention to the need to implement better hygiene and epidemiological practices in these areas. In order to avoid listerosis infection, fish and shellfish must be well-cooked before consumption.

DECLARATION OF INTEREST

None.

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Listeria Species in a California Coast Estuarine Environment

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***Listeria* species and *L. monocytogenes* were found in 81 and 62%, respectively, of fresh or low-salinity waters (37 samples) in tributaries draining into Humboldt-Arcata Bay, Calif., during a winter (January-February) sampling period. The incidence of *Listeria* species and *L. monocytogenes* in sediment (46 samples) from the same sites where water was sampled was 30.4 and 17.4%, respectively. One of three bay water samples contained *Listeria* species (including *L. monocytogenes*), while of 35 samples of oysters examined, only 1 was found positive for *Listeria* species (*L. innocua*). A given species or *L. monocytogenes* serogroup appeared to predominate in fresh water when domesticated animals (cows, horses) were nearby, whereas greater variety with no species predominance was observed in areas with no direct animal influence.**

Listeria monocytogenes has been implicated in recent foodborne outbreaks (7, 14–16, 20) which have focused attention on this organism and its modes of introduction into foods. A variety of animals including domestic farm animals can carry *Listeria* species in both infectious and latent states and are therefore considered potential vectors of this organism (3, 6, 8, 9, 12). It has been suggested (24, 26) that *Listeria* species are saprophytic and capable of surviving for long periods in a plant-soil environment. This factor may also play a role in transmission of this organism to foods.

Listeria species are present in aqueous environments such as river waters and sewage sludge (22) and most recently have been recovered from a variety of seafood products (23). Although *L. monocytogenes* can tolerate salt (4, 21), it is not known whether it can reach marine waters via freshwater tributaries or whether it is capable of prolonged survival in marine environments. Therefore, whether its presence in seafoods is due to environmental or postprocessing contamination or a combination of these and other factors is presently unknown.

This study was conducted to determine the incidence of *Listeria* species in freshwater tributaries draining into Humboldt-Arcata Bay, Calif. This estuary supports an active molluscan shellfishery and is impacted by humans and domesticated and wild animals.

MATERIALS AND METHODS

Samples and sites. Sediment, freshwater, saltwater, and oyster samples were collected over 13 consecutive days during January–February 1988. Specific sites sampled included those along various tributaries and portions of Arcata Bay (Fig. 1). Fresh water was sampled at sites 1 to 9, sediment samples were collected from sites 1 to 5 and 8, saltwater sampling locations were at sites 10 to 12, and oysters were from sites 13 to 17. Water and sediment samples were maintained at ambient temperature; oysters were kept on ice after sampling. All samples were analyzed within 6 h of collection by using an on-site mobile microbiological laboratory. At each sampling, water temperature was taken with a mercury thermometer and salinity was measured with either a salinometer (Beckman Instruments, Inc., Fullerton, Calif.) or a refractometer (Atago Co. Ltd., Tokyo, Japan). The visual observation of domesticated farm animals near the sampling site was noted. In each case in which the animals were present, they were within 200 m of the sampling site.

Sample collection. (i) Water. Water was sampled by three methods as follows. (A) Surface water samples were collected with sterile 4-liter screw-cap plastic bottles (Nalgene Labware Div., Nalge/Sybron Corp., Rochester, N.Y.) (sites 1 to 5 and 8, Fig. 1). (B) Sterile Moore swabs (sterile gauze pads) (2, 13, 18, 25) were suspended on a string for 7 to 8 days in situ approximately 1 m below the water surface at seven freshwater and three saltwater sampling stations (sites 1 and 4 to 12, Fig. 1). After 7 to 8 days, the swab was removed from the water, placed in a sterile plastic bag (Whirlpak; Nasco, Fort Attenson, Wis.), transported at ambient temperatures to the laboratory, and analyzed within 2 h. (C) A sterile Moore swab was placed within 2 h of collection in a 4-liter surface water sample in a plastic collection bottle and held in the laboratory at 22°C for 18 to 24 h. The Moore swab was then removed from the collection container and placed directly in 225 ml of nutrient broth (NB) (Difco Laboratories, Detroit, Mich.). For analysis of salt water (salinity, >30‰), only the examination of Moore swabs (method B) was used.

(ii) Sediment. Approximately 200 g of surface layer (2 to 5 cm) sediment was collected with sterile plastic scoops. Samples were placed in sterile Whirlpak bags. Sediment consistency was noted by visual observation (Table 1).

(iii) Oysters. Pacific oysters (*Crassostrea gigas*) in plastic mesh bags were attached to floats and suspended 0.5 to 2 m below the surface of Arcata Bay and not in contact with the bottom for 2 weeks before sampling. Bags contained 14 to 15 oysters. One bag was removed from each station at each sampling, and 12 oysters from each bag were analyzed.

Bacteriological analysis. (i) Water. A 1- to 2-liter volume was filtered through a 0.45-μm-pore-size 142-mm membrane filter (Millipore Corp., Bedford, Mass.). The filter was blended for 5 to 10 s in 225 ml of NB. All Moore swabs including those having an extended exposure in situ and those suspended in water samples in the laboratory were placed in 225 ml of NB.

(ii) Sediment. Sediments in plastic bags were mixed, and 25 g from each bag was added to 225 ml of NB.

(iii) Oysters. Oysters were scrubbed, rinsed with tap water, shucked, and blended for 90 s (1). Portions (25 g) of

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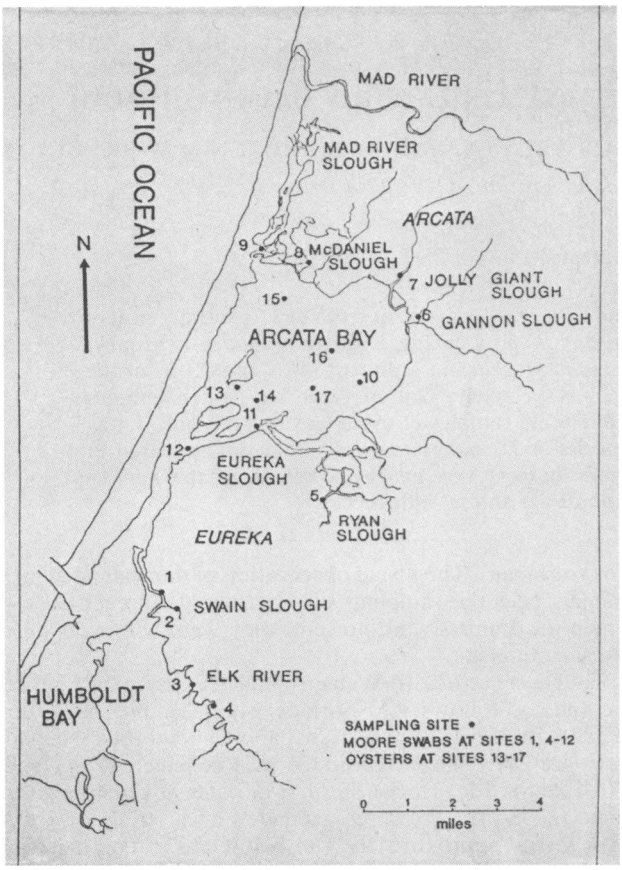

FIG. 1. Map of Humboldt-Arcata Bay area sampling sites. Fresh water, sites 1 to 9; sediment, sites 1 to 5 and 8; seawater, sites 10 to 12; and oyster, sites 13 to 17.

oyster homogenate were added to 225 ml of listeria enrichment broth (17) and to NB.

Enrichment and isolation procedures. The NB was incubated at 4°C (9, 22, 24) and after 7 and 28 days, 1 ml was transferred to 9 ml of thiocyanate-nalidixic acid nutrient broth (TN) (22) and incubated for 18 to 24 h at 35°C. Both undiluted and diluted (1:10, in 0.5% KOH) TN broth was streaked onto modified McBride agar (17) and incubated for 48 h at 35°C. The listeria enrichment broth was incubated and streaked as directed previously (17). A positive control consisting of *L. monocytogenes* V-7 serotype 1a:1 was inoculated into sterile NB and listeria enrichment broth, incubated, and recovered by all media used in this study.

Biochemical tests. The modified McBride agar plates were viewed by the oblique lighting technique of Henry (10, 17). Suspect gray-blue colonies, randomly selected, were stabbed into 7% sheep blood agar (Blood Agar Base no. 2; Oxoid Ltd., London, England) to detect the hemolysin reaction and into motility test medium (Difco) and held at 22°C for further confirmatory tests. Isolates were checked for purity by streaking onto tryptic soy agar containing 0.6% yeast extract (TSA-YE) (Difco) and incubated for 18 to 24 h at 35°C. Isolates from TSA-YE that were catalase positive and had characteristic tumbling motility in a wet mount were further characterized by the procedure described by Lovett (17).

L. monocytogenes isolates were serotyped (17) with Difco antisera for groups 1 and 4 and then further serotyped with more specific antisera provided by R. Bennett (Food and Drug Administration, Washington, D.C.). Final confirmation was conducted by colony hybridization (5, 11) with a ^{32}P-labeled oligonucleotide probe for the *Listeria* beta-hemolysin gene (5) supplied by F. M. Harrell (Food and Drug Administration, Minneapolis, Minn.).

RESULTS AND DISCUSSION

Fresh water. *Listeria* species were detected in 81% (n = 37) of freshwater samples. This is similar to the report of

TABLE 1. Distribution of *Listeria* species in freshwater and sediment samples

Source[a]	Sample type	No. of samples[b]	Temp (°C)	Salinity (‰)	Sediment composition	No. of samples positive for:					
						Listeria species	*L. monocytogenes* serotypes (1a:1/4b:6/4)	*L. innocua*	*L. seeligeri*	*L. welshimeri*	*L. ivanovii*
Elk River											
Site 1	Water	8*	8–12	5–17		7	0/4/0	3	1	4	0
	Sediment	3			Silt	0	0/0/0	0	0	0	0
Site 2+	Water	1	9.5	0.8		1	0/0/0	0	0	1	0
	Sediment	1			Silt	0	0/0/0	0	0	0	0
Site 3+	Water	2	7.5–11	0–0.6		2	2/2/0	0	0	1	0
	Sediment	4			Sand	3	1/0/0	0	1	1	0
Site 4+	Water	5*	8–10	0–0.7		4	0/4/0	1	0	1	0
	Sediment	4			Sand	3	0/1/0	0	0	2	0
Ryan Slough (site 5+)	Water	7*	6–11	0.2–1.2		6	0/4/1	0	2	2	0
	Sediment	22			Silt	6	1/5/0	1	1	1	0
McDaniel Slough (site 8)	Water	11*	8.5–12	0–0.7		10	5/3/1	2	8	6	1
	Sediment	12			Soil	2	0/0/0	0	2	0	0
Mad River, McDaniel Slough, delta+ (six sites in 1-mile [1.6-km] area)	Sediment	15	11–15	0–0.9	Peat	3	0/0/0	0	0	3	0

[a] +, Animals observed near sampling site.
[b] *, Total includes a Moore swab placed at this location for 7 to 8 days in addition to surface water samples collected.

Watkins and Sleath (22) of recovering *Listeria* species in all river waters (n = 7) sampled in the United Kingdom. *L. monocytogenes* (1a:1, 4b:6, or 4) was isolated from 62% of all water samples and was the most predominant of *Listeria* species (Table 1). A wide variety of *Listeria* species and, frequently, more than one species were isolated from each location (Table 1).

Two of the three techniques used here for analyzing freshwater samples, analysis of filters and analysis of Moore swabs incubated in the sample collection bottle in the laboratory, were effective for recovery of *Listeria* species at each sampling site. No *Listeria* species were recovered from Moore swabs suspended in situ for 7 to 8 days at each of seven freshwater sampling stations. Why organisms attached to Moore swabs in the laboratory but not to gauze suspended in situ is unknown. Perhaps attachment to gauze is affected by temperature, incubation time, salinity, or other conditions existing as a function of enclosure within the plastic sample container.

Sediment. *Listeria* spp. were recovered from 30.4% of 46 sediment samples collected at the same locations as the surface water samples (sites 1 to 5 and 8). The predominant species recovered, *L. monocytogenes*, was isolated from 17.4% of the 46 samples. Besides the sites sampled above, an additional 15 sediment samples having the consistency of peat were collected from the edges of a slow-flowing drainage system through grazing areas where sheep, cows, ducks, and geese were present. These samples were collected at six distinct sampling sites approximately 0.25 to 0.5 mile (0.4 to 0.8 km) apart in a delta region between McDaniel Slough and Mad River (Fig. 1). *L. welshimeri* was the only *Listeria* species isolated and was detected in 3 of the 15 samples (20%).

Despite the lower overall incidence of *Listeria* species in sediment compared with fresh water, the rate was similar to the 20.9% incidence of *Listeria* species recovered by Weis and Seeliger (24) from sediment in the south of the Federal Republic of Germany.

The proximity of domesticated animals to a sample site appeared to affect the incidence and predominant species recovered. Sediment samples from Elk River (sites 3 and 4) and Ryan Slough (site 5), which had domesticated animals nearby, had a higher incidence of *Listeria* species (75, 75, and 27.3%, respectively) than did sediment from those sites where animals were absent, such as from Elk River (site 1) (no *Listeria* species recovered) or McDaniel Slough, (site 8) (16.7%).

Distribution in fresh water and sediment. Why *Listeria* species are more prevalent in fresh water than in sediment was not determined but is probably due to a number of factors. Differences in species composition and levels of indigenous competing bacteria between different sample types and other conditions noted at the sample site such as the influence of animals, urbanization, changes in salinity due to tidal activity in the area, or sediment type (26) may also affect the apparent overall distribution and recovery of *Listeria* species in water compared with sediment at a given site.

These data indicate that the incidence of *Listeria* species remains high throughout the freshwater tributaries entering Humboldt-Arcata Bay. A given species or serogroup predominated in fresh water when domesticated animals were in close proximity to the sample site. For example, *L. monocytogenes* (4b:6) was predominant in water at Elk River (site 4). At site 3, *L. monocytogenes* serotypes 1a:1 and 4b:6 were predominant (cows were observed at both sites 3 and 4). *L. monocytogenes* (4b:6) was the main species isolated from waters of Ryan Slough, (site 5) (Table 1), where horses were observed. Both horses and cows can be sources of *Listeria* species (3, 8, 9, 12). The variety of *Listeria* species isolated from water appeared to be greater and no one particular species or serogroup predominated at sites without observable direct domesticated animal and/or human influence. This was illustrated at the Elk River (site 1) and McDaniel Slough (site 8) (Table 1), sites impacted by runoff from the urban area of Arcata, Calif. Direct animal influence was not observed at either site.

Slight variations in salinity due to tidal action did not appear to affect the distribution of *Listeria* species in this water system. Tidal influence was greatest for Elk River (site 1) (5 to 17‰ salinity); four *Listeria* species were recovered from 87% of samples from this location (Table 1). This is similar to data obtained at a site of negligible salinity (McDaniel Slough, site 8) where 90% of water samples were positive for *Listeria* species (five species isolated).

These data indicate that there was a consistent input of *Listeria* species from these freshwater tributaries draining into Humboldt-Arcata Bay. *Listeria* species could also be introduced to the bay via other sources. For example, *L. monocytogenes* (4b:6) and *L. innocua* were isolated from a water sample from an urban drain in Eureka, Calif., which emptied directly into Humboldt Bay. In addition, the influence of a large local seagull population observed here and the presence of other marine birds can also be a consistent source of *Listeria* species to the marine environment (6).

Bay water. Although Moore swabs suspended in situ were not effective for recovering *Listeria* species from fresh water, *Listeria* species were isolated from one (site 11) of three Moore swabs placed in situ in marine waters (sites 10 to 12). *Listeria* species recovered from this swab sample included *L. monocytogenes* 1a:1 and 1a:2, *L. innocua*, and *L. welshimeri*. The presence of *Listeria* species in marine water may indicate a recent contamination since a study (A. T. Fuad, S. D. Weagant, M. M. Wekell, and J. Liston, Abstr. Annu. Meet. Am. Soc. Microbiol. 1989, Q243, p. 370) has shown that *L. monocytogenes* levels decrease when low levels are inoculated into seawater. Effects of dilution by the large volumes of seawater in the marine environment may also result in lower levels of *Listeria* species in marine compared with fresh waters.

Oysters. *L. innocua* was isolated from 1 of 35 oyster samples analyzed from five different sites in Arcata Bay (Fig. 1) and was the only *Listeria* species found in oysters. This is the lowest incidence rate (2.8%) by sample type observed in this study (Fig. 2). The ability of *Listeria* species to survive in marine waters, the degree to which *Listeria* species are diluted, and the pumping rate by oysters are all factors that could affect the uptake and retention of *Listeria* species by oysters.

All *L. monocytogenes* isolated in this study gave a positive reaction with the oligonucleotide probe for the hemolysin gene. No other *Listeria* species isolated in this study reacted with the probe.

Conclusion. *Listeria* species were consistently recovered over a 13-day sampling period during the winter from freshwater tributaries draining into Humboldt-Arcata Bay. These tributaries, which are impacted by domestic farm animals, can contribute *Listeria* species to the Humboldt-Arcata Bay system. The incidence of *Listeria* species in sediments (30.4%) was much lower compared with the incidence in fresh water (81%). This difference could be due to a variety of reasons such as different levels of available nutrients,

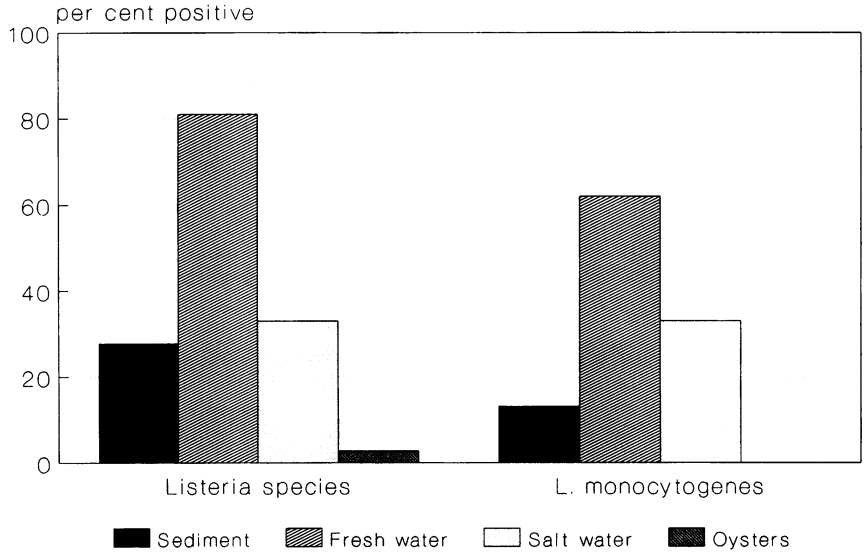

FIG. 2. Incidence of total *Listeria* species and *L. monocytogenes* by sample type.

presence of toxic compounds, and predation by other organisms (19). It is also possible that the lower incidence of recovered *Listeria* species could reflect an initiation of a viable but nonculturable state response by *Listeria* species to these various conditions. Although this survival strategy has not yet been demonstrated for *Listeria* species, it has been shown for a number of other microorganisms and is reviewed by Roszak and Colwell (19). Although the apparent incidence of *Listeria* species is lower in marine waters (33%) compared with fresh waters and was lowest in oysters (2.8%), *Listeria* species were detected throughout the watershed and therefore can be introduced to oysters raised there. These data suggest that the incidence of *Listeria* species is low in oysters held in this estuary during the winter months and most probably represents recent contamination from terrestrial sources.

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Conference for Food Protection
2012 Issue Form

Internal Number: 063
Issue: 2012 I-025

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Addition to Consumer Advisory, Section 3-603.11 of the Model Food Code

Issue you would like the Conference to consider:
The 2009 FDA Food Code recognizes that consumers should have notice regarding the risk of foodborne illness from raw or undercooked meats, poultry, seafood, shellfish, or eggs. However, the Consumer Advisory fails to provide adequate notice for persons to accurately assess the risk of severe illness and death from *Vibrio vulnificus* in raw oysters harvested from the Gulf of Mexico. An adequate advisory is modeled in title 17 of the California Code of Regulations § 13675 which provides a basis for the proposed addition to Section 3-603.11.
(http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/fdb%20Raw%20Oyst%20Sale%20Retail.pdf)

Public Health Significance:
Vibrio vulnificus in raw oysters harvested from the Gulf of Mexico poses a well-defined risk of severe illness and death to consumers with compromised immune systems, liver damage, diabetes, the genetic disorder hemochromatosis, and certain gastric disorders. *Vibrio* is associated with mild gastroenteritis in persons with healthy immune systems, and life-threatening infections in persons with pre-existing medical conditions. Each year 30 or more people are diagnosed with *V. vulnificus*-induced septicemia from raw oysters sourced to Gulf Coast waters and approximately half die from the infection. Even with aggressive treatment the case fatality rate is 30 to 40 percent and mortality is 100 percent if a patient is not treated within 72 hours of symptom onset. Because *V. vulnificus* presents as primary septicemia, a common disease with many causes, misdiagnosis almost certainly results in underreporting of the disease. It is critical that persons have adequate notice of the risk so that they will seek early medical care and inform their doctor they have eaten raw oysters. While the strongest prevention is to require all Gulf oysters shipped interstate to be treated post-harvest to eliminate the pathogen, the industry has resisted such requirements. The proposed warning is, therefore, consistent with industry preferences for consumer education in lieu of other controls. It is a critical requirement because other than self-identification, food establishments have no way of recognizing at-risk patrons. To the extent that patrons have adequate information about their own health status, the warnings may reduce the number of illnesses and deaths (with the attendant bad publicity associated with

news reports and lawsuits). Additionally, since consumer perceptions can alter choices, thus reducing demand, industry interests and public health walk hand-in-hand with providing adequate notice that allows at-risk populations to understand and assess the danger of consuming raw oysters.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 3-603.11, be amended as follows (new language shown with underline):
3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.*
(D) Every FOOD ESTABLISHMENT that offers raw oysters harvested from the Gulf of Mexico (any oyster harvested from the Gulf waters bordering the states of Alabama, Florida, Louisiana, Mississippi, or Texas) shall provide a written warning to any person who orders raw oysters, stating:
WARNING
THIS FACILITY OFFERS RAW OYSTERS FROM THE GULF OF MEXICO. EATING THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS WHO HAVE LIVER DISEASE, CANCER, DIABETES, OR OTHER CHRONIC ILLNESSES THAT WEAKEN THE IMMUNE SYSTEM. If you eat raw oysters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician.
(E) Warnings under subsection (D) are not required whenever the FOOD ESTABLISHMENT has received a copy of a current verification letter from the dealer and tags or labels are as required by Section 3-202.18 of this Code demonstrating that the oysters have been subjected to an oyster treatment process sufficient to reduce *Vibrio vulnificus* to an undetectable level, as defined in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 2004 Edition.

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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Conference for Food Protection
2012 Issue Form

Internal Number: 034
Issue: 2012 I-026

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Hand Antiseptics

Issue you would like the Conference to consider:
An update to the language in the 2009 FDA Food Code, Section 2-301.16 Hand Antiseptics is needed to account for the regulatory procedures that can also be used to make a hand sanitizer compliant with the Food Code. Due to the absence of any specific regulation in FDA's 21 Code of Federal Regulations (CFR) for hand antiseptics and indirect food contact, the Food Code serves as the sole guidance for the use of hand antiseptics in retail food facilities. These procedures are already referenced in Annex 3 of the Food Code (Chapter 2- 301.16 Hand Antiseptics) and therefore updating the language in Chapter 2 would help avoid any confusion and misunderstandings by Inspectors in the field.

Public Health Significance:
Chemicals may be poisonous or toxic if not used properly and in accordance with FDA regulations. The lack of clear and explicit guidance surrounding the use of hand antiseptics in food facilities poses a risk and could contribute to the improper use of chemicals that may subsequently cause public health issues such as the adulteration of food, or potentially acute and chronic effects to both the consumer and the employee of the food facility.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):

2-301.16 Hand Antiseptics.

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

(1) Comply with one of the following:

(a) Be an approved drug that is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness; [Pf] or

(b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, [Pf] and

(2) Comply with one of the following:
(a) Have components that are exempted from the requirement of being listed in federal food additive regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles;[Pf] or
(b) ~~Comply with and b~~Be listed in the following sections and used up to the maximum allowable concentration permitted by that regulation:
(i) 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers ~~as regulated for use as a food additive with conditions of safe use,~~ [Pf] or,
(ii) 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food, [Pf] ~~and~~ or
(c) Have components that have been appropriately cleared for use as hand sanitizers with incidental food contact through GRAS notifications/ affirmations or a Food Contact Notification (FCN) with FDA, and,
(3) Be applied only to hands that are cleaned as specified under § 2-301.12. [Pf]
(B) If a hand antiseptic ~~or a hand antiseptic solution used as a hand dip~~ does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:

1. (1) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; [Pf] or
2. (2) Limited to situations that involve no direct contact with food by the bare hands. [Pf]

(C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine. [Pf]

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Conference for Food Protection
2012 Issue Form

Internal Number: 097
Issue: 2012 I-027

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Use of Galvanized Metal with Acidic Foods

Issue you would like the Conference to consider:
Restricting the use of galvanized metals from contact with food except by local variance for the specific process it is intended to be used for.
Per the 2009 FDA Food Code Public Health Reasons for 4-101.15, zinc may leach into acidic foods if they contact galvanized metal. However, the solubility of zinc is subject not only to pH but also temperature and the corrosive environment of inorganic salts. The inorganic salts can come into contact with the metal from the food or disinfectants used as part of the process.

Public Health Significance:
Setting this guideline would place the requirement of providing data to the regulatory authority in order to acquire a variance.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
4-101.15 Galvanized Metal, Use Limitation.
Galvanized metal may not be used for UTENSILS or FOODCONTACT SURFACES of EQUIPMENT <u>unless, it is shown that zinc does not transfer to FOOD under its specified use.</u>[P]

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Conference for Food Protection
2012 Issue Form

Internal Number: 100
Issue: 2012 I-028

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Chemicals for Washing Fruits and Vegetables

Issue you would like the Conference to consider:
Clarify the language in 2009 FDA Food Code Section 3-302.15 Washing fruits and vegetables, to ensure chemicals used for washing fruits and vegetables follow manufacturer's directions or EPA registered label use instructions.

Public Health Significance:
Food Code Section 7-204.12 specifies that chemicals used to wash fruits and vegetables should meet the requirements specified in 21 CFR 173.315, Chemicals used in washing or to assist in the peeling of fruits and vegetables. In addition to identifying chemicals that may be used, 21 CFR 173.315 also states:
"(d) To assure safe use of the additive... The label or labeling of the additive container shall bear adequate use directions to assure use in compliance with all provisions of this section."
Adding language to the Food Code indicating that use directions should be followed would clarify requirements for safe use, and uphold the public health and consumer food standards set by the Code.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):
3-302.15 Washing Fruits and Vegetables
(B) *Fruits and vegetables may be washed by using chemicals as specified under 7-204.12 and shall be used in accordance with the manufacturer's directions or EPA registered label use instructions*.

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Conference for Food Protection
2012 Issue Form

Internal Number: 099
Issue: 2012 I-029

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Testing for Hot Water Sanitizing

Issue you would like the Conference to consider:
The 2009 FDA Food Code addresses the failure of having test kits for chemical sanitizing (automatic dish machine) as a priority. However, nowhere in the food code does it require the same of hot water sanitization test kits. In fact the Code is silent on this issue (no specificity relating to hot water test kits). Unless a method of ascertaining the level of hot water sanitization occurring in the machine is identified (e.g., the surface of the utensil has met 160°F requirement), validating the machine's operational criteria cannot be objectively measured.

Validating whether the surface temperature has met the required 160°F requirement provides assurance that the utensil has been properly cleaned which includes sanitization. Failure to validate can have negative consequences as failure to validate a temperature of a potentially hazardous food item.

Public Health Significance:
Validation that efficacious sanitization is occurring is an important part of the overall cleaning procedure, whether through manual cleaning (3-compartment sink) or automatic (ware washing machines) cleaning. In automatic operations, heat treatment occurs when the final rinse spray is higher than the upper limit specified by the manufacturer's instructions.

It is commonly understood that if utensils are not cleaned properly, microorganisms are potentially transmitted via foods to other foods by utensils. Therefore, validating that cleaning and sanitization has occurred is an important component in the reduction of disease transmission via food.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-703.11(B), be amended as follows (new language shown with underline and deleted language shown with strike-through):

Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 and achieving a UTENSIL surface

temperature of 71°C (160°F) ~~as measured by an irreversible registering temperature indicator; P or~~ ***shall be validated by the use of a test kit or similar equipment***; or

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Conference for Food Protection
2012 Issue Form

Internal Number: 035
Issue: 2012 I-030

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Food Equipment Certification

Issue you would like the Conference to consider:
The 2009 FDA Food Code contains language in Chapter 4 - *Equipment, Utensils, and Linens* recognizing a single organization for the accreditation of certification programs for food service equipment. Specifically, Section 4-205.10 of the Food Code limits the acceptability of food equipment certification programs to those accredited by the American National Standards Institute (ANSI). ANSI, a private, non-governmental organization, is one of three nationally recognized, U.S. based accreditation bodies that are qualified to accredit product certification programs. The identification of ANSI as the sole (proprietary) source for qualified accreditation providers is unnecessarily restrictive.

Public Health Significance:
The reliance on properly accredited third- party certification programs to evaluate food service equipment to nationally recognized standards that address sanitation and safety is a reliable mechanism to establish compliance with Sections 4-1 and 4-2 of the Food Code. The establishment of clear requirements for determining the acceptability of accreditation bodies is consistent with current practice while supporting an open marketplace based on demonstrated compliance.

Both t*he American National Standards Institute (ANSI)* and the *International Accreditation Service (IAS)* are U.S. domiciled accreditation bodies that are signatory members of the *International Accreditation Forum (IAF),* meaning both organizations are recognized nationally and internationally as having equivalent levels of confidence for providing accreditation services. Accreditation is increasingly being used by regulators and the market as an impartial, independent and transparent means of assessing the competence of conformity assessment bodies.

Regulators in the United States increasingly rely on an integrated system of accreditation and certification to demonstrate that products and services comply with regulatory requirements. In the United States, examples of the reliance on systems of accreditation and certification include programs administered by the Environmental Protection Agency (EPA), the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC). The EPA Water Sense® and Energy Star® programs require that manufacturers submit products to an accredited certification agency for testing and evaluation in order to

establish compliance with established standards and criteria. Both programs establish qualification criteria for recognition of accreditation bodies based on a framework for accreditation developed by IAF. IAF provides the technical basis for the recognition of the competence of accreditation bodies. IAF conducts an initial onsite evaluation, routine surveillance and periodic re-evaluations of accreditation bodies to determine compliance with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Standard 17011 *Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies*. Accreditation bodies found to be operating accreditation programs that comply with these requirements become signatories to the IAF Multilateral Recognition Arrangement. The criteria for the accreditation of product certifying bodies is detailed in ISO/IEC Guide 65, *General requirements for bodies operating product certification systems* and the International Accreditation Forum (IAF) *Guidance on the Application of ISO/IEC Guide 65.*

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-205.1, be amended as shown below (new language shown with underline and deleted language shown with strike-through):

Acceptability

4-205.10 Food Equipment, Certification and Classification.

Food equipment that is certified or classified for sanitation by ~~an American National Standards Institute (ANSI) accredited~~ a certification program accredited by a U.S. domiciled accreditation body that is a signatory to the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) is deemed to comply with Parts 4-1 and 4-2 of this chapter.

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Attachments:

- "Food Equip Cert Issue Supporting Attachments"

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Supporting Attachments

1. 2009 FDA Food Code, Chapter 4, Part 4-2, item 4-205.10 - Web Address: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm188064.htm#part4-2
2. U.S. EPA Water Sense® Product Certification, Version 2.0, Section 4.0, Sub-section 4.1 - Web Address: http://www.epa.gov/WaterSense/docs/cert_system_508.pdf
3. International Accreditation Forum website - Web Address: http://www.iaf.nu/
4. International Accreditation Forum MLA Information - Web Address: http://www.iaf.nu//articles/IAF_MLA/14
5. International Accreditation Forum List of United States Domiciled MLA Signatory Accreditation Bodies - Web Address: http://www.iaf.nu/articles/IAF_MEM_USA__all/112
6. IAS International - Web Address: http://www.iasonline.org

Conference for Food Protection
2012 Issue Form

Internal Number: 008
Issue: 2012 I-031

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Modify FDA Food Code §3-304.11 to include linens and napkins

Issue you would like the Conference to consider:
The current wording of FDA Food Code §3-304.11 states that "food shall only contact surfaces of: (A) equipment and utensils that are cleaned as specified under Part 4-6 of this Code and sanitized as specified under Part 4-7 of this Code; or (B) single-service and single-use articles." By limiting the surfaces that food may contact to only equipment, utensils, single-service and single-use articles, this section negates the allowance for linens and napkins where they are approved for use. Linens and napkins are not included in the definitions of equipment, utensils, and single-service or single-use articles in the Food Code. However Food Code §3-304.13 allows for their use when they are lining containers for the service of food provided they're replaced each time the container is refilled for a new customer.

Public Health Significance:
By emphasizing what is permissible for food contact and what is not, the Food Code can avoid providing conflicting guidance to stakeholders. By including linens and napkins in §3-304.11, the Food Code will clearly identify that linens and napkins can be used for food contact, as specified in §3-304.13, without confusion.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):

3-304.11 Food Contact with Equipment and Utensils

FOOD shall only contact surfaces of:

(A) EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code;[P] or

(B) SINGLE-SERVICE and SINGLE-USE ARTICLES;[P]or

(C) Linens and napkins as specified in §3-304.13.

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Conference for Food Protection
2012 Issue Form

Internal Number: 056
Issue: 2012 I-032

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Allowance for a Direct Drain Connection in Warewashing Equipment

Issue you would like the Conference to consider:
Deleting the prohibition of a direct drain connection for warewashing sinks or warewashing machines from Section 5-402.11 of the 2009 FDA Food Code (as modified by the Supplement issued in 2011). This prohibition is in direct conflict with the major model plumbing codes such as the Universal Plumbing Code and the International Plumbing Code. Many localities adopt these codes, and this creates a tiered system whereby food establishments in localities without a plumbing code must submit to a requirement that establishments in areas with plumbing codes are often required not to comply with. In warewashing, the final step in the process is a sanitizing step with a solution with residual sanitizer or high temperature water. This step acts as a "fail-safe" to overcome the risk of an unnoticed sewage backup in the sink.

Public Health Significance:
There is minimal risk to public health from allowing a direct drain connection in a warewashing sink.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting an amendment to Section 5-402.11 of the 2009 Food Code (as modified by the Supplement issued in 2011) as specified below (deleted language is in strikethru format).

5-402.11 Backflow Prevention.

(A) Except as specified in ¶¶ (B)~~,~~ and (C)~~, and (D)~~ of this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food~~, portable equipment, or utensils are~~ is placed. P

(B) *Paragraph (A) of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building*.

~~(C) *If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.*~~

(~~D~~C) *If allowed by law, a ~~warewashing or~~ culinary sink may have a direct connection*.

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Conference for Food Protection
2012 Issue Form

Internal Number: 006
Issue: 2012 I-033

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Temp Measuring Device for Warewashing Machines w/Hot Water SANITIZING rinse

Issue you would like the Conference to consider:
The next revision of the FDA Food Code should require the Person-in-Charge of a food establishment that has a warewashing machine using a hot water sanitizing final rinse to have a temperature measuring device that measures the utensil surface temperature.
The Food Code currently requires under 4-302.14 Sanitizing Solutions, Testing Devices that "A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided" and furthermore under 4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration that the "Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device."
As far as hot water mechanical operations, the Food Code currently requires, in part, under 4-703.11(B) that "...Hot water mechanical operations...and achieving a UTENSIL surface temperature of 71 degrees C (160 degrees F) as measured by an irreversible registering temperature indicator."
In the case of hot water mechanical operations, the Food Code does not explicitly require both the availability and the use of an irreversible registering temperature indicator or similar device.
It should also be noted that the January 2000 FDA Plan Review Guide, *Part 8 - Warewashing Facilities*, under mechanical warewashing utilizing hot water for sanitization on page 81, states: "An approved maximum registering thermometer or high temperature test papers shall be available and used."
Reliance on the machine's fixed TEMPERATURE MEASURING DEVICE to determine if SANITIZATION has been achieved can be problematic as these devices are not routinely calibrated and may be in disrepair even if the machine itself is working properly. The use of a field temperature indicator (or similar) in conjunction with the fixed pressure gauge and fixed TEMPERATURE MEASURING DEVICE is appropriate to determine if SANITIZATION has been achieved.

Public Health Significance:
Effective SANITIZATION destroys organisms of public health significance that may be present on food equipment and utensils after cleaning or which may have been introduced into the rinse solution.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-302.13, be amended as follows (new language shown with underline):
Temperature Measuring Devices, Manual and Mechanical Warewashing
(A) In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.
(B) In mechanical WAREWASHING operations, an approved irreversible registering indicator or waterproof maximum registering thermometer shall be provided and used regularly for measuring the final rinse temperature at the utensil surface.

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Conference for Food Protection
2012 Issue Form

Internal Number: 031
Issue: 2012 I-034

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
The 2009 FDA Food Code Introduced New Confusing Terms

Issue you would like the Conference to consider:
The new terms introduced into the 2009 FDA Food Code are not food safety-related terms that are relevant to educating the public, the regulated industry and regulatory officials. Removing the public health naming convention of identifying violations as risk factors, public health interventions, or good retail practices requires a re-education process that does not emphasize food safety or foodborne illness prevention. Significant progress has been made in linking the terms (risk factors, public health interventions, good retail practices) to a culture of food safety. We are concerned that use of the terms listed below will create confusion and set back progress in improving compliance in all facilities, particularly in "mom and pop" food service operations.

Core item

1. "Core item" means a provision in this Code that is not designated as a priority item or a priority foundation item.
2. "Core item" includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

Priority Item.

1. "Priority item" means a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.
2. "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
3. "Priority item" is an item that is denoted in this Code with a superscript P? ^{P}.

Priority Foundation Item.

1. "Priority foundation item" means a provision in this Code whose application supports, facilitates or enables one or more priority items.
2. "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel

training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and

3. "Priority foundation item" is an item that is denoted in this Code with a superscript Pf - ^{Pf}.

Public Health Significance:

The main purpose of the FDA Food Code is to assist regulators and the regulated industry in prioritizing actions that proactively improve food employee behaviors and food preparation practices mitigating and eliminating the risk of foodborne illness.

The new terms and levels of priority introduced in the 2009 FDA Food Code are difficult for regulators to articulate and difficult for regulated industry to understand. Without clear understanding there is a high probability of reducing the effectiveness of the Code itself. Time and effort spent re-educating regulators, operators and employees would be better spent on reinforcing the food safety-related and well-understood terms already in use.

Recommended Solution: The Conference recommends...:

the re-creation of the Critical Item Committee. The re-established Committee will be charged with:

1. Using the food safety terminology below in lieu of the terms listed above, or
2. Recommending easily understood (common usage) replacement terms that must be tested using surveys of both regulators and regulated industry,
3. Report back to the 2014 Biennial Meeting on Committee Activities and submit Issues that recommend revsion to the body of the code to align with the the revised language, and strike the existing terminology from the code (Core, Priority, etc.).

Submitter offers the Proposed Revised language for the Committee's Consideration:

Good Retail Practices

1. "Good Retail Practices" means a provision in this Code that is not designated as a Risk Factor or intervention ITEM.
2. "Good Retail Practices " includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

Risk Factors and Intervention Items

1. "Risk Factor Item" means a provision in this Code whose application supports, facilitates or enables one or more RISK FACTOR items.
2. "Intervention Item " includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and
3. "Risk Factor Item" is an item that is denoted in this Code with a superscript Rf - ^{Rf}.
4. "Intervention Item" is an item that is denoted in this Code with a superscript I - ^{I}.

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Conference for Food Protection
2012 Issue Form

Internal Number: 106
Issue: 2012 I-035

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Updating of the Food Establishment Inspection Report

Issue you would like the Conference to consider:
We are requesting that the Conference consider the following proposal:
The current Inspection Form 3-A in the 2009 Food Code Annex 7 and Instructions for Marking form 3-B are based on old section designations of critical and non-critical. When the 2009 code was modified to reflect the three tier designations of Priority (P), Priority Foundation (Pf) and Core (C) these forms were not updated.
We would like FDA to format the Inspection Form 3-A and the Instructions for Marking Form 3-B in Annex 7 to reflect the (P), (Pf), and (C) designations.
We have submitted a draft (attached) of an Inspection Form 3-A that has been divided and grouped according to the (P), (Pf) designated violations in the upper part of the form and the (C) designated violations in the lower part of the form. A draft Instructions for Marking document 3-B has been developed to show the (P), (Pf) and (C) designations to ensure that inspection observations are accurately recorded on the Food Establishment Inspection Report.
The documents attached are presented as drafts. The documents submitted were developed for the State of Oklahoma and would need to be made "generic" for use in future Code publications.

Public Health Significance:
The Food Establishment Inspection Report is the official regulatory document that measures compliance of the establishment with regulatory requirements. The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey this information to the permit holder or person in charge (PIC) at the conclusion of the inspection.
Reformatting the Food Establishment Inspection Report (3-A) and Guidance Marking Document (3-B) by providing a uniform and consistent inspection process will help bring uniformity and assist permit holders in understanding the three-tier designations in jurisdictions that have adopted the 2009 Food Code.
The formatting of the document to reflect the Priority, Priority foundation and Core designations will communicate to the operator the severity of the violations and will provide

appropriate timeframes for corrective action, thereby reducing foodborne illness risk to the public.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting that the 2013 Food Code contain updated versions of the Food Establishment Inspection Report 3-A and Instructions for Marking Form 3-B that are currently provided in Annex 7 of the 2009 Food Code in order to reflect the Priority, Priority Foundation and Core designations.

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Attachments:

- "DRAFT Food Establishment Inspection Report- Page 1"
- "DRAFT Food Establishment Inspection Report - Page 2"
- "DRAFT Instructions for Marking Guide"

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Consumer Protection Division
Food Inspection Report
State Code OAC 310:257

Inspection Date	Inspection Time	Mgr. Cert	County #	Establishment#	License Expiration	Type	Class	Priority

Purpose of Inspection: 1 – Routine 2 – Compliance 3 – Issue License Application 4 – Complaint 5 – Other 6 – Out of Business 7 – Follow-Up Activity 8 – Reserved

Number of Repeat Risk Factor/Intervention Violations | **Follow-up:** | **On or Before Date:**

Establishment | **Owner**

Physical Address | **City** | **Zip Code** | **Phone #** / **Cell Phone #**

PRIORITY & PRIORITY FOUNDATION VIOLATIONS

Priority items are proven measures that are directly linked to the elimination, prevention or reduction of hazards associated with foodborne illness.
Priority Foundation items incorporate specific actions, equipment or procedures to control risk factors that contribute to foodborne illness.
NOTE: Items 1-35 Require Immediate Action or by date noted on Pg 2 - Not to exceed 10 days from date of inspection.

IN=in compliance **OT**=not in compliance **NO**=not observed **NA**=not applicable **CDI**=corrected on-site during inspection **R**=repeat violation

	IN	OT	NO	NA	● CDC Risk Factors & Food Code Interventions	CDI	R
Supervision/Licenses							
1					Valid license to operate; non-transferable		
2 ●					PIC present, demonstration of knowledge, performs duties		
3					Special processes (Variance, ROP, shellfish tanks, HACCP)		
Employee Health							
4 ●					Ill workers–PIC & EMP responsibilities: Report symptoms & diagnosis; Restrict/Exclude (removal, retain or adjust)		
Control of Hands as a Vehicle of Contamination							
5 ●					Hands clean, washed, maintained; Hand antiseptics		
6 ●					No Bare Hand Contact with Ready-to-Eat foods Or alternate methods; Glove limitations		
7					Adequate hand wash facilities: supplied, accessible; Toilets properly supplied		
Approved Source							
8 ●					Food, water, ice: obtained from approved source		
9 ●					Food in good condition, safe, unadulterated, segregated		
10 ●					Required records (shellstock tags, parasite destruction)		
Protection from Contamination							
11 ●					Food separated/protected; Proper tasting procedures; Self-serve operations; Single service use when required		
12					Disposition of returns, previously served, Reconditioned, unsafe food		
13					Prohibited animals; Prohibited food operation locations		
14					Sinks used for intended purposes		
15					Food equipment: improper use, operation (Materials, design)		
16					Insects, rodents, & other pests controlled		

	IN	OT	NO	NA	● CDC Risk Factors & Food Code Interventions	CDI	R
Time/Temperature Control for Safety (TCS)							
17 ●					Cooking time & temperatures; Plant food cooking		
18 ●					Reheating procedures for hot holding		
19 ●					Cooling time & temp; cooling methods		
20 ●					Hot holding temps; received at proper temp		
21 ●					Cold holding temps; received at proper temp		
22					Date marking and disposition		
23 ●					Time as public health control, procedures/records		
24 ●					Non-continuous cooking process / partial cook		
25					Adequate facilities/equipment to maintain food temps		
26					Probe thermometers provided & accurate		
Consumer Advisory, Highly Susceptible Populations							
27					Consumer advisory, Child menu, Allergen label		
28					Pasteurized food used; Prohibited food not offered Pasteurized eggs used where required		
Chemicals							
29					Food additives; approved, properly used		
30					Toxic substances properly identified, stored, used		
Warewashing, Food Contact Surfaces							
31					Warewash, sanitize equipment: Design, supplies, operated; Test strips; Temp gauges; Alarms		
32					Warewashing; Sanitize at ppm/temp		
33					Food contact surfaces of equipment & utensils clean		
Plumbing							
34					Water: adequate pressure, sufficient capacity		
35					Plumbing sewage system: design, approved, installed Cross-connection prohibited, air gaps, disposal		

CORE VIOLATIONS

Core items relate to general sanitation & maintenance, equipment design & maintenance, and physical facilities & structures.
NOTE: Items 36-58 must be corrected within 90 days or by date noted on Pg. 2.

		● Food Temperature Controls	CDI	R
36		Approved thaw methods; Active cool containers stored properly		
37		Thermometers provided, accurate, conspicuous		
Food Identification				
38		Food properly labeled, original container, honestly presented		
Prevention of Food Contamination				
39		Contamination prevented during food preparation, storage & display; Washing fruits/vegetables		
40		Personnel: clean, jewelry, hair restraints, FH Permits		
41		Eating, drink, tobacco use; No discharge from eyes, nose, mouth		
42		Wiping cloths: properly used & stored; Sponges prohibited		
Proper Use of Utensils				
43		In-use utensils proper storage, cleaning frequency; Utensils, equip & linens: properly stored, dried, handled; Linens clean		
44		Single-use, single-service articles: properly stored, used		
Utensils, Equipment and Vending				
45		Food & non-food contact surfaces cleanable, design		
46		Manual/Mechanical warewashing facilities: maintained, operated; Pressure guages, data plates; Use limitation, pre-cleaning		
47		Non-food contact surfaces clean; Cleaning frequency		

		● Physical Facilities	CDI	R
48		Plumbing sys: maintained, backflow device installed, inspected		
49		Toilet facilities: accessible, properly constructed, cleaned Self closures		
50		Break/locker areas: used, provided, maintained; Living areas separated; Laundry facilities		
51		Hand wash sinks: designed, clean, used; Proper signage		
52		Floors, walls, ceilings (premises): clean, free of litter; Removal of pests		
53		Floors, walls, ceilings (physical facilities): design, maintained, good repair; Outer openings protected		
54		Service Sinks; Maintenance & cleaning tools: use, storage		
55		Outdoor areas: constructed, maintained clean		
56		Garbage/refuse: properly disposed, fac constr, maintained		
57		Ventilation: installed, maintained; Lighting: adequate, shielded		
58		Other		

Any one of the following 3 requires a Follow-up Inspection:
1. Five (5) or more marked of any items flagged with a "●".
2. Eleven (11) or more marked of any items 1 - 35.
3. Six (6) or more marked of any items 1-35 Plus eight (8) or more of any items 36-58.

Oklahoma State Department of Health
1000 NE 10th Street, Oklahoma City OK 73117-1299
Telephone (405) 271-5243 Fax (405) 271-3458
Website: www.ok.gov/health

Consumer Protection Division

Food Inspection Report
State Code OAC 310:257

Establishment	**Establishment #**	**Date**

TEMPERATURE OBSERVATIONS

Item/Location	Temp	Item/Location	Temp	Item/Location	Temp

OBSERVATIONS AND CORRECTIVE ACTIONS

Item Number	Violations cited must be corrected within the time frames below	**Correct By**:

Comments:

Inspector Signature	**RS#**	**Inspector Phone #**
Person In Charge Name		**Person In Charge Signature**
Establishment Email		**Establishment Phone #**

OAC 310:257 - Subchapters & Paragraphs Listed Below
Good Retail Practices

	Food Temperature Control	
36	Microwave, Slacking, Thawing, Cooling methods	5-47; 5-55; 5-56; 5-58 b
37	Equipment thermometers provided, conspicuous	7-37 a-d
	Food Identification	
38	Food properly labeled, original container, honestly presented	5-2 f,g; 5-15 b; 5-19; 5-24; 5-39; 5-50 b; 5-65; 5-66; 5-67 a, b1-4, b6-7, c,d; 5-68
39	Contamination prevented during food preparation, storage & display Washing fruits and vegetables	5-17; 5-21 d; 5-23 a3-8; 5-27; 5-29; 5-32; 5-36; 5-37; 5-38; 5-40; 5-42; 5-44 b; 5-45; 5-71 8; 13-8 b
	Mobile pushcarts, retail food service establishment, commissary	17-2 a; 17-2 c; 17-4 d; 17-5 b; 17-6
40	Personnel: cleanliness, jewelry, hair restriants	3-16; 3-17; 3-20
41	Eating, drinking, tobacco; No discharge from eyes, nose, mouth	3-18; 3-19
42	Wiping cloths proper use & storage; Sponges prohibited 5-33;	5-33; 7-6; 7-102
	Proper Use of Utensils	
43	In-use utensils properly stored, cleaning frequency; Utensils, linens, equipment properly stored, dried, handled; Linens clean	5-31; 7-59 a,b; 7-96 thru 7-99; 7-101; 7-105 a,b,d 7-106, 7-107 b; 7-108; 7-109; 17-6
44	Single-use, single-service articles: properly stored, used	7-80; 7-81; 7-105 a,c; 7-106; 7-107 a,c
	Utensils, Equipment & Vending	
45	Food / non-food contact surfaces: cleanable, designed, constructed used	5-34 b,c,d; 5-35; 7-1 2,3,4,5; 7-2; 7-9; 7-10; 7-11; 7-12 1B, 2B; 7-13; 7-16 a2,b; 7-17 thru 7-21; 7-27; 7-28 1-4; 7-29 thru 7-34; 7-46 thru 7-49; 7-60 thru 7-64; 7-103; 7-104; 17-1 c
46	Manual/Mechanical warewashing facilities: maintained, operated; Pressure gauges, data plates; Use limitation, pre-cleaning; Design; drain boards	7-25; 7-38; 7-39; 7-43; 7-44; 7-45; 7-51 c,d,e,f 7-52; 7-57; 7-65; 7-66; 7-67; 7-69; 7-74; 7-76; 7-87 thru 7-91
47	Non-food contact surfaces clean; Equip/utensil cleaning frequency	7-82 b,c; 7-84; 7-85
	Physical Facilities	
48	Plumbing systems: maintained, backflow devices installed, inspected	9-14 b,c,d; 9-22; 9-24; 9-30 2; 9-31 2,3; 9-32 thru 9-36; 9-37 2-5; 9-39; 9-40; 9-42; 9-43; 9-44 b; 9-45; 9-47 b,c,d; 9-48; 9-51; 9-53
49	Toilet facilities: proper construction, accessible, supplied, cleaned; Self closures	9-19; 9-61; 11-14; 11-36; 11-47; 11-48
	Mobile pushcarts, retail food service establishment,	17-2 c2, d1; 17-4 f
50	Break rooms, Locker areas: used, provided, maintained; Living areas separate; Laundry facilities	7-54; 7-59 c; 7-100; 11-22; 11-33; 11-37; 11-49
51	Hand washing sinks designed, clean, used; Proper signage	9-13 b; 11-26; 11-27; 11-47
52	Floors, walls, ceilings (premises): clean, maintained free of litter Removal of pests	11-41; 11-42; 11-51; 11-53
53	Floors, walls, ceilings (physical facilities): properly designed, maintained, good repair; Outer openings protected Mobile food service establishment	11-1; 11-3 through 11-10; 11-15; 11-16; 11-40; 11-46 17-3 a
54	Service sinks; Maintenance and cleaning tools properly used & stored	7-86; 9-20; 11-45; 11-52
55	Outdoor areas: constructed, maintained, clean	11-2; 11-17; 11-18; 11-19
	Mobile Commissary & servicing area	17-5 e
56	Garbage & refuse: properly disposed, facilities constructed, maintained	9-55 thru 9-60; 9-62 thru 9-73; 11-20
57	Ventilation: installed, maintained; Lighting: adequate, shielded	7-22; 7-26; 7-53; 11-11; 11-12; 11-31; 11-32; 11-43

Instructions for Marking Guide – 2009 Food Code

Priority items- proven meausres that are directly linked to the elimination, prevention or reduction of hazards associated with foodborne illness.
Priority Foundation items- incorporate specific actions, equipment or procedures to control risk factors that contibute to foodborne illness.

Supervision	
1. IN OUT 15-12, 15-21 17-2(c)(3) & (d)(2) 17-3(b) & (d) 17-4(c) & (e) 17-5(c) Note: References above are based on Oklahoma State Department of Health (OSDH) Food Code	<u>Valid License to Operate; non-transferable</u> 15-12: Prerequisite for operation 15-21: Licenses not transferable <u>Mobile pushcarts</u> 17-2(c)(3): indoor carts shall have a licensed commissary within confines of facility 17-2(d)(2): outdoor carts shall have a licensed commissary <u>Mobile F. S. E</u> 17-3(b): shall remain at one physical location no more than 12 hours unless in conjunction with a single event or celebration 17-3(d): business name & OSDH license number clearly visible on outside of vehicle during operation <u>Mobile Retail F. S. E</u> 17-4(c): shall remain at one physical location no more than 12 hours unless in conjunction with a single event or celebration 17-4(e): business name & OSDH license number clearly visible on outside of vehicle during operation <u>Commissary & servicing area requirements</u> 17-5(c): Commissaries shall be licensed FSE if used for food production
●2. IN OUT 2-101.11[Pf] 2-102.11 [Pf] 2-103.11 [Pf]	<u>PIC present, demonstration of knowledge, performs duties</u> 2-101.11: Assignment 2-102.11: Demonstration 2-103.11: Person in Charge
3. IN OUT N/A 3-404.11(A)[P] 3-502.12 (A),(B4),(C),(E1) [P] 4-204.110(A) [P] 8-103.12(A)[P] 3-404.11(B)[Pf] 3-502.11 [Pf] 3-502.12(B) 1-3,5,6 [Pf] 3-502.12(D-1)(D-2a,f,g,h) [Pf] 3-502.12 (D3, D4) [Pf] 3-502.12 (E-2,3,4) [Pf] 4-204.110(B)[Pf] 8-103.11 [Pf] 8-103.12(B)[Pf] 8-201.14 [Pf]	<u>Special processes (Variance, ROP, shellfish tanks, juice, HACCP)</u> 3-404.11(A): Treating juice - (packaged under HACCP PLAN - 5 log reduction) 3-502.12(A): ROP, criteria-(ROP shall control C.bot and Listeria) 3-502.12(B 4): ROP, criteria-(14 days/use-by or sell-by) 3-502.12(C): ROP, criteria-(no ROP of fish unless maintained frozen) 3-502.12(E1): ROP cheese packaging 4-204.110(A): Molluscan shellfish tanks-(marked display only) 8-103.12(A): Conformance w/ approved procedures –(complies w/ HACCP plans) 3-404.11(B)Treating juice – (food establishment - label if not treated to reduce microorganisms) 3-502.11: Variance requirement 3-502.12(B) 1-3,5,6: ROP w/o a variance, criteria -(ROP HACCP plan requirements/instructions; proper discard, no BHC, physical barriers, training program) 3-502.12(D-1)(D-2a,f,g,h)(D3, D4): ROP w/o variance, cook-chill or sous vide 3-502.12 (E-2,3,4): ROP, cheese (HAACP, labeling, 30 day shelf life) 4-204.110(B): Molluscan Shellfish Tanks-(variance if offered for consumption) 8-103.11: Documentation of Proposed Variance & Justification 8-103.12(B): Conformance with approved procedures- (documentation, monitoring & records) 8-201.14: Contents of HACCP plan

Employee Health	
●4. IN OUT 2-201.11(A)(D)(F) [P] 2-201.12 [P] 2-201.13 [P] 2-201.11 (B)(E) [Pf]	<u>Ill workers – PIC & employee responsibilities; Report symptoms & diagnosis; Restrict/Exclude (removal, retain or adjust)</u> 2-201.11 (A,D,F): Responsibility of PIC to require reporting by food employees and applicants-(employee to report diagnosis, symptoms-excluded/restricted) 2-201.12: Exclusions and Restrictions 2-201.13: Removal, adjustment, or retention of exclusions and restrictions 2-201.11 (B,E): Responsibility of the PIC to require reporting by food employees and applicants
Control of Hands as a Vehicle of Contamination	
●5. IN OUT N/O N/A 2-301.11 [P] 2-301.12 [P] 2-301.14 [P] 2-301.15 [Pf] 2-301.16 [Pf] 2-302.11 [Pf]	<u>Hands clean, washed, maintained; Hand antiseptics</u> 2-301.11: Clean Condition (hands arms) 2-301.12: Cleaning Procedure (how to wash) 2-301.14: When to Wash 2-301.15: Where to Wash 2-301.16: Hand Sanitizers (CFR, how to use) 2-302.11: Maintenance (fingernails trimmed, no polish, gloves good repair)
●6. IN OUT N/O N/A 3-301.11(B) [P] 3-304.15(A) [P] 3-301.11(C) [Pf]	<u>No BHC with RTE foods or alternate methods</u> 3-301.11(B): Preventing Contamination from Hands (no bare hand contact with RTE-or shall use alternate methods) 3-304.15(A): Gloves, Use Limitation (if gloves used; one task only, discard when necessary) 3-301.11(C): Preventing contamination from hands-(Minimize bare hand/arm contact with exposed food that is not in a RTE form)
7. IN OUT 5-202.12(A) [Pf] 5-203.11(A) [Pf] 5-204.11 [Pf] 5-205.11 [Pf] 6-301.11 [Pf] 6-301.12 [Pf] 6-302.11 [Pf]	<u>Adequate/accessible handwashing facilities/soap/paper towels/toilet tissue</u> 5-202.12(A): Hand washing Facility, installation (water at 100°F at hand sink) 5-203.11(A): Numbers & Capacities, handwashing Facilities 5-204.11: Location & Placement, handwashing Facilities 5-205.11: Using a hand washing facility-(maintained, no other purpose) 6-301.11: Hand washing cleanser, availability 6-301.12: Hand drying provision 6-302.11: Toilet tissue, availability-(toilet paper available at toilets)
Approved Source	
●8. IN OUT 3-201.11(A) (B) [P] 3-201.12 [P] 3-201.13 [P] 3-201.14 [P] 3-201.15 [P] 3-201.16 [P] 3-201.17 [P] 3-202.13 [P] 3-202.14 [P] 3-202.16 [P] 3-202.110(B) [P], 3-303.11 [P] 5-101.11 [P], 5-101.13 [P] 5-102.11 [P], 5-102.12 [P] 3-201.11(C&E) [Pf] 3-202.110(A) [Pf] 5-102.13 [Pf]	<u>Food, water, ice: obtained from approved source</u> 3-201.11(A) (B): Compliance with food Law-(source, home prepared prohibited) 3-201.12: Food in a Hermetically sealed Container-(regulated food processor) 3-201.13: Fluid Milk and Milk Products 3-201.14: Fish 3-201.15: Molluscan Shellfish 3-201.16: Wild Mushrooms; 3-201.17: Game Animals 3-202.13: Eggs 3-202.14: Eggs and Milk Products, Pasteurized 3-202.16: Ice 3-202.110(B): Juice Treated –(pasteurized, raw sold from production site only) 3-303.11: Ice Used as Exterior Coolant, prohibited as ingredient 5-101.11: Approved system- (water); 5-101.13: Bottled drinking water 5-102.11: Quality, standards (water); 5-102.12: Non-drinking water <u>Food labeling/Water sampling/ Juice from approved processor</u> 3-201.11(C&E): Compliance with food law-packaged, frozen fish in raw form, whole-muscle intact beef (labeled, written specs.) 3-202.110(A): Juice treated –(HACCP system) 5-102.13: Sampling-(non-community H_20 sampled)

●9. IN OUT 3-101.11 P 3-202.15 Pf 6-404.11 Pf	Food in good condition, safe, unadulterated, segregated 3-101.11: Safe, Unadulterated and Honestly Presented 3-202.15: Package Integrity-(packages in good condition) 6-404.11: Distressed Merchandise, Segregated and Location
●10. IN OUT N/A 3-402.11(A) P 3-202.17(A) Pf , 3-202.18(A)Pf 3-203.12 Pf 3-402.12(A&C) Pf	Required records (shellstock tags, parasiste destruction) 3-402.11(A): Parasite destruction-(fish freezing requirements) 3-202.17(A):Shucked Shellfish, Packaging and Identification-(proper labels) 3-202.18(A): Shellstock identification-(proper labels) 3-203.12: Shellstock, maintaining identification-(Labels-90 days) 3-402.12(A&C): Records, creation and retention-(frozen records/letter from supplier)
Protection from Contamination	
●11. IN OUT N/O 3-301.12 P 3-302.11(A1)-a&b P 3-302.11(A2)P 3-304.11 P 3-306.11 P 3-306.13(A) P 4-502.12 P 3-306.13(B&C) Pf 4-302.11Pf	Food separated/protected; Proper tasting procedures; Self-service operation; Single service use when required 3-301.12: Preventing Contamination when Tasting 3-302.11(A1)-a&b; 3-302.11(A2): Packaged and unpackaged food-separation, packaging, and segregation-(Raw animal food separate from RTE and each other) 3-304.11: Food Contact with Equipment and Utensils Food separated/protected; Proper tasting procedures; Self-service operation; Single service use when required continued… 3-306.11: Food Display-(protection from self-serve food contamination/guards) 3-306.13(A): Consumer Self-Service Operations-(Raw not for self-service) 4-502.12: Single-service and Single-use Articles, required Use-(if inadequate ware washing) 3-306.13(B&C): Consumer Self-Service Operations-(RTE self-service protection/salad bars monitored) 4-302.11: Utensils, consumer self-service-(available for each food item)
12. IN OUT N/O N/A 3-306.14(A) P 3-701.11(A-D) P	Disposition of returns, previously served, Reconditioned, unsafe food 3-306.14(A): Returned Food and Re-Service of Food-(not re-served) 3-701.11(A-D): Discarding or reconditioning unsafe, unadulterated, or contaminated food
13. IN OUT N/O N/A 6-202.111P 2-403.11(A)Pf 6-501.115(A)Pf	Prohibited animals; Prohibited food operation locations 6-202.111: Private homes and living or sleeping quarters, use prohibition-(no food service operations) 2-403.11(A): Handling Prohibition-(employees may not touch animals) 6-501.115(A): Prohibiting Animals-(live animals not allowed)
14. IN OUT N/O 6-501.15 Pf	Sinks used for intended purpose 6-501.15: Cleaning maintenance tools, preventing contamination- (food prep/hand & ware washing sinks used for no other purpose)
15. IN OUT N/O 4-101.11(A) P 4-101.13(A) P 4-101.14(A) P 4-101.15P 4-101.13(B)P 4-101.13(C) P 4-102.11(A1)(B1)P 4-201.12P 4-204.110(A)P, 4-204.111 P 4-202.11Pf, 4-202.12A(1)Pf	Food equipment: improper use, operation (Materials,design) 4-101.11(A): Characteristics-(food contact material may not impart, must be safe) 4-101.13(A): Lead in ceramics, china, crystal, use limitation 4-101.14(A): Copper, Use Limitation, 4-101.15: Galvanized Metal, Use Limitation 4-101.13(B): Lead in Pewter Alloys, Use Limitation 4-101.13(C): Lead in solder and flux, Use Limitation 4-102.11(A1)(B1): Characteristics-(single-service/single-articles safe) 4-201.12: Food temperature measuring device-(no glass except candy) 4-204.110(A): Molluscan Shellfish tanks- (display tanks not for human consumption) 4-204.111: Vending Machine, Automatic Shutoff 4-202.11: Food-Contact Surfaces-(Multi-use; proper construction) 4-202.12A(1): CIP equipment-(cleaning & sanitizing through a fixed system)
16. IN OUT 11-50Pf(1,2,4)---OSDH code reference	Insects, rodents, & animals not present 11-50(1,2,4):Controlling Pests, (presence shall be controlled, inspections, no harborages)

Time/Temperature Control for Safety (TCS)	
●17. IN OUT N/O N/A 3-401.11A(1-3)&B(2)[P] 3-401.12(C)[P] 3-401.13 [Pf]	Cooking time & temperatures; Plant food cooking 3-401.11A(1-3) & B(2): Raw Animal Foods-(cook times and temperatures) 3-401.12(C): Microwave Cooking-(cook temp.) 3-401.13: Plant food cooking for hot hold
●18. IN OUT N/O N/A 3-403.11(A-D) [P]	Reheating procedures for hot holding 3-403.11(A-D): Reheating for Hot Hold
●19. IN OUT N/O N/A 3-501.14 [P] 3-501.15(A)[Pf]	Cooling time & temperature; cooling methods 3-501.14: Cooling-(time/temperature parameters) 3-501.15(A): Cooling methods
●20. IN OUT N/O N/A 3-202.11(D) [P] 3-501.16(A1)[P]	Hot holding temperatures, received at proper temperature 3-202.11(D): Temperature-(received at 135º) 3-501.16(A1): TCS food, hot and cold holding-(135º or above)
●21. IN OUT N/O N/A 3-202.11(A)(C) [P] 3-501.16(A2) [P] 3-501.16(B)[P] 3-202.11(E)(F) [Pf]	Cold holding temperatures, received at proper temperature 3-202.11(A)(C): Temperature-(received at 41º/eggs 45º) 3-501.16(A2): TCS, hot & cold holding-(41º or below) 3-501.16(B): TCS, hot & cold holding- (eggs refrigerated equipment ambient air of 45º or less) 3-202.11(E)(F): Temperature-(shipped and received frozen, no signs of temperature abuse)
22. IN OUT N/O N/A 3-501.18 [P] 3-501.17 [Pf]	Date marking & disposition 3-501.18: RTE, TCS Food, Disposition-(RTE must be discarded if date expired or no date) 3-501.17: RTE, TCS, date marking –(41º for 7 days & other procedural options)
●23. IN OUT N/O N/A 3-501.19(B)1,3,4[P] 3-501.19(C)1,4,5 [P] 3-501.19(A)(B2)(C2)(C3)[Pf]	Time as public health control, procedures/records 3-501.19(B)1,3,4 & 3-501.19(C)1,4,5: Time as a Public Health Control-(4hr/6hr start & discard times) 3-501.19(A)(B2)(C2)(C3): Time as a public health control –(RTE, TCS, Procedures/labeling)
●24. IN OUT N/O N/A 3-401.14(A-E) [P] 3-401.1(F)1-5 [Pf]	Non-continuous cooking process/ partial cook 3-401.14(A-E): Non-Continuous Cooking of Raw Animal Food-(procedures for partial cooking of meats) 3-401.1(F)1-5: Non-continuous Cooking of Raw Animal-(procedural requirements)
25. IN OUT N/O N/A 4-301.11 [Pf]	Adequate facilities/equipment to maintain food temperatures (hot/cold hold, cool, reheat) 4-301.11: Cooling, Heating, and Holding Capacities-(adequate equipment to maintain food temperatures)
26. IN OUT N/O N/A 4-203.11 [Pf] 4-203.12 [Pf] 4-204.112(E)[Pf] 4-302.12 [Pf] 4-502.11(B)[Pf]	Probe thermometers provided & accurate (food, air, dishmachines) 4-203.11: Temperature Measuring Devices, Food-(scaled & accurate) 4-203.12: Temperature Measuring Devices, Ambient Air and Water-(scaled & accurate) 4-204.112(E): Temperature Measuring Devices-(± 1º C or 2º F) 4-302.12: Food Temperature Measuring Device-(provided, thin tip when needed) 4-502.11(B): Good Repair and Calibration-(calibrated to manufacturer specs.)

Consumer Advisory, Highly Susceptible Populations	
27. IN OUT N/A 3-401.11(D2)[Pf] 3-602.11(B5)[Pf] 3-603.11[Pf]	<u>Consumer advisory / Child menu / Allergen labeling</u> 3-401.11(D2): Raw Animal Foods-(children's menu does not offer under cooked comminuted meat 3-602.11(B5): Food allergens –(major food allergen ingredient) 3-603.11: Consumption of animal foods that are raw, undercooked, or not otherwise processed to eliminate pathogens –(Consumer Advisory: disclosure/reminder)
28. IN OUT N/A 3-302.13[P] 3-801.11(A)2,3[P] 3-801.11B,C,E[P]	<u>Pasteurized food used; Prohibited foods not offered; Pastuerized eggs used where required</u> 3-302.13: Pastureized eggs, substitute for raw eggs for certain recipes 3-801.11(A)2,3[P] & 3-801.11B,C,E: Pasteurized foods, prohibited reservice, and prohibited food
Chemicals	
29. IN OUT N/A 3-202.12[P], 3-302.14[P]	<u>Food additives: approved, properly used</u> 3-202.12: Additives-(must use approved additives) 3-302.14: Protection from Unapproved Additives
30. IN OUT 7-201.11[P] 7-202.12(A,B)[P] 7-203.11[P] 7-204.11[P] 7-204.12(A)[P] 7-204.13[P] 7-204.14[P] 7-205.11[P] 7-206.11[P] 7-206.12[P] 7-206.13(A)[P] 7-207.11(B)[P] 7-207.12[P] 7-208.11(B)[P] 7-301.11[P] 6-501.111(C)[Pf], 7-101.11[Pf] 7-102.11[Pf], 7-202.11(A)[Pf] 7-202.12(C)[Pf] 7-207.11(A)[Pf]	<u>Toxic substances properly identified, stored, used</u> 7-201.11: Storage Separation-(separate from food) 7-202.12(A,B): Conditions of Use-(toxic items properly used and applied) 7-203.11: Poisonous or Toxic Material Containers-(can't put food in toxic item container) 7-204.11: Sanitizers, Criteria-(meet 40 CFR) 7-204.12(A): Chemicals for Washing Fruits and Vegetables, Criteria-(21 CFR) 7-204.13: Boiler Water Additives, Criteria 7-204.14: Drying Agents, Criteria-(21 CFR) 7-205.11: Incidental Food Contact, Criteria-(lubricants meet 21 CFR), 7-206.11 Restricted Use Pesticides, Criteria-(use according to 40 CFR), 7-206.12 Rodent Bait Stations-(covered, tamper resistant) 7-206.13(A): Tracking Powders, Pest Control and Monitoring-(no tracking powders) 7-207.11(B): Restriction and Storage-(employee medicines only) 7-207.12: Refrigerated Medicines, Storage-(stored in a container, identified) 7-208.11(B): Storage-(first aid supplies properly stored) 7-301.11: Separation-(toxic items for retail sale properly stored) 6-501.111(C): Controlling Pests-(methods to control are approved) 7-101.11: Identifying Information, Prominence-(toxic items labeled w/manufacturer) 7-102.11: Common Name-(working toxic item container labeled with common name) 7-202.11(A): Presence and Use, Restrictions-(on site only for food operations & maintenance) 7-202.12(C): Conditions of use –(application by Certified Operators only) 7-207.11(A): Restriction and Storage-(employee medicines only)

Ware washing, Food Contact Surfaces	
31. IN OUT N/A N/O 4-204.115 [Pf], 4-204.116[Pf] 4-204.117 [Pf], 4-301.12(A, B)[Pf] 4-302.14[Pf], 4-501.17 [Pf] 4-501.116[Pf]	<u>WW, sanitize equipment: design, adequate supplies, properly operated;</u> <u>Test strips, temperature gauges, alarms</u> 4-204.115: Warewashing Machines, Temperature Measuring Devices-(wash, rinse, sanitize temps measured); 4-204.116: Manual Ware washing Equipment, Heaters and Baskets-(integral heating device with baskets) 4-204.117: Warewashing Machine, Automatic dispensing of Detergents and Sanitizers-(automatically dispensed and have an alarm) 4-301.12(A, B): Manual Warewashing, Sink Compartment Requirements-(three compartments, adequate size) 4-302.14: Sanitizing Solutions, Testing Devices-(test kit required) 4-501.17: Warewashing Equipment, Cleaning Agents-(cleaning agent required) 4-501.116: Warewashing Equipment, Determining Chemical Sanitizer Concentration-(concentration determined using a test kit)
32. IN OUT N/A N/O 4-501.111 [P] 4-501.114[P] 4-703.12[P] 4-501.19[Pf] 4-501.110 [Pf] 4-501.112(A) [Pf]	<u>Ware washing sanitize as required at ___ ppm/temperature</u> 4-501.111: Manual Ware washing Equipment, Hot Water Sanitization Temperature 4-501.114: Manual and Mechanical Warewashing Equipment, Chemical Sanitization-temperature, pH, concentration, and hardness 4-703.12: Hot water and chemical (sanitization) 4-501.19: Manual Warewashing Equipment, Wash Solution Temperature 4-501.110: Mechanical Warewashing Equipment, Wash Solution Temperature 4-501.112(A): Mechanical Warewashing Equipment, Hot Water Sanitization Temperature
33. IN OUT N/A 4-602.11(A,C)[P] 4-702.11 [P] 4-601.11(A) [Pf]	<u>Food contact surfaces of equipment and utensils clean</u> 4-602.11(A,C): Equipment Food-contact Surfaces and Utensils-(cleaned and sanitized between uses) 4-702.11: Before Use After Cleaning-(sanitized before use) 4-601.11(A): Equipment, Food-contact Surfaces, Nonfood-contact Surfaces, and Utensils-(clean to sight and touch)
Plumbing	
34. IN OUT 5-103.11 [Pf] 5-103.12 [Pf] 5-104.11[Pf] 5-104.12[Pf]	<u>Water (hot and cold): adequate pressure, sufficient capacity</u> 5-103.11: Quantity and Availability, Capacity-(water source sufficient capacity to meet peek demands including mobiles and seasonals) 5-103.12: Pressure-(adequate pressure) 5-104.11: Distribution, delivery, and retention, system 5-104.12: Alt.water supply – (when interrupted delivered in approved containers/tanks)
35. IN OUT 5-101.12 [P], 5-201.11 [P] 5-202.11(A) [P] 5-202.13 [P] 5-202.14 [P] 5-203.14 [P] 5-205.12 [P] 5-205.14 [P] 5-205.15(A)[P] 5-301.11(A)[P] 5-302.16(A)[P] 5-303.11[P] 5-304.11[P] 5-304.14(A)[P] 5-402.11(A)[P]	<u>Plumbing/sewage system: designed, approved, installed;</u> <u>Cross-connections prohibited, air gaps, disposal</u> 5-101.12:System Flushing and Disinfection-(water system disinfected after repair, before use) 5-201.11: Materials approved 5-202.11(A): Approved System and Cleanable Fixtures-(installed according to law) 5-202.13: Backflow Prevention, Air Gap-(water supply air gap twice the diameter of H_2O line) 5-202.14: Backflow Prevention Device, Design Standard-(backflow properly designed) 5-203.14: Backflow Prevention Device, When Required-(preclude backflow, hose bibb if hose attached or required by law) 5-205.12(A): Prohibiting Cross Connection 5-205.14: Water Reservoir of Fogging Devices, Cleaning 5-205.15(A): System Maintained in Good Repair-(repaired according to law) 5-301.11(A): Materials, Approved-(mobile water tank materials safe) 5-302.16(A)Hose, Construction and Identification-(hoses for conveying water-safe) 5-303.11: Filter, Compressed Air 5-304.11: System Flushing and Disinfection-(tanks pumped, flushed, disinfected) 5-304.14(A): Tank, Pump, and Hoses, Dedication-(FOOD hoses no other purpose) 5-402.11(A): Backflow Prevention-(no direct connection with sewage and food/equipment sinks)

	Plumbing/sewage system: designed, approved, installed; Cross-connections prohibited, air gaps, disposal cont…
5-402.13[P]	5-402.13: Conveying Sewage-(sanitary sewage system, vehicles)
5-403.11[P]	5-403.11: Approved sewage Disposal System-(public or approved on-site system)
5-205.12(B) [Pf]	5-205.12(B): Prohibiting Cross Connection (identify non-potable H_20 piping)
5-205.13[Pf]	5-205.13: Scheduling Inspection for a Water System Device-(water treatment devices
5-402.14[Pf]	required inspections)
	5-402.14: Removing Mobile food Establishment Wastes-(approved waste servicing area)

Core items- relate to general sanitation & maintenance, equipment design & maintenance, and physical facilities & structures.

Food Temperature Control	
36.	Approved thaw methods; Active cool containers stored properly
3-401.12	3-401.12: Microwave Cooking (procedures; rotate, standing time)
3-501.12	3-501.12 : Time/temperature control for safety food (TCS), slacking
3-501.13	3-501.13 : Thawing
3-501.15(B)	3-501.15(B): Cooling Methods-(foods properly arranged, uncovered if no contamination)
37.	Thermometers provided, accurate, conspicuous
4-204.112(A-D)	4-204.112(A-D): Temperature Measuring Devices-(inside hot and cold holding/storage units; integral or permanently fixed)
Food Identification	
38.	Food properly labeled, original container, honestly presented
3-201.11 (F,G)	3-201.11 (F,G): Compliance with food Law-(meat and egg safe handling)
3-202.17(B)	3-202.17(B): Shucked Shellfish, Packaging and Identification-(no label, shall be subject to hold order)
3-203.11	3-203.11: Molluscan Shellfish, Original Container-(remain in container until sale or preparation)
3-302.12	3-302.12: Food Storage Containers, Identified with Common Name of Food
3-305.13	3-305.13: Vended TCS food, Original Container
3-402.12(B)	3-402.12(B): Records, creation and retention (supplier letter)
3-601.11	3-601.11: Standards of Identity-(packaged foods comply with 21 CFR, 9 CFR)
3-601.12	3-601.12: Honestly Presented-(foods offered, not mislead, no color wraps; lights, etc.)
3-602.11(A)(B1-B4)(B6-7)(C-D)	3-602.11(A)(B1-B4)(B6-7)(C-D): Food Labels-(packaged in FSE labeled under 21 CFR & 9 CFR, bulk foods for self-serve labeled)
3-602.12	3-602.12: Other Forms of Information-(warnings if required, date labels readable)
Prevention of Food Contamination	
39.	Contamination prevented during food preparation, storage & display; Washing fruits/vegetables
3-202.19	3-202.19: Shellstock, Condition-(clean, alive)
3-301.11(D)	3-301.11(D): Preventing Contamination from Hands(written policy)
3-302.11(A3-A8)(B)	3-302.11(A3-A8)(B): Packaged and Unpackaged Food-Separation, Packaging, and Segregation-(protect by clean sanitized equip. covered, cleaned packaging, separate unwashed fruits)
3-302.15	3-302.15: Washing Fruits and Vegetables-(shall be thoroughly washed prior to preparation)
3-303.12	3-303.12: Storage or Display of Food in Contact with Water or Ice-(packaged foods not allowed if entry of water, cans and bottles in draining ice)
3-304.13	3-304.13: Linens and Napkins, use Limitation-(only for lined containers changed after each use)
3-304.17	3-304.17: Refilling Returnables-(proper procedures)
3-305.11	3-305.11: Food Storage-(protected by properly stored, not exposed, 6 inches off floor)
3-305.12	3-305.12: Food Storage Prohibited Areas
3-305.14	3-305.14: Food Preparation-(protected while being prepared)
3-306.12	3-306.12: Condiments, Protection
3-306.14(B)	3-306.14(B): Returned food and Re-Service of Food-(Non-TCS food may be reserved under certain conditions)
3-307.11	3-307.11: Miscellaneous Sources of Contamination

3-801.11(H) 7-204.12(B)	Contamination prevented during food preparation, storage & display; Washing fruits/vegetables cont… 3-801.11(H): Pasteurized foods, Prohibited Reservices, and Prohibited Food (reserving packaged foods is limited under certain conditions) 7-204.12(B): Chemicals for Washing Fruits and Vegetables-(ozone allowed)
40. 2-303.11 2-304.11 2-402.11	Personnel: clean, jewelry, hair restraints, FH permits 2-303.11: Prohibition-(no jewelry except plain ring) 2-304.11: Clean Condition-(clean clothes) 2-402.11 : Effectiveness-(proper hair restraints)
41. 2-401.11 2-401.12	Eating, drinking, tobacco use; No discharge from eyes, nose, mouth 2-401.11: Eating, Drinking, or Using Tobacco 2-401.12: Discharges from the Eyes, Nose and Mouth
42. 3-304.14 4-101.16 4-901.12	Wiping cloths: properly used and stored; Sponges prohibited 3-304.14: Wiping Cloths, Use Limitation-(proper storage, approved use) 4-101.16: Sponges, Use Limitation-(not allowed on food contact surfaces or equip.) 4-901.12: Wiping Cloths, Air-Drying Locations-(air dry after laundered if no contamination)
Proper Use of Utensils	
43. 3-304.12 4-401.11(A&B) 4-801.11 4-802.11 4-803.11 4-803.12 4-901.11 4-903.11 (A),(B),(D) 4-903.12 4-904.11(B) 4-904.12 4-904.13	In-use utensils proper storage, cleaning frequency; Utensils, equipment & linens: properly stored, dried, handled; Linens clean 3-304.12: In-Use Utensils, Between-Use Storage 4-401.11(A&B): Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention-(proper storage utensils/linens) 4-801.11: Clean Linens-(clean linens separate from soiled) 4-802.11: Specifications-(linens, gloves, wiping clothes laundered) 4-803.11: Storage of Soiled Linens-(clean non-absorbent containers or laundry bags) 4-803.12: Mechanical Washing-(linens, except for wiping cloths must be mechanically laundered) 4-901.11: Equipment and Utensils, Air-drying Required-(utensils, equipment air-dried) 4-903.11 (A),(B),(D): Equipment, Utensils, Linens and Single-Service and Single-Use Articles-(proper storage, air drying/self-draining, 6” from floor) 4-903.12: Prohibition-(equip. utensils, linens prohibited storage) 4-904.11(B): Kitchenware and Tableware-(knives, forks, spoons properly presented) 4-904.12: Soiled and Clean Tableware-(removed to prevent contamination of clean tableware) 4-904.13: Preset Tableware-(protected, removed)
44. 4-502.13 4-502.14 4-903.11 (A),(C) 4-903.12 4-904.11(A),(C)	Single-use, single-service articles: properly stored, used 4-502.13: Single-service and Single-use Articles, use limitation-(not reused) 4-502.14: Shells, Use Limitation-(shells used only once) 4-903.11 (A, C): Equipment, Utensils, Linens and Single-Service and Single-Use Articles-(single use, single serve proper storage, protected) 4-903.12: Prohibition-(single use, single serve prohibited storage) 4-904.11(A),(C): Kitchenware and Tableware-(single use/serve properly presented, dispensed, wrapped)

Utensils, Equipment and Vending	
45.	Food & non-food contact surfaces cleanable, design
3-304.15(B,C,D)	3-304.15(B,C,D): Gloves, Use Limitation-(restrictions on slash and cloth gloves)
3-304.16	3-304.16: Using Clean tableware for Second Portions and Refills-(clean plates used
4-101.11(B,C,D,E)	at buffets, signage, except drink cups if properly handled)
4-101.12	4-101.11(B,C,D,E):Characteristics-(durable, sufficient weight, smooth, resistant)
4-101.17	4-101.12: Cast Iron, use Limitation
4-101.18	4-101.17: Wood, Use Limitation
4-101.19	4-101.18: Nonstick coatings, Use Limitation
4-102.11 (A2, B2)	4-101.19: Nonfood Contact Surfaces
4-201.11	4-102.11 (A2, B2) Characteristics-(single-use/serve clean no transfer of odors, colors, tastes)
4-202.12(A2, B)	4-102.11 (A2, B2) : Equipment and Utensils-(constructed to be durable)
4-202.13	4-202.12(A2, B): CIP Equipment-(self-draining, easily disassembled)
4-202.14	4-202.13: "V" Threads, Use Limitation
4-202.15	4-202.14: Hot Oil Filtering Equipment
4-202.16	4-202.15: Can Openers
4-202.17	4-202.16: Nonfood-Contact Surfaces-(easily cleanable)
4-204.12	4-202.17: Kick Plates, Removable
4-204.13(A-D)	4-204.12: Equipment openings, Closures and Deflectors
4-204.14	4-204.13(A-D): Dispensing Equipment, Protection of Equipment and Food
4-204.15	4-204.14: Vending Machine, Vending Stage Closure
4-204.16	4-204.15: Bearings and Gear Boxes, leakproof
4-204.17	4-204.16 : Beverage Tubing, Separation-(tubing and cold plates may not contact drink ice)
4-204.18	4-204.17: Ice Units, Separation of Drains
4-204.19	4-204.18: Condenser Unit, Separation
4-204.121	4-204.19: Can Openers on Vending Machines
4-204.122	4-204.121: Vending Machines, Liquid Waste Products
4-204.123	4-204.122 : Case Lot Handling equipment, Moveability
4-205.10	4-204.123: Vending Machine doors and Openings
4-402.11	4-205.10: Food Equipment, Certification and Classification
4-402.12	4-402.11: Fixed Equipment, Spacing or Sealing-(counter mounted; installed for
4-501.11	cleaning, sealed to counter, proper spacing, elevated on legs)
4-501.12	4-402.12: Fixed Equipment, Elevation or Sealing-(floor mounted; sealed or elevated)
4-501.13	4-501.11: Good Repair and Proper Adjustment
4-902.11	4-501.12: Cutting Surfaces-(cutting boards)
4-902.12	4-501.13: Microwave Ovens-(meet safety standards)
	4-902.11: Food-Contact Surfaces-(lubricants applied)
	4-902.12: Equipment-(reassembled no contamination to food contact surfaces)
46.	Manual/Mechanical WW facilities: maintained, operated; Pressure gauges, data plates; Use limitation, pre-cleaning
4-203.13	4-203.13 : Pressure Measuring Devices, Mechanical Warewashing Equipment-
4-204.113	(proper increments)
4-204.114	4-204.113 : Warewashing Machine, Data Plate Operating Specifications-(data plate
4-204.118	accessible, readable, required information)
4-204.119	4-204.114: Warewashing Machines, Internal Baffles
4-204.120	4-204.118: Warewashing Machines, Flow Pressure Device (provided)
4-301.12 C,D,E	4-204.119: Warewashing Sinks and Drainboards, Self-Draining
4-301.13	4-204.120: Equipment compartments, Drainage-(sloped drainage of condensate, drippage)
4-302.13	4-301.12 C,D,E: Manual Warewashing, Sink Compartment Requirements-
4-501.14	(alternative where approved, restrictions if 2 compartment, exemptions)
4-501.15	4-301.13: Drainboards
	4-302.13: Temperature Measuring Devices, Manual Warewashing
	4-501.14: Warewashing Equipment, Cleaning Frequency
	4-501.15: Warewashing Machines, Manufacturers' Operating Instructions-(operated according to instructions)

	Manual/Mechanical WW facilities: maintained, operated; Pressure gauges, data plates; Use limitation, pre-cleaning cont…
4-501.16	4-501.16: Warewashing Sinks, Use Limitation-(not used for handwashing)
4-501.18	4-501.18: Warewashing Equipment, Clean Solutions (maintained clean)
4-501.113	4-501.113: Mechanical Warewashing Equipment, Sanitization Pressure
4-501.115	4-501.115: Manual Warewashing Equipment, Chemical Sanitization Using
4-603.12	Detergent-Sanitizers-(detergent-sanitizer same for cleaning and sanitizing)
4-603.13	4-603.12: Pre-cleaning-(food debris scrapped or pre-washed)
4-603.14	4-603.13: Loading of Soiled Items, Warewashing Machines-(proper loading to
4-603.15	exposes and allows for draining)
4-603.16	4-603.14: Wet Cleaning-(procedure is effective)
	4-603.15: Washing, Procedures for Alternative Manual Warewashing Equipment
	4-603.16: Rinsing Procedures
47.	Non-food contact surfaces clean; cleaning frequency
4-601.11(B),(C)	4-601.11(B),(C): Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and
4-602.12	Utensils-(food contact- free of encrusted grease, dust, dirt accumulations)
4-602.13	4-602.12:Cooking and Baking Equipment-(frequency)
	4-602.13: Nonfood Contact Surfaces-(frequency)
Physical Facilities	
48.	Plumbing systems: maintained, backflow devices installed, inspected where required
5-203.15	5-203.15: Backflow Prevention Device, Carbonator
5-204.12	5-204.12: Backflow Prevention Device, Location-(located to be serviced and maintained)
5-205.15(B)	5-205.15(B)System Maintained in Good Repair-(plumbing in good repair-leaks)
5-301.11(B,C)	5-301.11(B,C): Materials, Approved-(mobile water tanks durable, smooth)
5-302.11	5-302.11: Enclosed System, Sloped to Drain (mobile water tank)
5-302.12	5-302.12: Inspection and Cleaning Port, Protected and Secured
5-302.13	5-302.13: "V" Type Threads, Use Limitation-(only if hose permanently attached)
5-302.14	5-302.14: Tank Vent, Protected
5-302.15	5-302.15: Inlet and Outlet, Sloped to Drain
5-302.16(B-E)	5-302.16(B-E): Hose, Construction and Identification-(hoses, durable resistant, smooth)
5-303.12	5-303.12: Protective Cover or Device-(water inlet, outlet and hose)
5-303.13	5-303.13: Mobile Food Establishment Tank Inlet
5-304.12	5-304.12: Using a Pump and Hoses, Backflow Prevention-(proper use to prevent backflow)
5-304.13	5-304.13: Protecting Inlet, Outlet, and Hose Fitting
5-304.14 (B)	5-304.14 (B): Tank, Pump, and Hoses, Dedication-(if used for food may be used for water if cleaned and sanitized)
5-401.11	5-401.11: Capacity and Drainage-(mobile sewage holding tank properly sized and drained)
5-402.11(B,C,D)	5-402.11(B,C,D): Backflow Prevention-(exceptions for floor drains & warewashing)
5-402.12	5-402.12: Grease Trap-(installed to be cleanable)
5-402.15	5-402.15: Flushing a Waste Retention Tank--- mobile
5-403.12	5-403.12: Other Liquid Wastes and Rainwater-(disposed according to law)
49.	Toilet facilities: accessible, proper construction, cleaned; Self closures
5-203.12	5-203.12: Toilets and Urinals-(required)
5-501.17	5-501.17: Toilet Room Receptacle, Covered
6-202.14	6-202.14: Toilet Rooms, Enclosed-(tight-fitting, self-closing door)
6-402.11	6-402.11: Toilet Rooms, Convenience and Accessibility
6-501.18	6-501.18: Cleaning of Plumbing Fixtures
6-501.19	6-501.19: Closing Toilet Room Doors

50. 4-301.14 4-401.11(C) 4-803.13 6-202.112 6-305.11 6-403.11 6-501.110	Break/Locker areas: used, provided, maintained; Living areas separated; Laundry facilities 4-301.14: Clothes Washers and Dryers-(required if laundering, except for wiping cloths) 4-401.11(C): Equipment, Clothes Washers and Dryers, and Storage Cabinets, contamination Prevention-(washer/dryer location) 4-803.13: Use of Laundry Facilities-(used only for establishment needs) 6-202.112: Living or Sleeping Quarters, Separation 6-305.11: Designation-(dressing rooms/areas/lockers provided if necessary) 6-403.11: Employee Accommodations, Designated Areas-(break rooms/locker rooms no contamination) 6-501.110: Using Dressing Rooms and Lockers-(shall be used, orderly storage)
51. 5-202.11(B) 5-202.12(B, C, D) 6-301.13 6-301.14 6-501.18	Handwash sinks designed, clean, used; Proper signage 5-202.11(B): Approved System and Cleanable Fixture-(hand sinks easily cleanable) 5-202.12(B, C, D): Handwashing Facility, installation(15 seconds if metered, automatic follows manufacturer installation) 6-301.13: Handwashing Aids and Devices, Use Restrictions-(food and mop sinks not for handwashing, not provided with soap and towels) 6-301.14: Handwashing Signage 6-501.18: Cleaning of Plumbing fixtures-(handsinks cleaned as necessary)
52. 6-501.12 6-501.13 6-501.112 6-501.114 **Cleaning issues**	Floors, walls, ceilings (premises): clean, free of litter; Removal of pests 6-501.12: Cleaning, Frequency and Restrictions-(often as necessary, least amount of food exposed) 6-501.13: Cleaning Floors, Dustless Method 6-501.112: Removing Dead or Trapped Birds, Insects, Rodents, and other Pests 6-501.114: Maintaining Premises, Unnecessary Items and Litter-(items only necessary to operations, no litter)
53. 6-101.11 6-201.11 6-201.12 6-201.13 6-201.14 6-201.15 6-201.16 6-201.17 6-201.18 6-202.15 6-202.16 6-501.11 6-501.17 **Construction and repair issues**	Floors, walls, ceilings (physical facilities): design, maintained, good repair; Outer openings protected 6-101.11: Indoor Areas, Surface Characteristics-(floors, walls, ceilings design, construction, LRV in prep and wash areas) 6-201.11: Floors, Walls and Ceilings-(smooth easily cleanable) 6-201.12: Floors, Walls, and Ceilings, Utility Lines-(exposed lines exposed) 6-201.13: Floor and Wall Junctures, Coved, and Enclosed or Sealed 6-201.14: Floor Carpeting, Restrictions and Installation 6-201.15: Floor Covering, Mats and Duckboards 6-201.16: Wall and Ceiling Coverings and Coatings 6-201.17: Walls and Ceilings, Attachments 6-201.18: Walls and Ceilings, Studs, Joists, and Rafters 6-202.15: Outer Openings, Protected-(tight fitting doors/windows; self-closing; screening) 6-202.16: Exterior Walls and Roofs, Protective barrier (walls and roofs protect from weather and vermin) 6-501.11: Premises, Structures, attachments, and Fixtures-(kept in good repair) 6-501.17: Absorbent Materials on Floors, Use Limitation
54. 4-603.11 5-203.13 6-501.16 6-501.113	Service sinks; Maintenance and cleaning tools properly used and stored 4-603.11: Dry Cleaning-(restrictions if used) 5-203.13: Service Sink-(mop sink required, cannot use toilets) 6-501.16: Drying Mops-(position to allow drying) 6-501.113: Storing Maintenance Tools-(stored properly to maintain areas)

55. 6-102.11 6-202.17 6-202.18 6-202.19	<u>Outdoor areas: constructed, maintained, clean</u> 6-102.11: Outdoor Areas, Surface Characteristics-(parking lot, driveways, sidewalks etc. constructed to be cleaned, minimize dust and mud) 6-202.17: Outdoor Food Vending Areas, Overhead Protection 6-202.18: Outdoor Servicing Areas, Overhead Protection 6-202.19: Outdoor Walking and Driving Surfaces, Graded to Drain
56. 5-501.11 5-501.12 5-501.13 5-501.14 5-501.15 5-501.16 5-501.18 5-501.19 5-501.110 5-501.111 5-501.112 5-501.113 5-501.114 5-501.115 5-501.116 5-502.11 5-502.12 5-503.11 6-202.110	<u>Garbage & refuse: properly disposed, facilities constructed, maintained</u> 5-501.1: Outdoor Storage Surface-(constructed to be durable, sloped to drain) 5-501.12: Outdoor Enclosure-(if used durable) 5-501.13: Receptacles-(durable, rodent resistant, leak-proof) 5-501.14: Receptacles in Vending Machines 5-501.15: Outside Receptacles-(lids, effective cleaning, no accumulations of litter) 5-501.16: Storage Areas, Rooms, and Receptacles, Capacity and Availability-(provided in food areas and toilet rooms) 5-501.18: Cleaning Implements and Supplies (other supplies as needed) 5-501.19: Storage Areas, Redeeming Machines, Receptacles and Waste handling Units, Location 5-501.110: Storing Refuse, Recyclables, and Returnables-(inaccessible to rodents) 5-501.111: Areas, Enclosures, and Receptacles in Good Repair 5-501.112: Outside Storage Prohibitions 5-501.113: Covering Receptacles 5-501.114: Using Drain Plugs 5-501.115: Maintaining Refuse Areas and Enclosures 5-501.116: Cleaning Receptacles 5-502.11: Frequency (removal) 5-502.12: Receptacles or Vehicles (removal method) 5-503.11: Community or Individual Facility (solid waste removal) 6-202.110: Outdoor Refuse Areas, Curbed and Graded to Drain
57. 4-202.18 4-204.11 4-301.14 6-202.11 6-202.12 6-303.11 6-304.11 6-501.14	<u>Ventilation: installed, maintained; Lighting: adequate, shielded</u> 4-202.18: Ventilation Hood Systems, Filters (design) 4-204.11: Ventilation Hood Systems, Drip Prevention 4-301.14: Ventilation Hood Systems, Adequacy 6-202.11 : Light Bulbs, Protective Shielding 6-202.12: Heating, Ventilation, Air Conditioning System (systems installed so as to not cause contamination) 6-303.11: Lighting, Intensity 6-304.11: Ventilation, Mechanical (sufficient to remove air odors/particulates) 6-501.14: Cleaning Ventilation Systems, Nuisance and Discharge Prohibition
58.	Other

Conference for Food Protection
2012 Issue Form

Internal Number: 053
Issue: 2012 I-036

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Designation of Water Temperature at Handwashing Sinks as a Core Item

Issue you would like the Conference to consider:
To designate Section 5-202.12 (A) of the 2009 FDA Food Code as a Core Item, thereby changing the designation of delivery of water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet from a Priority Foundation to a Core Item.

Public Health Significance:
FDA Food Code Chapter 5 [Plumbing, Water and Waste] Section 5-202.12, Handwashing Sink, Installation, paragraph (A), recommends that, "A handwashing sink shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet..." This provision is currently designated as a Priority Foundation Item even though the temperature is specific to plumbing equipment and is not included in the handwashing procedures in section 2-301.12.

Hand-washing is an important food safety practice and specific procedures for hand washing are included in the Food Code in Section 2-301.12. The mechanical action of washing one's hands, use of soap, length of time hands are washed, rinsing, hand drying and proper hand-wash training have all been noted as important factors in accomplishing proper hand washing. More specifically, paragraph 2-301.12 (B) recommends that "warm water" be used for hand washing and rinsing, without a specific water temperature. Therefore the water temperature alone will not contribute directly to the elimination, prevention or reduction to an acceptable level, hazard associated with foodborne illness as specified in priority item definition.

Sighting a specific threshold water temperature does not predicate successful hand-washing, which can be accomplished at various water temperatures. This is supported by the work of Michaels et al (2002, see attached) which concluded that there was no statistical difference in log reductions for both resident and transient bacteria during handwashing based on water temperature (see attachment). The results reported by Michaels confirm the observations made by Price (Price 1938) and Larson (Larson *et al*. 1980) indicating water temperature has little or no effect on the removal of bacteria from hands.

In summary, specific procedures such as handwashing frequency, length and technique have been shown to have a direct impact on the risk factors that contribute to foodborne illness, and therefore are aligned with the definition of a priority foundation item.
However, the temperature of water delivered at a handwashing sink does not directly contribute to the elimination, prevention or reduction (to acceptable levels) of the hazards associated with foodborne illness. The temperature of the water is more consistent with the definition of a Core Item, which relates to general sanitation, operational controls, sanitation standard operating procedures (SSOP), facilities or structures, equipment design, or general maintenance. The plumbing recommendations listed in section 5-202.12 are consistent with the definition of a core item.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):
Section 5-202.12 Handwashing Sink, Installation.
(A) A HANDWASHING SINK shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet. ~~Pf~~ C

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Attachments:

- "Michaels, Barry, et al. (2002) "Water temperature as a factor in handwa"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Water temperature as a factor in handwashing efficacy

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Keywords:
antibacterial soap, handwashing, personal hygiene, skin damage, skin flora, water temperature

Abstract

For many years, sanitarians have specified that the hands of food service workers should be washed and rinsed in warm or hot water to reduce the risk of cross-contamination and disease transmission. In the food service environment, it has been suggested that handwashing with water at higher temperatures contributes to skin damage when frequent handwashing is necessitated, and that insistence on hot water usage is a deterrent to handwashing compliance. Separate handwashing studies involving different water temperatures and soap types (antibacterial versus non-antibacterial) were performed. The 'glove-juice' technique was employed for microbial recovery from hands in both studies. Initial work evaluated antimicrobial efficacy based on water temperature during normal handwashing with bland soap. Uninoculated, sterile menstrua (tryptic soy broth or hamburger meat) was used to study the effects of treatment temperatures (4.4°C, 12.8°C, 21.1°C, 35°C or 48.9°C) on the reduction of resident microflora, while Serratia marcescens-inoculated menstrua was used to evaluate treatment effects on the reduction of transient contamination. Results of this first study indicated that water temperature exhibits no effect on transient or resident bacterial reduction during normal handwashing with bland soap. The follow-up study examined the efficacy and skin irritation potential involving water temperatures with antimicrobial soaps. Hands of participants were contaminated with *Escherichia coli* inoculated ground beef, washed at one of two water temperatures (29°C or 43°C) using one of four highly active (USDA E2 equivalency) antibacterial soaps having different active ingredients (PCMX, Iodophor, Quat or Triclosan). Skin condition was recorded visually and with specialized instrumentation before and after repeated washing (12 times daily), measuring total moisture content, transepidermal water loss and erythema. Overall, the four soap products produced similar efficacy results. Although there were slight increases in Log_{10} reductions, visual skin irritation, loss of skin moisture content and transepidermal water loss at higher temperatures, results were not statistically significant for any parameter.

Introduction

A critical and thorough evaluation of simple handwashing procedures reveals numerous variables to be considered by food service managers in order to achieve maximum or appropriate de-germing of the hands and fingernail regions. Numerous studies have explored issues such as type of soap (i.e. antibacterial versus plain, liquid versus bar), amount of soap, nailbrush use, drying technique (i.e. cloth versus paper towels, paper towels versus air-drying), and application of instant hand sanitizers (postwash liquids). Previous studies indicate that these variables are crucial in achieving effective removal of transient bacteria from the hands under controlled testing conditions. Rarely mentioned in the scientific literature is testing to determine specific guidelines for water temperatures and flow rates. Many of the currently employed hand-

washing practices are based on untested traditions that could possibly result in compromised skin health. It is expected that warm or hot water would be beneficial in reducing bacterial counts from hands during handwashing, as heat provides energy for the increased solubility and melting of fats, oils and other soils which may serve as vehicles for bacterial transfer from hands. Warm/hot water, combined with the detergents present in soap, should theoretically provide greater emulsification of contaminating soils on the skin, resulting in a more efficient lifting of these soils for rinsing away.

Some food safety experts strongly recommend the use of antimicrobial soaps for food service workers, while others are now focusing on handwashing frequency. With the rise of antibiotic resistance, increased concern has been expressed with respect to antimicrobial soap usage. The reasoning has been that when warm/hot water is combined with antimicrobial soap, the temperature of activation is approached, accelerating chemical reactions and improving kill rates. Soil emulsification should allow for greater exposure of microorganisms in the contaminating soil to the antimicrobial active agents. Thus, bacterial population numbers may be reduced two ways: through soil emulsification and lifting/rinsing away, and inactivation provided by the antimicrobial agent(s) with higher temperatures doing a significantly better job. The infected food worker is the focus of improved hygiene measures, and food safety managers and regulators would be remiss to not try to optimize effectiveness. Asymptomatic food handlers have been identified as being responsible for approximately one-third of outbreaks traced back to the infected worker. Poor personal hygiene has been cited as a contributory factor in an average of 30% of foodborne illness outbreaks occurring in the U.S. between the years of 1973 and 1997 (Bean & Griffin 1990; Bean *et al*. 1996; Olsen *et al*. 2000). The vast majority of foodborne illness outbreak cases attributed to the infected food handler occurs in the food service environment (Michaels *et al*. 2002).

The main initiative in hand hygiene is the reduction of potentially pathogenic microorganisms from contaminated skin surfaces. Optimization of all variables involved in this task must not only provide sufficient removal and/or kill of potential pathogens, but must also refrain from damaging the skin, as this can affect handwashing compliance (Boyce and Pittet 2001) and seriously compromise food service safety. Skin damage associated with work from routine and frequent handwashing has also been seen to result in colonization of workers hands with potential pathogens.

With so many variables involved in such a 'simple procedure', it would make sense to explore and maximize all possible aspects of the process while minimizing negative collateral. This is especially important due to the many observations of food service workers revealing what is considered to be poor habits in handwashing techniques. Studies indicate that handwashing compliance drops considerably without supervision and monitoring, or in situations where skin damage occurs. This further amplifies the need to strengthen knowledge of all variables that might improve or weaken daily handwashing practices throughout the food processing and service industry.

As described by Price, two types of flora exist on the hands, transient and resident species (Price 1938). The transient flora is generally removed fairly easy. They do not have adhesion characteristics that hold them to the skins' surface and are somewhat suppressed by secretions and competitive exclusion by the resident flora (Dunsmore 1972). Resident flora is removed more slowly. Because of coevolution, resident flora have adapted to conditions on the skins' surface that cause rapid die-off of most transients. Invaginations such as the nail fold, hair follicles and sebum-producing sebaceous glands support a rich resident flora. Transient flora may consist of pathogens, spoilage bacteria or harmless environmental species. Under certain conditions, transient flora can change status and become permanent residents. Resident flora, as a rule, are not pathogenic types. Although colonization with coagulase-positive staphylococcus is fairly common (Noble & Pitcher 1978). Frequent or prolonged exposure of the skin to microbial contamination in soils, skin damage or fissures provide portals of entry to deeper tissue, and may result in many pathogenic bacteria found among the resident species (Price 1938; Kaul & Jewett 1981). Food workers in a number of different food industry segments (including catering and bakery) have been found colonized by varying numbers of potential pathogens (Seligman & Rosenbluth 1975).

The effective water temperature used for washing and rinsing hands was a topic of intense discussion at the U.S. Year 2000 Conference for Food Protection. This biannual conference assembles federal and state regulators, food safety academicians, food service industry scientists and safety managers to establish and recommend guidelines to the United States Food and Drug Administration (FDA) for inclusion into the FDA Model Food Code. This code, as adopted by individual US states, forms the basis for food safety regulation and enforcement activities to the food service industry. Several submitters of issues, brought before science and technology council (Council III), expressed their concern regarding the use of higher water temperatures as recommended of the food service/processing industry (Table 1). The United States Food and Drug

Table 1 Submitters and handwashing water temperature issues at the year 2000 Conference for Food Protection

Submitter	Issue	Reason
L. Wisniewski (Select Concepts – Consulting)	'Warm Water'	1. Hand Discomfort Decreases Frequency
M. Scarborough (Georgia Department of Human Resources, Division of Public Health)	37.7°C (100°F)	1. No Science (43°C vs. 37.8°C) 2. Plumbing Code @ 100°F Max. (Safety Concerns)
J. Budd (Healthminder/Sloan Valve Company)	35°C (95°F)	1. No Scientific Basis 2. Max Soap Efficacy at 35°C 3. Hand Comfort 4. Hot Water Discourages Hand Washing
E. Rabotoski (Wisconson ConferenceFood Protection)	'Tempered' 29.5°C (85°F) to 43°C (110°F)	1. Hand Discomfort 2. Possible Scalding
B. Adler (Minnesota Department of Health)	Impose Temp. Range 43°C 110°F To 54.4°C (130°F)	1. Need upper limit or subject to OSHA 2. Food workers Don't Wash 25 Sec. So Cannot Scald.
Reimers (H.E.B. Grocery Company)	'Tempered' To Warm	1. No Science . 2. Max Soap Efficacy 3. 43°C Risks Injury 4. Waste Water as Wait for Temp. at 43°C

Administration (FDA) Food Code provides recommendations for the food service industry to follow regarding food handling practices, application of HACCP principles and personal hygiene implementation (US Public Health Service 1999; US Public Health Service 2001). The main goal of the FDA has been the creation of uniform practices throughout all of the United States. The 1999 FDA Food Code requires sinks used for handwashing to be equipped so as to be 'capable of providing water of at least 43°C (110°F), accomplished through use of a mixing valve or a combination faucet' [tap] (US Public Health Service 1999).

All but one of the submitters requested temperature decreases with the intent of improving hand comfort, as the discomfort associated with higher temperatures results in decreases in hand washing frequency or compliance. Several submitters note a lack of scientific information on the subject. There is concern that a minimum handwashing temperature of 43°C (110°F), in addition to causing discomfort, will result in injury or scalding and may even be in conflict with local plumbing codes. Two submitters point out that soaps currently available target maximum effectiveness at around 35°C (95°F). Two submitters requested that the minimum temperature of 110°F (43°C) be changed to warm water or that it be tempered to a range of 85°F (29.5°C) to 110°F (43°C). and finally, one submission sought to place an upper temperature limit of 130°F (54.4°C), for fear that these regulations would be subject to Occupational Safety and Health Administration (OSHA) scrutiny and criticism without a limit. Interestingly, it was noted in this submission, through reference to the Consumer Product Safety Commission, that second or third-degree burns have been shown to occur in the elderly at temperatures not much over 43°C (110°F). Council I and the General assembly of voting delegates passed a recommendation to lower the regulatory water temperature minimum to 29.5°C (85°F). In recognition of concern expressed by a number of stakeholders with regards to the issue of handwashing water temperature, the initial results of the work described in this report and the will of state voting delegates, the 2001 Food Code lowered the required handwash water temperature to 37.8°C (100°F) (US Public Health Service 2001).

The universe of food handling situations requiring effective personal hygiene spans from temporary handwash stations set up in produce fields and county fairs to advanced state of the art clean room style kitchens used to produce extended shelf life ready-to-eat foods sold at retail. In quick service restaurants, workers frequently switch between food and money handling. Due to the potential for money to carry potential pathogens, as described by Michaels, hands may require washing from up to 40 times or more in an 8-h shift (Michaels 2002). In many of these situations, it is difficult to provide water meeting strict temperature ranges. With regard to international settings, it is doubtful that underdeveloped parts of the world will easily be able to tap into warm/hot water supplies, much less into clean water sources at all. Water temperature shortcomings have been a common point of criticism by

food safety experts when reviewing handwashing procedures in the developing world as part of HACCP activities. Further, no matter where the location, it is difficult to manage and monitor food handlers to insure that minimum temperature levels are maintained during all handwashing activities. When subject to regulatory inspections, in the U.S., violations are given to food industry entities based on Food Code specifications. In some cases, based on accumulation of violations with water temperature being one of them, mandatory 48 h closure can result. This appears to be both costly and unnecessary based on the results of the studies described here.

In an extensive literature review of the effect of water temperature on hygienic efficiency, only two existing experimental studies shed light on this issue. Both of these involved hand sampling studies, in which the objective was to remove, identify and enumerate as many bacteria on the hands as possible, either as normal or transient flora. In hand scrubbing experiments, Price found that at temperatures from 24°C (75.2°F) to 56°C (132.8°F) there was no difference in de-germing rate (Price 1938). Since he scrubbed hands with a brush for a specific period of time, each in turn in a series of sterile wash basins, he might have been capable of seeing differences upon counting the flora in each basin. After conducting over 80 experiments in a 9-year period, Price concluded that the largest variable in determining the rate of removal of bacteria from the hands was the vigorousness of scrubbing. Other factors such as soap used or water temperature were less important. In later hand sampling experiments by Larson and others (implementing the glove juice method for recovery of microorganisms), no differences in isolation rates were seen at either 6°C (42.8°F) or 23°C (73.4°F) (Larson *et al.* 1980). While this information is inconclusive and does not answer questions concerning bacterial loads suspended in a confounding soil, they tend to indicate that there may not be a noticeable difference in efficacy over a range of temperatures from 6°C (42.8°F) to 56°C (132.8°F).

Various menstrua have been used for handwashing efficacy studies. For studies involving transient flora, the most often used soil is tryptic soy broth (TSB). Microorganisms exhibit good survivability, with even distribution of contaminating microorganisms into skin cracks, creases and invaginations being possible. Ground beef probably represents the most appropriate menstrua because of concern for risks of *E. coli* O157:H7 infection, but is only occasionally used (Sheena & Stiles 1982; Stiles & Sheena 1985). Meade and others have shown numerous sporadic cases of foodborne illness have been tied to poor personal hygiene after ground beef preparation (Mead *et al.* 1997). In addition, due to it's viscosity, thixotrophic properties and level of organic soil, it would appear to be a good surrogate for fecal material.

A review of pertinent literature was also undertaken to determine if, independent of efficacy, facts on skin damage support a lowering of the temperature. The Consumer Product Safety Commission (CPSC) has noted that residential water heater thermostat settings should be set at 49°C (120°F) to reduce the risk of the majority of tap water scald injuries. Although the majority of scalding attributed to the home occur in children under the age of five and the elderly, third-degree burns are known to result in a two second exposure to 66°C (150°F), six-seconds at 60°C (140°F) and 30 s at 54.4°C (130°F) (US Consumer Product Safety Commission 2000). As we age, our skin becomes thinner, loosing suppleness. This fact is important as many seniors are now actively involved in the food service industry. Due particularly to the elder risk, some have recommended that water be delivered from the tap at even lower temperatures of less than 43°C (110°F) (Stone *et al.* 2000).

The activity of soaps, friction and rinsing become crucial since the temperatures recommended in handwashing water alone would not provide thermal destruction of pathogenic microorganisms. Relevant to the discomfort issue associated with hot water is a previously conducted study by Horn and Briedigkeit involving dishwashing soaps (Horn & Briedigkeit 1967). In that study, participants were only able to withstand water temperatures at 43°C, 45°C, and 49°C (110°F, 113°F and 120°F), with tolerance levels due to discomfort peaking at one-minute (Horn & Briedigkeit 1967). Even though considerably longer than the 10–25 second exposure period that would result from handwashing, it is indicative of the fact that temperatures from 43°C and upwards (110°F and upwards) are at or near the human discomfort threshold.

Friction has been described as a key element in removing microbial contaminants from hands (Price 1938; Kaul & Jewett 1981). Friction applied during hand drying is instrumental in finishing the process (Madeline & Tournade 1980; Knights *et al.* 1993; Michaels *et al.* 2002). Removal of transient flora appears to be even more friction dependent than removing resident flora. Surfactant and antimicrobial compounds in soap are responsible for lifting soil and killing microorganisms suspended in the soil. When using bland soap to wash hands, handwashing efficacy appears to be dependent on the effects of surfactant action of the soap along with friction applied during the washing and rinsing process. Rinsing also provides the necessary removal by dilution. To facilitate appro-

priate rinsing of the hands, some personal hygiene consultants have suggested the practice of using thicker, higher viscosity soaps in larger doses, which would require a longer, more vigorous rinsing routine.

Price, upon noticing that in his scrubbing experiments that water temperature had little effect at degerming of the skin, commented that water applied to the skin at a given temperature quickly reaches equilibrium with normal skin surface temperature unless hands are totally immersed (Price 1938).

Skin oils derived from sebum are liquid in the sebaceous gland and solidify on the skin surface. Beef tallow has a melting point range between 35°C and 40°C (95°F and 104°F), while lard or butterfat are liquefied at around 30°C (86°F) (Lide 1990). If handwashing efficacy for both resident and transient floras embedded in both natural and artificially applied fats depended on thermal melting, then log10 reduction figures should have been greatest at the highest temperature and least at temperatures causing fats and sebum to congeal.

Fats such as tallow or lard are distinguished from oils in that the latter are liquids at room temperature. Hand soap formulations are designed to lift soil through their foaming action, dispersing and solubilizing organic soils through action of detergent surfactants. Primary micelles are formed, having hydrophilic and hydrophobic groups attached to each end of the surfactant monomer. Soaps with multiple surfactants form mixed micelles, which increases efficiency with various soil mixtures. In water and organic soil mixtures, these form complex micelle structures around hydrocarbon moieties (encapsulation) resulting in microemulsions. Thus, the soap provides a 'bridge' between the oily droplet and water, permitting the soapy water to 'wash away' greasy material.

Materials and methods

The quantity of soap used for handwashing has the ability to effect handwashing efficacy, as shown by Larson (Larson *et al*. 1987). Various investigators (Michaud *et al*. 1972, 1976; Ojajarvi 1980; Stiles & Sheena 1987; Mahl 1989; Larson *et al*. 1990; Rotter & Koller 1992; Miller & James-Davis 1994; Paulson 1994) have used soap amounts in the range of 2.5–5.0 mL in their handwashing efficacy protocols. The higher levels are considered excessive, except in the area of hospital infection control. Many food service operations set soap dispensers at 1 mL per pump, and employees often times use multiple pumps. For this study, 3 mL of soap was chosen to represent an amount found to be significantly effective in an earlier study described (Larson *et al*. 1987).

Determination of appropriate handwashing duration for these studies (15 s) was arrived at through review of various governmental regulatory standards, test method guidelines and food safety specialist recommendations along with previous handwashing study observations. Suggested lathering times by specific entities are: The 1999 FDA Food Code (US Public Health Service 1999) (20 s), The American Society for Testing and Materials (American Society for Testing and Material 1995) (15 s), The Association for Professionals in Infection Control and Epidemiology (APIC) (Jennings & Manian 1999) (minimum of 10 s), and The American Society for Microbiology (American Society For Microbiology 1996) (a 10–15 second vigorous scrub). Several studies support a washing duration of at least 10 s, with sufficient transient removal efficiency achieved by 30 s. A study by Stiles and Sheena involving workers in a meat processing facility determined that a wash of 8–10 s was too short for adequate soil removal from the hands (Stiles & Sheena 1987). A study by Ojajarvi compared a 15 second and 2 minute wash, with the latter providing only an additional 3% transient bacterial reduction (Ojajarvi 1980). One observational study in food service indicates average duration times of 20 s in a silver service restaurant kitchen (Ayers 1998).

In our first study, the effects of water temperature on the reduction of both resident (normal) and transient bacteria during handwashing was performed at each of the following temperatures: 4.4°C (40°F), 12.8°C (55°F), 21.1°C (70°F), 35°C (95°F), or 48.9°C (120°F). Two separate laboratories participated in this work. Silliker Laboratories (South Holland, IL, USA) was responsible for transient flora experiments while Bio-Science Laboratories (Bozeman, MI, USA) performed normal flora studies. For transient flora studies, the experimental subjects' hands were artificially contaminated with Serratia marcescens in Tryptic Soy Broth (TSB) or irradiated ground hamburger. Sterile, uninnoculated TSB and irradiated ground hamburger were used as confounding soils in testing for the reduction of the resident flora. Following hand contamination, baseline microbial counts were acquired using the 'glove-juice' method on one hand. Hands were moistened and washed/lathered for 15 seconds with 3 mL bland (nonantibacterial) soap, rinsed for 10 seconds (water flow rate of 7 L/minute) at the assigned water temperature (also used for the prelather moistening), and the opposing hand was then sampled using the same glove-juice technique. No drying of hands was performed, which would have had the effect of diminishing differences between experimental groups. Baseline and postwash readings were then compared to obtain bacterial reduction values. For this study, no skin condition assessments were performed.

The first study was performed using a non-antibacterial soap and examined temperature effects on bacterial reductions based on the solubility of greasy soils. It did not address the increased temperature effect on antimicrobial activation or possible skin damage. Therefore, the second study was undertaken, which not only involved a comparison of the microbial reduction effects of four antibacterial soaps at two different temperatures, but also evaluated skin conditions on the hands of participants throughout the study. The potential of each soap to cause negative skin changes at each water temperature combination was assessed by measuring the skin moisture content, rate of water loss from the skin, skin scaliness by computerized analysis of a digitized skin image, and by visual assessment of the dryness and erythema. This study was performed at BioScience Laboratories, employing eight subjects and using four different antimicrobial soaps, each having a different antimicrobial active ingredient. The soaps had antimicrobial activity equivalent to USDA E2 ratings (50-p.p.m. chlorine equivalency). The active ingredients in these products were Quaternary Ammonium (3% dual Quat formulation), Triclosan (1%), Parachlorometaxylenol (PCMX-3%), and Iodophor (7.5% PVP-I). Participants consisting of paid volunteers performed multiple handwashes during two five-day test periods (weeks one and two) seven days apart using *Escherichia coli* (ATCC #11229) contaminated gamma irradiated ground beef. On days one through five of weeks one and two, the skin condition was evaluated visually, for moisture content using the Corneometer® CM825, for total evaporative water loss using the TC350 Tewameter, and digitally using the Skin Visiometer® SV 500 with Visioscan® VC98. The visual skin dryness and erythema (redness) scoring was performed by a single blinded (unaware of subjects antimicrobial soap product/water temperature configuration) evaluator trained in assessment of skin damage or irritation using a 0–6 scoring system (see Table 2) as originally described by Griffith and others (Griffith *et al*. 1969). Log_{10} reduction data was determined with the first wash of days one, three and five under each water temperature condition. After handling the contaminated ground beef in a way to uniformly contaminate hands, one hand was sampled immediately (again, using the 'glove-juice' technique) for a baseline reading. The subjects' then washed both hands at the specific water temperature (85° ± 2°F for week one and 110° ± 2°F for week two) with their randomly assigned product with their opposing hand being sampled to establish microbial counts. Each subject then washed 11 consecutive times with their assigned test product each day drying hands between washes, then hands were evaluated visually and digitally 30 minutesfollowing the last wash. In all washing cases, lathering was performed for 15 seconds and rinsing for 10 seconds with three mL of the assigned test product.

Table 2 Grading scale for evaluating the skin of the hands*

Grade	Description
0	No visible damage, 'perfect' skin
1	Slight dryness, ashen appearance, usually involving dorsum only
2	Marked dryness, slight flaking involving dorsum only
3	Severe dryness dorsum, marked flaking, possibly fissures in webs
4	Severe flaking dorsum, surface fissures possibly with slight palmar dryness
5	Open fissures, slight erythema (>10% of dorsal and interdigital surface), with or without severe dryness, no bleeding
6	Bleeding cracks, deep open fissures, or generalized erythema (>25% of area)

*Griffith *et al*. 1969.

Results and discussion

After extensive statistical analysis of the results from the first set of experiments, it was determined that there was no significant difference in bacterial log_{10} reductions for either resident or transient bacteria at any of the test washing and rinsing temperatures. See Figs 1 and 2 for transient and resident flora data, respectively. Average log_{10} reduction results for each soap are presented in Fig. 3.

After extensive statistical analysis of the second experiment with antibacterial soaps involving the 2 sample *T*-test, Kruskal–Wallis test and Mann–Whitney test, no statistical difference in log_{10} reductions was detected between the two wash temperatures for any of the products or as a group. Overall, the four products produced similar handwashing efficacy results. Although most of the washes at the higher temperature did produce a slight increase in bacterial reductions, it was not enough to be considered statistically significant. Figure 4 shows Tewameter® readings measuring *trans* epidermal water loss, while Figs 5 and 6 show visual dryness and baseline adjusted Corneometer® values, respectively. Skin scaliness values using a Visiometer® are shown in Fig. 7. Along with the slight additional reduction of bacteria at the higher temperature was increased skin visual dryness, increased transepidermal water loss and decreased scaliness, also determined to be statistically insignificant. Skin scaliness is highest on day one and two at the higher temperature but for days three, four and five, this reverses.

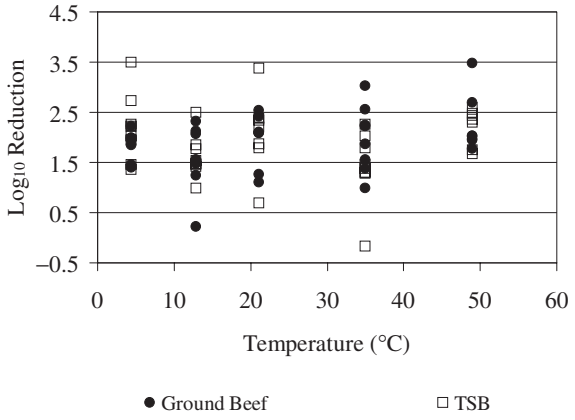

Figure 1 Handwashing efficacy (Log_{10} reduction) for transient flora (*S. marcescens*) in ground beef and TSB at selected water washing and rinsing temperatures.

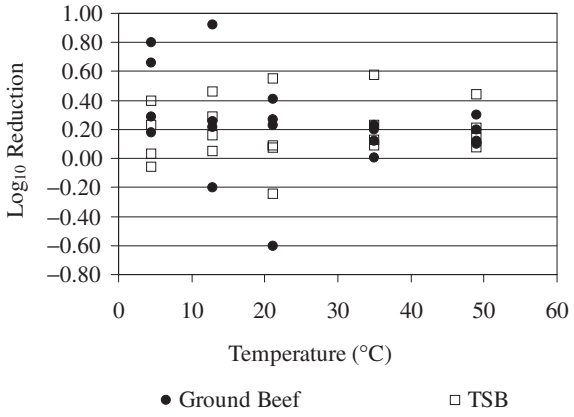

Figure 2 Handwashing efficacy (Log_{10} reduction) for resident flora in ground beef and TSB at selected water washing and rinsing temperatures.

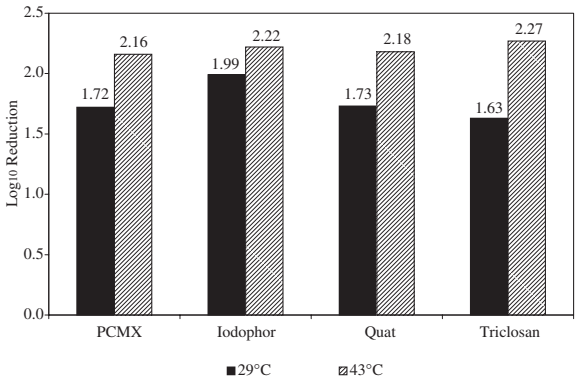

Figure 3 Average Log_{10} reduction of transient flora (*E. coli*) in ground beef using selected antimicrobial soaps.

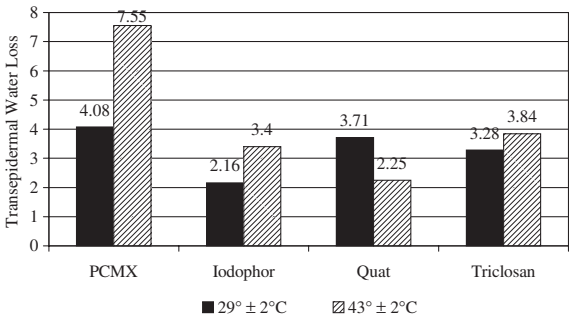

Figure 4 Average Tewameter® readings selected antimicrobial soaps at 2 different water temperatures.

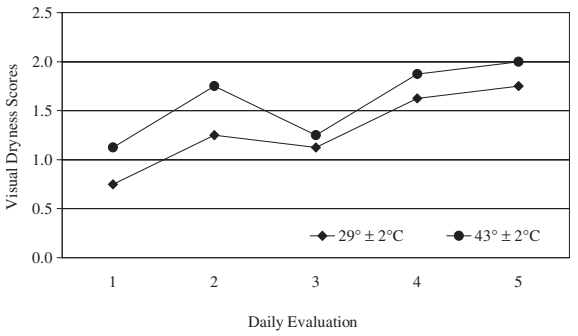

Figure 5 Average baseline-adjusted visual dryness scores (8 subjects) resulting from washing hands with 4 different E2 antimicrobial soaps for 5 days (12 ×/day).

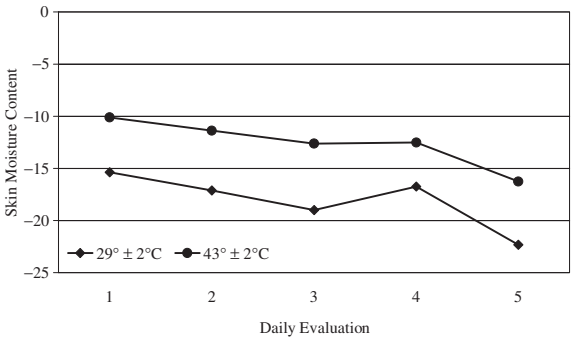

Figure 6 Baseline-adjusted Corneometer® readings (8 subjects) resulting from washing hands with 4 different antimicrobial soaps for 5 days (12 ×/day) at two different handwashing temperatures.

It is conceivable that the higher temperatures more rapidly removed loose layers of stratum corneum.

The results from both of these experiments are in agreement regarding the lack of hygienic benefits of washing hands at higher water temperatures and particularly at temperatures at the upper end of human tolerance, sometimes described as 'hot as you can stand'. From the first study, it is realized that higher water temperatures have no significant effect on the

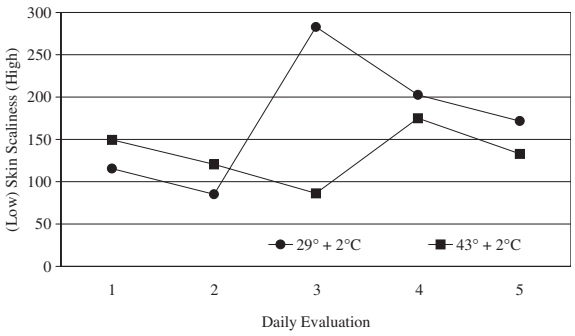

Figure 7 Average baseline-adjusted skin scaliness (8 subjects) resulting from washing hands with 4 different antimicrobial temperatures as measured using Visiometer®.

reduction of resident or transient bacteria in either easy to remove soil (TSB) or difficult to remove soil (ground beef) when using plain soap at a wide range of temperatures and using a standard hand wash. The second study provides additional support to the results of the first study by showing no statistically significant effect for the use of 110°F water (compared to 85°F water) to remove transient microorganisms embedded in ground beef from the hands when using any one of four different antibacterial based soaps or antibacterial soaps as a group. This experiment did show the trend toward higher kill as well as higher level of skin damage supporting propositions put forward by both camps. Log_{10} reductions do reflect slightly greater efficacy at higher temperatures but not at the level of significance expected, most probably due to the rapid equilibration to hand temperature described by Price (Price 1938).

Water has been identified as a skin irritant in its own rite, and part of this irritant potential can be exacerbated by temperature increase (Tsai & Maibach 1999). Repeated water exposure causes extraction or dilution of natural moisturizing factors in the stratum corneum. The water-holding property of the stratum corneum is provided in part by intercellular lipids and lipid rich sebaceous gland secretions (Noble & Pitcher 1978). The intercellular lipids, which when chromatographically fractionated, can be separated into cholesterol, cholesterol esters, phospholipids, free fatty acids, glycolipids and ceramide (Noble 1975; Imokawa *et al*. 1986). Loss of these lipid components results in a chapped and scaly skin appearance (Imokawa & Hattori 1985). Water induced irritation is known to exist in workers involved in continuous wet work, resulting in chapped and dry skin after wet work is completed (Halkier-Sorensen & Thestrup-Pedersen 1991).

Instances of primary irritant dermatitis to certain chemicals has been found to occur when hot water at 43°C (110°F) was used rather than lukewarm at 23°C–25°C (73°F–77°F) (Rothenborg *et al*. 1977). Detergent/surfactant formulations are known to cause changes to the stratum corneum such as disaggregation, swelling and morphological deterioration of corneocytes (Shukuwa *et al*. 1997). It has been found that heat plays a part in accelerating irritation of certain chemicals found in these detergent formulations. Berardesca and others found a significant difference between the temperatures of 20°C and 40°C (68°F and 104°F) in skin irritation to 5% sodium lauryl sulphate solution for a 4-day exposure period (Berardesca *et al*. 1995; Ohlenschlaeger *et al*. 1996). This irritation is documented using transepidermal water loss (TEWL) measurements, erythema (skin redness), skin reflectance, hydration (capacitance) and desquamation (stripping). Gross hand edema has been found to occur at temperatures between 35°C (95°F) and 45°C (113°F) when hands are completely immersed at those temperatures (King 1993). A significant increase in blood flow has also been shown in comparisons between 37°C and 43°C degrees (99°F and 110°F) (Nagasaka *et al*. 1987). Overall, these studies tend to show that food service workers derive no significant measurable benefit by using hot water (105°F +) to wash and rinse hands. Use of water at higher temperatures does seem to result in physiological changes collectively described as skin damage. There may be severe consequences of frequent use of hot water for handwashing at temperatures above 43°C (110°F), which can damage skin and heighten susceptibility to both allergens present in the food service environment and/or colonization (Larson *et al*. 1998). Rather, water temperature should be set at what is considered comfortable and generally conducive to handwashing.

The central components of effective handwashing thus consist of soap use in a way that promotes emulsification of soil (through vigorous friction/mechanical action) followed by thorough rinsing and drying, which again adds friction to the equation. Guidelines for handwashing in food service should probably not specify water temperature descriptors other than perhaps the word 'comfortable' when it comes to defining effective handwash standards. 'Warm' or 'tempered' would probably be acceptable, but more importantly as indicated by Jennings and Manian (1999), 'running water' should be to rinse away emulsified soils and associated transient contamination. Fingertips should be pointed down and hands rinsed and dried in a way to focus on parts of the hand that have shown to be missed during normal handwashing. This includes fingertips, thumbs and fingernail regions.

Conclusions

A review of the literature on the subject of handwashing water temperature requirements showed considerable variation with respect to expert opinion on optimal temperature for removal of microbial contaminants form hands. There in fact was a virtual absence of data to back up the various positions on the subject. Sanitarians and food safety experts have specified water temperatures varying from room temperature (running water) up to 'as hot as you can stand', the latter of which is probably in the range of from 49°C (120°F) to 55°C (131°F). Regulations in the US and elsewhere tend to focus on temperatures between 43°C (110°F) and 49°C (120°F). Concern that these temperatures could be detrimental to skin health without documented efficacy led to the experiments described here. Hands were contaminated with soils similar to those encountered in the food service environment. These soils contained marker bacteria allowing handwashing efficacy to be determined at specified water temperatures against both transient flora and resident flora simultaneously.

The initial experiment involved testing with bland non-antimicrobial soap at 5 temperatures from 4.4°C (40°F) to 49°C (120°F). Independent of soil or bacterial type (resident or transient) there was no significant difference in efficacy attributed to water temperature. In the second experiment antimicrobial soaps (4) were used having different antimicrobial active ingredients, at each of two water temperatures, 29.5°C (85°F) and 43°C (110°F). Skin condition was monitored with frequent handwashes (12 ×/day) for the second set of water washing temperature experiments. In this experiment, even though slightly higher efficacy with was seen with antimicrobial soaps at higher temperatures, overall, there was no statistical difference in efficacy as measured in Log_{10} reduction at the two water temperatures (regardless of soil or microflora types). Concomitant to the increase in efficacy at higher temperatures was a consistent trend for increases in measures of skin damage, such as skin moisture content, transepidermal water loss and erythema. This was also found not to be statistically significant.

Both the trend for higher efficacy of soaps with attendant skin damage at higher temperatures are grounded in theory. Under the conditions of these experiments neither was shown to be proven for practical application. Since efficacy is not markedly improved at higher temperatures but rather the real danger exists of skin damage, requirements for specific handwashing water temperature should be relaxed to improve acceptance of frequent handwashing by food workers at appropriate times to reduce foodborne illness potential. Water temperature should be in a comfortable range, perhaps tempered.

As has been shown by many previous researchers, overall handwashing effectiveness is more dependent on the vigorousness of execution than details such as the type of soap, the length of handwash or in this case water temperature. The results obtained in these experiments confirm the observations made by Price (Price 1938) and Larson (Larson *et al*. 1980) indicating water temperature had little or no effect on the removal of bacteria from hands. While their original reports dealt with optimizing skin sampling efficacy, for the types of experiments performed and described in the current report.

Unfortunately, food service regulatory authorities, health inspectors and environmental health officers in the US and elsewhere have fixated on handwashing water temperature because it is measurable and in the somewhat mistaken belief that higher temperatures would result in cleaner hands. Up until recently, the existence of adequate hygiene facilities (functioning toilet, toilet paper, functioning sink, soap and paper towels) and water temperature measurement were to some extent the only measurable qualities whereby food safety inspectors could cite food service facilities for violation. Poor personal hygiene is often used after the fact to describe as a contributing factor aiding to an outbreak. With handwash monitoring devices employees' handwashing can be monitored, documented and verified within the HACCP framework (Michaels 2002). With this new technology and information from this report indicating that water temperature for handwashing is relatively unimportant, perhaps regulatory authorities will be able to focus on other more important factors having a bigger impact on food safety.

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Conference for Food Protection
2012 Issue Form

Internal Number: 011
Issue: 2012 I-037

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Designation of Manual Warewashing Wash Solution Temperature as a Core Item

Issue you would like the Conference to consider:
To designate Section 4-501.19 of the 2009 FDA Food Code as a Core Item, thereby changing the designation for the provision that, "The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions" from a Priority Foundation to a Core Item.

Public Health Significance:
Effective manual warewashing in retail food establishments is dependent on a number of variables including the cleaning agent used, the type of manual washing processes, the equipment used, the volume and type of wares being washed, as well as where they originate (i.e., hot or cold environments). The temperature of the water used for washing is also a variable and no specific temperature is required to assure an effective process.

The washing step is intended to ensure that the wares/equipment being cleaned are visually free of soil prior to sanitization. The washing step is not intended to be a sanitizing step and therefore is not the step that reduces risk or impacts public health. A Priority Foundation item is, by definition, "an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury."

In practice, maintaining a specific wash solution temperature for manual warewashing can be challenging under certain situations such as washing in refrigerated environments in meat markets. To overcome this challenge, food retailers have worked with their chemical suppliers to provide cleaning agents (detergents) that work effectively in a variety of different environments and in various water temperatures with consistent results. Other methods such as applying force to the surface of wares via brush and/or spray devices have proven very effective in removing soil that can easily be rinsed prior to being sanitized, regardless of the water temperature. Employees are more likely to wash wares effectively and for a longer time if doing so in water that is comfortable and which achieves the intended purpose.

A Core Item is defined as "an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures,

equipment design, or general maintenance." Other provisions in the Food Code that recommend water temperatures for washing are not designated as Priority Foundation and changing Section 4-501.19 to a Core Item would be more appropriate and consistent. Furthermore, the CFP Criticality Committee (CFP, Crit Item, recommendation for changing a Food Code Section, Chapter 2 (part) 3 and 4 and terminology, summary 8-16-07) overwhelmingly (>77%) recommended that Section 4-501.19 be classified as a Core item and not a Priority Foundation.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-501.19, be revised to reclassify the designation from a Priority Foundation (Pf) item to a Core (C) item as indicated below (new language shown with underline and deleted language shown with strike-through):

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions. ~~Pf~~ C

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Conference for Food Protection
2012 Issue Form

Internal Number: 068
Issue: 2012 I-038

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Amendments to Public Information and Public Posting

Issue you would like the Conference to consider:
Rigorous health inspections are a critical component of an effective food safety system. The FDA Food Code recognizes that the results of restaurant inspections are public documents and should be available for public review. However, complex rules regarding public access create difficulty for consumers who wish to consider inspection results.

Public Health Significance:
Consumer access to the results of these inspections plays an important role in maintaining the efficacy and credibility of the inspection system, and allows consumers to consider critical food safety information when making restaurant choices. Recent data show that nearly half of all foodborne illnesses are contracted from food prepared outside the home, compared with only 20 percent linked to home-prepared food. Although food establishments should be routinely inspected, the results of those inspections are not readily available to consumers, who thus have no way of minimizing their risk by knowing how an establishment performed on its most recent food safety assessment.
In some jurisdictions, consumers must submit a formal Freedom of Information Act request to the regulatory authority to access an inspection report. The addition of the following language to the Model Food Code will ensure public access to inspection results at the food establishment, improving consumer access and decision-making, without placing any additional or undue burden on food establishments. For more information, see http://www.cspinet.org/dirtydining/index.html.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be modified by adding new language in underlined format to Part 8-4 Inspection and Correction of Violations as noted below:
8-403.50 Public Information.
Except as specified in § 8-202.10, the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it at the FOOD ESTABLISHMENT and otherwise as provided in law.
8-403.51 Public Posting.

The REGULATORY AUTHORITY shall make available the results of the inspection report by requiring the timely posting of the most recent inspection results in a clear and legible form at the entrance, front window, or similarly prominent consumer-accessible area of the FOOD ESTABLISHMENT. Results may be posted in the form of a letter grade, numerical score, or other form as determined by the REGULATORY AUTHORITY.

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Conference for Food Protection
2012 Issue Form

Internal Number: 064
Issue: 2012 I-039

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Addition to Section 8-4 Inspection and Correction of Violations

Issue you would like the Conference to consider:
The FDA Food Code recognizes that the results of restaurant inspections are public documents and should be available for public review. However, complex rules regarding public access create difficulty for consumers who wish to consider inspection results.

Public Health Significance:
Consumer access to the results of these inspections plays an important role in maintaining the efficacy and credibility of the inspection system, and allows consumers to consider critical food safety information when making restaurant choices. Recent data show that nearly half of all foodborne illnesses are contracted from food prepared outside the home. Although food establishments are routinely inspected, the results of those inspections are not readily available to consumers-who thus have no way of minimizing their risk by knowing how an establishment performed on its most recent food safety assessment. In some jurisdictions, consumers must submit a formal Freedom of Information Act request to the regulatory authority to access an inspection report. The addition of the following language to the 2009 FDA Food Code will ensure public access to inspection results at the food establishment, improving consumer access and decision-making, without placing any additional or undue burden on food establishments. For more information, see http://www.cspinet.org/dirtydining/index.html.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended by adding language as follows:
8-403.50 Public Information.
Except as specified in § 8-202.10, the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it at the FOOD ESTABLISHMENT and otherwise as provided in law.

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Conference for Food Protection
2012 Issue Form

Internal Number: 083
Issue: 2012 I-040

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Packaged Food Labeling Clarification

Issue you would like the Conference to consider:
Foods can be wrapped in non-durable containers for sale in food service establishments, including carry-out restaurants and delis. It is the interpretation of some regulatory authorities, that foods wrapped in non-durable packaging for self-service are required to be labeled per the current labeling law. There are violations that are currently being reported for this practice. Foods served in non-durable packaging in a food service establishment should not fall under the requirements of the labeling law which was meant for foods in durable packages from a food processing plant.

Public Health Significance:
It is important that all foods requiring labeling under the law are in fact labeled for the protection of the consuming public with special dietary or health needs. It is equally effective to have information available (foodservice employee, signage, written hard copy or online website) for foods in a foodservice environment that do not meet the "packaged" definition.
The 2009 Food Code defines "Packaged" as follows:
Packaged.
(1) "Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.
(2) ***"Packaged"*** *does not include a wrapper, carry-out box, or other nondurable container used to containerize FOOD with the purpose of facilitating FOOD protection during service and receipt of the FOOD by the CONSUMER.*

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:
1) The FDA reinforces the legal definition of "packaged" in Section 1-201.10 (2), regarding the difference between durable and non-durable packaging.
2) The FDA adds language similar to the following to the next 2013 Food Code, Annex section 3 - Public Health Reasons/ Administrative Guidelines; Chapter 1 - Purpose and

Definitions, that describes the circumstances that labeling of foods in non-durable packaging is exempt:
a) Foods in non-durable packaging held in a cold display unit in the service line are available to the customer in a self-service format. Foodservice employees and/ or information are available to address ingredient questions.
b) "Grab-n-go" type items in kiosks in the front of a restaurant are available as a convenience to the customer in a self-service format. Foodservice employees and/ or information are available to address ingredient questions.

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Conference for Food Protection
2012 Issue Form

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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Reuse-Refill of Multi-use Tableware (To go containers)

Issue you would like the Conference to consider:
Amend 2009 FDA Food Code Sections 3-304.17 and 4-603.17 to allow for institutional type facilities (such as schools or assisted living communities) to provide reusable tableware/containers to consumers, who can then return the tableware for cleaning, sanitizing, and reuse by the food establishment. The consumer at the time of return, would receive cleaned and sanitized reusable tableware/containers that can be refilled with food.
Background:
Because of the trend toward recycling and attempting to limit the use of single service dishware in the waste stream, the PA Department of Agriculture has received several variance requests over the last few years to allow for colleges to use refillable containers that are provided to students by the food establishment. The variance requests have been reviewed and approved based on the limited scope of the consumers using the food establishment, as well as the following parameters:

- The reusable containers meet the criteria established in Chapter 4 for Equipment, Utensils and Linens, and are intended for multiple use.
- The facility establishes procedures for return of the containers that include, return area outside of any food preparation areas, inspection by a food establishment employee for general cleanliness and condition, and a direct pathway to the warewashing area which minimizes any potential cross contamination
- Food establishment accomplishes warewashing as required in the Food Code, and complies with storage and other handling requirements.
- A mechanism is in place to identify/verify the consumer population that is purchasing and returning reusable containers.

The trend toward recycling and environmental friendliness will continue - companies are manufacturing reusable containers and marketing them, especially in institutional settings, and more institutions will be looking at reducing waste and cutting costs. Since 2008, FDA has received several interpretation questions regarding re-use of to-go boxes and similar containers, and the Commonwealth of PA has received 2 requests to the Department of Agriculture, and at least one request through a County Health Department.
The 2009 Food Code prohibits a food establishment from refilling containers with PHF/TCS food in Section 3-304.17, and Section 4-603.17 prohibits cleaning and refilling containers,

other than beverages, unless by a food processing plant. Thus any jurisdiction that has facilities utilizing reusable food containers must make independent determinations through the variance process as to what is acceptable and required if approving the reuse or refilling of these multi-use food containers.

Public Health Significance:
Because of the trend toward recycling and attempting to limit the use of single service dishware in the waste stream, the Pennsylvania Department of Agriculture has received several variance requests over the last few years to allow for colleges to use refillable containers that are provided to students by the food establishment. The variance requests have been reviewed and approved based on the limited scope of the consumers using the food establishment, as well as the following parameters:

- The reusable containers meet the criteria established in FDA Food Code Chapter 4, Equipment, Utensils and Linens, and are intended for multiple use.
- The facility establishes procedures for return of the containers that include, return area outside of any food preparation areas, inspection by a food establishment employee for general cleanliness and condition, and a direct pathway to the warewashing area which minimizes any potential cross contamination
- Food establishment accomplishes warewashing as required in the Food Code, and complies with storage and other handling requirements.
- A mechanism is in place to identify/verify the consumer population that is purchasing and returning reusable containers.

The trend toward recycling and environmental friendliness will continue - companies are manufacturing reusable containers and marketing them, especially in institutional settings, and more institutions will be looking at reducing waste and cutting costs. Since 2008, FDA has received several interpretation questions regarding re-use of to-go boxes and similar containers, and the Commonwealth of Pennsylvania has received 2 requests to the Department of Agriculture, and at least one request through a County Health Department.
The current Food Code prohibits a food establishment from refilling containers with PHF/TCS food in Section 3-304.17, and Section 4-603.17 prohibits cleaning and refilling containers, other than beverages containers, unless performed by a food processing plant. Thus any jurisdiction that has facilities utilizing reusable food containers must make independent determinations through the variance process as to what is acceptable and required if approving the reuse or refilling of these multi-use food containers.
Non-uniformity in determining what criteria must be in place for approving variances related to reuse-refilling of these multi-use containers will result in jurisdictions establishing differing standards for the tableware/container, the types of food establishments that can use the reuseable tableware, the recordkeeping, and the food establishment handling, cleaning, and sanitizing, and storage of the reusable tableware.
Adding a standard set of provisions regarding when this practice is permitted will enhance uniformity among jurisdictions, provide a set of standards for industry to comply with, and protect the public.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA requesting amendments to the 2009 Food Code (as modified by the Supplement issued in 2011), Sections 3-304.17 and 4-603.17 specifically,

and other affected Food Code sections FDA identifies, to allow food establishments operating in institutional type settings with known consumers to provide reusable tableware/containers which can be returned and reused/refilled by that food establishment. In amending those sections, language should:

1. identify specific criteria and procedures for food establishment approval of the process
2. verify the consumer population (eg, IDs, Swipe Cards)
3. confirm tableware/containers comply with 2009 Food Code Chapter 4 standards for Multi-use Equipment & Utensils
4. establish procedures for return/reuse of tableware/containers that include inspection by a food employee
5. establish procedures for limiting cross-contamination potential when tableware/containers are returned, inspected, cleaned and sanitized, and stored.

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Conference for Food Protection
2012 Issue Form

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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Creation of Distribution and Storage, Transportation and Delivery Committee

Issue you would like the Conference to consider:
Food Safety and the prevention of food borne illnesses requires product protection, temperature control and other control steps throughout the food chain (from farm to fork). The process of distribution of food, food packaging, and sanitation chemicals to retail is one area that has been identified by studies (Interstate Food Transportation Project by Michigan Department of Agriculture and others), in publications (see attachments: 1) Food Safety Magazine - Maintaining the Cold Chain. 2) Food Logistics - Cold Chain Champions), and by the media (ABC News and Indiana videos available upon request) as one with food safety risks and opportunities. While Regulations are expected to be forthcoming via the Food Safety Modernization Act (FSMA)/Safe Food Transportation Act (SFTA), there exists a need to define and promulgate best practices and guidance documents in areas like temperature control, allergens, product protection, and other areas.

Public Health Significance:
Products must be protected from contamination, temperature abuse, and microbial growth to prevent food borne illnesses. Industry, Regulatory, Academia, Consumer Organizations, and others collaborating together to identify best practices assure these protections will add additional levels of food safety and consumer protection to the food chain.

Recommended Solution: The Conference recommends...:
the creation of a Distribution and Storage, Transportation and Delivery Committee. The Committee will be composed of Conference members from all constituencies especially subject matter experts in distribution, logistics and transportation. The Committee will be charged with:
1) Defining the scope of the distribution industry that will be addressed by the Committee, and identifying risks and opportunities for the Conference,
2) Soliciting best practices and existing documents that relate to distribution and storage of foods including Global Food Safety Initiative (GFSI) and other Standards to recommend best practices to the Conference,
3) Engaging with Federal and State agencies, especially those involved in Food Safety Moderization Act (FSMA)/Safe Food Transportation Act (SFTA) or existing transportation

inspection programs, to align proposed committee recommendations with regulatory requirements as they may be promulgated,
4) Reporting back to the 2014 Biennial Meeting summarizing its activities and recommending best practices in the areas of distribution and storage, transportation and delivery, and
5) Submitting Issues to the 2014 Biennial Meeting to recommend new FDA Food Code language and/or identify new charges for the Committee, if any.

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Attachments:

- "Food SAfety Magazine - Maintaining the Cold Chain"
- "Food Logistics - Cold Chain Champions"

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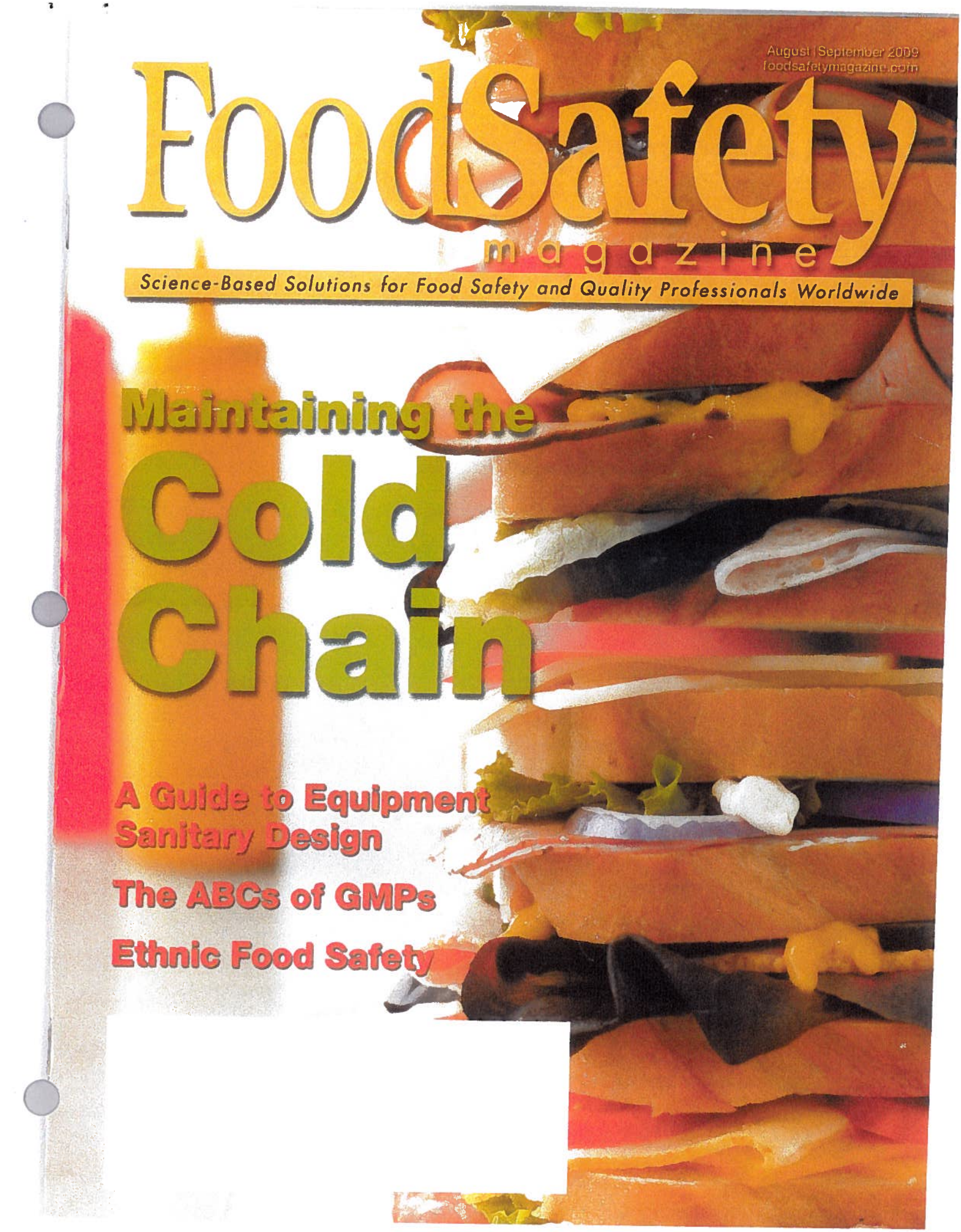
FoodSafety magazine

Science-Based Solutions for Food Safety and Quality Professionals Worldwide



Maintaining the Cold Chain

A Guide to Equipment Sanitary Design

The ABCs of GMPs

Ethnic Food Safety

FOODSERVICE DISTRIBUTION: Maintaining the Cold Chain

BY JORGE A. HERNANDEZ

Each day, millions of cases of product are delivered to restaurants, hospitals, universities and other food-away-from-home destinations. Moving these food products safely and efficiently from farm to fork requires an elaborate, highly coordinated series of links in a long chain of trading partners. Distributors serve as the intermediary between manufacturers and foodservice operators, procuring palletized and bulk inventory items from manufacturers, then breaking them down to case and unit quantities for foodservice operators.

While distribution may be the least highlighted link in the food safety chain, the safety and quality measures taken by successful distribution centers are no less important than the Hazard Analysis and Critical Control Point (HACCP) plan at the supplier's facility or the careful handling and preparation by the operator.

It's a Big, Big Distribution World

The U.S. distribution chain includes more than 15,000 companies operating thousands of warehouses and fleets of trucks. A typical broadline foodservice distributor may serve anywhere from 1,000 to 6,000 accounts from a single distribution center, and offer customers more than 10,000 food and non-food items. Other types include specialty distributors, which focus on specific product categories or customer segments; distribution systems, which serve large restaurant chains; and other businesses such as terminal markets and warehouse clubs.

In 2009, U.S. distributors' annual sales will be an estimated $211 billion, down from $217 billion in 2008 and $216 billion in 2007, according to Technomic Inc., a foodservice research and consulting firm. "The commercial foodservice market, particularly restaurants, is in a major slump, and distributors are a reflection of what the end-market is doing," says Robert Goldin, executive vice president of Technomic.

The largest distribution companies are Sysco Corp., headquartered in Houston, TX; U.S. Foodservice, based in Rosemont, IL; and Performance Food Group in Richmond, VA. Other major players included in Technomic's 2008 Power Distributors List include (in order of size): Gordon Food Service, Grand Rapids, MI; Reinhart FoodService, LaCrosse, WI; Services Group of America, Scottsdale, AZ; Maines Paper & Food Service, Conklin, NY; Shamrock Foods Co., Phoenix, AZ; Ben E. Keith Foods, Fort Worth, TX; and Cheney Brothers, Riviera Beach, FL.

"Customers should be aware of the food safety differences between distributors, especially in a down economy when many are making choices based on price."

It's All About Food Protection

Every distribution company has its own system for ensuring food protection, which includes food safety (protecting food from accidental contamination) and food defense (guarding food from intentional contamination).

"Best-in-class foodservice distributors go to great lengths and expense to protect the products they deliver," says Steve Potter, senior vice president of industry relations for the International Foodservice Distributors Association (IFDA), a trade association serving the foodservice distribution industry. Several federal agencies oversee food regulation and safety in America, including the U.S. Department of Agriculture (USDA), which regulates and monitors meat, poultry and egg products; the U.S. Food and Drug Administration (FDA), which ensures the safety of the production, processing, packaging and storing of domestic and imported foods; and the Centers for Disease Control and Prevention (CDC), which collaborates with USDA and FDA on disease surveillance and outbreak response.

Of the three, USDA and FDA interact most often with the foodservice supply chain. The "best practices" guidelines (more on these later) prepared by these agencies cover a multitude of processes, from general sanitation to packing and production to transportation and warehousing.

The common thread among best practices can be summed up in four words: "maintaining the cold-chain." A key part of every successful distributor's food safety program involves refrigerated docks, multiple refrigeration zones within distribution centers and multi-temperature trailers.

"In many ways, the transportation of food can be viewed as an extension of storage," writes Robert James Hart in his article "Food Science–The Transportation of Food," a scholarly examination of the chemical and molecular structure of foods and how they break down, for the book *Food Transportation*.[1] "A refrigerated [truck] is essentially a cold store on wheels. There may be additional engineering complications in designing and maintaining such a mobile storage facility, but the food science considerations are much the same."

Problems and Vulnerabilities

While food safety is a priority for every reputable distributor, it's often taken for granted by customers. Maintaining the cold chain from farm to fork is challenging. The average shipment–both inbound, from supplier to distribution center, and especially outbound to customers–consists of less-than-truckload quantities of food products. The number of products delivered to a customer can be in the hundreds. Each of these products must be loaded correctly to prevent cross-contamination with raw product and damage by heavier items at the bottom of a stack.. And they must be stored at the correct temperatures (frozen, refrigerated or dry) in the truck to maintain quality and safety. The food has to retain its chill throughout the multi-stop delivery process, especially in the heat of summer when the "reefers" (truck refrigeration units) have to work extra-hard to maintain temperature. In other words, there is plenty of opportunity for error.

Although food distribution companies must adhere to government regulations calling for greater food protection scrutiny (e.g., the Bioterrorism Act of 2002), enforcement is rare. On the supplier front, over-extended government food inspections run by FDA, USDA and state regulatory agencies continue to lag in both coverage and accuracy, as evidenced by the recent foodborne illness outbreak traced back to one less-than-scrupulous peanut processing company.

"Customers should be aware of the food safety differences between distributors, especially in a down economy when many are making choices based on price," says Greg Pallaske, director of regulatory compliance for food safety and quality assurance, U.S. Foodservice." That's why it's so important to evaluate the food safety policies and procedures and operations of your foodservice distribution company."

Frank Ferko, U.S. Foodservice's head of distribution food safety and quality assurance, agrees. "Most people are inward-looking when it comes to food safety," says Ferko, who has more than 33 years of experience in the restaurant, food processing and distribution businesses. "If you're in manufacturing, you

worry about food quality at your facility. If you're at a restaurant, you worry about your kitchen. That doesn't mean you can assume other areas are fully on target."

Areas of Food Safety Risk

The major areas of concern for food distributors start with the cold chain and time/temperature control, and include sanitation, cross-contamination and shipping logistics such as merge-in-transit. At the warehouse, food safety hot-spots include damaged goods and will-call.

Maintaining control of the cold chain is one of the biggest challenges for food distributors. Take mixed loads, for example, in which a trailer carries frozen, refrigerated and dry items in sections ideally separated by moveable bulkheads. There should also be chutes blowing the appropriately tempered air into the chilled compartments.

That's not always the case in the real world. "Some companies don't see a problem with putting frozen and refrigerated items in a trailer set at 26 °F and shipping the food halfway across the country," Ferko says. "We saw a lot of that last summer when gas prices rose above $4 per gallon, and companies were trying to cut corners."

> "Food safety works best when it is built into the overall design of both the facility and the trucks."

Combining frozen and refrigerated products is usually more of a food quality issue than a food safety issue, but it still ends up affecting operators' bottom lines. "French fries, for example, that are held at 20 °F and then brought back down to 0 °F will have moisture build-up on the surface," Ferko says. "When you dump them into the fryer, the surface moisture will cause problems with the oil and the fries will come out too dry."

Frozen breaded chicken held at too high a temperature suffers too, when moisture from the meat gets into the breading, which causes it to brown unevenly or flake off, while reducing the useable life of the fryer oil. Quality also takes a hit when refrigerated items are stored at the wrong temperature, as with delicate leafy greens that will freeze or wilt.

Certain foods–particularly seafood, sensitive pre-cut produce and ready-to-eat products–can become unsafe if not held at appropriate temperatures. Safety-conscious companies require time and temperature recorders for shipment of these foods. If the time-to-result indicates the temperature has exceeded safe limits, the best practice is to refuse the shipment and discard the product.

"We sometimes find that refrigerated seafood product shipped by vendors has been above 41 °F in the mid- to high-40 °F range for too long," Ferko says. "This can occur when the product is unloaded for redistribution to another truck, or when it's part of a longer-than-usual delivery that caused the truck's refrigeration unit to be turned off too long. In this case, the product should be rejected as unacceptable."

The practice of on-the-dock redistribution from one truck to another, called merge-in-transit or cross-docking, offers plenty of chances for temperature mishaps where food is involved *if* the docks are not refrigerated or if product sits for too long at the wrong temperature. The system was developed by retailers that ship dry foods or consumer goods as a way to speed deliveries while reducing warehouse and handling costs.

Companies using merge-in-transit should have refrigerated distribution docks and undergo a rigorous inspection process before such a program is implemented. In fact, U.S. Foodservice recently launched a pilot cross-docking program at two facilities in Chicago and one in Atlanta, with plans to expand the program to up to eight facilities throughout the country by next summer.

Returns and Will-Call

Returns and will-call areas, where customers can pick up product directly from the warehouse to meet last-minute needs, carry significant potential for both food safety and food defense to be compromised if the cold chain is not maintained. With returned product, the key point is to make sure that potentially unsafe product (food that has been out of the distributor's control) does not reenter the stream of outgoing goods for delivery to another, unsuspecting customer.

Reputable distributors will have a designated returns area, where all products are held for evaluation. Depending on results of the investigation, products will either be returned to the vendor, returned to shelves, donated to a food bank or destroyed.

Whether buying from a distributor, a terminal market or a warehouse club, "customers who want to put frozen or refrigerated product into their trunks and drive an hour or so back to their restaurant are creating risk," Ferko says. "The challenge lies in educating customers about transporting product safely. That said, you can't manage their business for them." Distributors should, however, limit customer access to the facility for their will-call business.

Food Defense Vulnerabilities

Protecting food from intentional contamination, a form of bioterrorism, is an issue that is sometimes overlooked. "Anyone with bad intentions can easily contaminate food–a customer at the salad bar, a restaurant employee, and so on," says Ferko, who sits on the food defense committee of the Conference for Food Protection. "Food defense is primarily about limiting access to products. It's also about understanding what might happen and monitoring who has access to food. If your company is limiting access by locking trucks, sealing cases within trailers with tamperproof tape, restricting access to distribution facilities, and performing background checks on new hires, you're already making progress on the food defense front."

Food defense measures taken by food companies are voluntary rather than mandated by government regulations. They're also relatively minimal, considering the critical nature of the nation's food supply and the shock wave that would ensue if a successful bioterrorism

attack on the food supply occurred.

"You do the things that are reasonable to protect the product, employees and customers," Ferko says.

A "Best Practices" Approach to Safe Food Distribution

For operators selecting a food distribution partner, or for distributors evaluating their own food safety operations, below is a series of questions followed by best practices suggested by regulatory agencies and the industry.

In the Distribution Center

What are some food safety aspects built into your distribution facility?

Food safety works best when it is built into the overall design of both the facility and the trucks. This includes having sufficient capacity for dry and refrigerated food products (chilled and frozen), providing easy access to all areas for cleaning, adequate insulation and temperature-control capacity. For facilities, it is important to restrict access by unauthorized entry through use of fences and locks, and of course, to have programs to prevent environmental contamination and infestation by insects or vermin.

How many temperature zones are in the distribution facility? How are they monitored?

A foodservice distribution warehouse typically has three temperature zones–ambient, cooler and frozen. Temperature ranges in the cooler area should properly protect meat, dairy and produce. The freezer should be at 0 °F or below. Larger facilities will have both an ambient and a refrigerated receiving dock area.

Best-in-class facilities are equipped with monitoring systems that track temperatures within each zone around the clock. Should a temperature go above or below the target range, the system sends a message (via email, text, fax or phone) to the warehouse manager so the situation can be corrected.

How do you ensure proper first-in, first-out product rotation at the warehouse?

Product rotation at distribution facilities is tracked and carefully managed. As each pallet of product is received on the dock, it is assigned a "license plate"–a bar code and a unique ID number that describes the contents. The product is then taken to the aisle and slot in which it will be stored, and the location number is entered into the system. Received product typically is placed into "reserve" slots. When the "pick" slot for that product becomes empty, warehouse staff will be directed by computer as to which pallet to insert next to ensure first-in, first-out accuracy.

How is food safety addressed in the picking process?

The slotting system at the warehouse is laid out in a manner that lets pickers assemble orders as they pass through the warehouse. As pickers move through aisles to fill food orders, they put the heaviest items on the bottom of the pallet for stability and to prevent damage. Typically, ambient products are placed with other ambient products, cooler with cooler and frozen with

Food Defense in Your Distribution System

An important part of safeguarding the nation's food supply involves protecting food in transit—90% of which is shipped by truck. Because of globalization, the journey that food takes from field to table can be thousands of miles, with many stops along the way. Challenges include the vast size of the area covered, the broad number of food distributors and their varied levels of knowledge about food defense, the relative lack of government regulation, the potential for unobserved access to food products, and a less-controlled setting that makes safeguards more challenging to implement. In short, today's world calls for food defense plans just as much as food safety plans.

A successful food protection program must focus on two areas: food defense and food safety. "Food defense" means preventing *intentional adulteration* by biological, chemical, physical or radiological agents. "Food safety" refers to guarding food against *unintentional* contamination.

"The distribution of ingredients and products is a vital component of our food delivery system, which is why it's important for food distributors and companies to know their suppliers and understand the food protection measures being used," says Jon Woody, policy analyst for the U.S. Food and Drug Administration's (FDA's) Office of Food Defense, Communication and Emergency Response.

Three food categories are considered to be especially vulnerable to contamination. Perishable products, such as meat or dairy products, must be monitored closely because their relatively short shelf-lives place an additional burden on the industry's ability to respond in a timely manner. The second category includes products that require extensive human interaction to be ready for market, such as produce or nuts that can come from multiple suppliers and are mixed and repackaged multiple times. The category of secondary ingredients, such as seasonings, breadings and peanut butter, is also especially susceptible to contamination.

Woody says food suppliers and distributors should have food defense plans in place that restrict access to facilities, and call for padlocks on truck trailers and regular, company-wide vulnerability assessments.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has released a number of initiatives designed to help suppliers, distributors and operators on the food defense front. Those initiatives are: ALERT (targeting foodservice managers), FIRST (aimed at employees, the first line of defense) and CARVER+Shock, a comprehensive online planning tool to help companies set food defense priorities. Information about all of them can be downloaded from the CFSAN Web site.

One other useful tool comes from the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). The FSIS *Guide to Developing a Food Defense Plan for Warehouse and Distribution Centers* is a 15-page, step-by-step document that includes evaluation forms covering everything from outside security to personnel to developing and implementing the overall plan.

The bottom line is that having a food defense plan helps suppliers, distributors and operators maintain the safety of the food products they handle—and most of all, helps protect everyone's business.

frozen to protect product integrity. Chemicals and cleaning products are segregated and placed separately on the delivery truck.

Who inspects incoming product for quality?

Distributors should have trained personnel inspecting the quality, condition and temperature of inbound products–especially perishable items. An in-house quality assurance program should include daily in-slot inspections of perishable products.

What happens to products that don't pass the quality test?

Products close to their expiration date or damaged while at the facility should be logged, segregated from other products for further inspection and returned to the supplier or dumped, if necessary.

Who inspects the facility? How often, and is it on a pre-determined schedule or by surprise?

Warehouse sanitation requires continuous effort at multiple levels. Supervisors should ensure floor and in-slot cleanliness on an ongoing basis. Audits should be regularly conducted by management. Many distributors contract with independent, third-party audit companies that conduct inspections at least once a year. Best-in-class companies hold inspections twice a year to identify and correct any food safety and sanitation issues. Distributors should be able to show you records of recent audit results.

On the Trucks

What are basic requirements for trucks to meet food safety standards?

Delivery vehicles should be of sturdy construction so as to permit easy rear- and side-door locking and sealing. Trucks should be sufficiently insulated and refrigerated so as to protect cargo against damage. Interior walls and floors should be clean and free of cracks or holes that could allow the entry of pests, vermin or dust, or negatively impact temperature control. As with the facility, the truck design should permit effective inspection, cleaning, disinfection and temperature control. Ideally, interior surfaces should be made of materials suitable for direct food contact, such as stainless steel or food-grade epoxy resins.

Regular cleaning programs are needed to keep the container interior free of dirt and debris. Equal attention to cleanliness is required for cargo pallets, load-securing devices and loading equipment such as hand trucks, forklifts and conveyors. When possible, transport vehicles should be reserved for "food use only" to reduce risks of cross-contamination.

What are your pre-loading procedures?

The pre-loading check should make sure that any residues from previous cargo have been removed. The cooling unit should be checked to make sure it's in good repair and operational. Portable bulkheads should be in good condition, free from tears or holes, and form a tight seal when in use. Air chutes (if present) should be properly in place for effective air circulation. Trailers should be pre-cooled at least an hour before loading to chill insulation and air.

How does a distributor handle loads that include both frozen and refrigerated products?

The optimum transport method for mixed loads is to use trailers with compartments set at different temperatures. These compartments are created through the use of portable, insulated bulkheads. Typically, frozen products are in the forward compartment at 0 °F or below, and cooler/dry product is in the rear at 41 °F or below. The practice of transporting frozen and refrigerated mixed loads in one compartment set at an intermediate temperature is not advisable for times longer than a few hours.

Cold Chain Assurance

How is the cold chain maintained during loading?

Product is typically brought to the dock in a sequence that minimizes the amount of time spent on the dock during loading and unloading. Best-in-class companies go to great lengths to ensure that product temperatures for meat, poultry and eggs do not exceed 40 °F before loading. Most larger distributors do their loading and unloading from refrigerated docks.

How is the product integrity maintained while in transit?

Once the truck pulls away from the dock, the product's safety and integrity becomes the responsibility of the driver. Leading companies have in-transit checks on temperature and refrigeration units. Some have implemented automatic time/temperature recording devices. Many also require warehouses to maintain log books documenting product condition upon arrival and during storage. A few companies have outfitted trucks with onboard computers and GPS systems so as to track location of product at all times.

What about unloading procedures? How is food safety ensured?

Product should be inspected for quality, damage and temperature (if appropriate) before being accepted at any point during the delivery process. Proper documentation is crucial to maintain records of product condition and packaging upon receipt. The documentation should also record temperature readings and note whether there was any sign of spillage, damage or pests. Perishable product should be moved immediately from the loading dock into the appropriate temperature zone in the warehouse or at the foodservice operation.

How are contaminated or returned products handled?

The distributor should have procedures for contaminated products to ensure they are separated from safe product. The procedures should cover products brought back by drivers upon their return to the warehouse. A monitoring plan and record-keeping system should document all steps taken. For food safety and food defense reasons, best-in-class companies would never sell a returned refrigerated/ready-to-eat product to another customer.

Useful links:

- International Foodservice Distributors Association, **www.ifdaonline.org**
- Center For Food Safety & Applied Nutrition, **www.foodsafety.gov/list**
- Conference For Food Protection, **www.foodprotect.org**
- Food Politics Blog, **www.foodpolitics.com**

A Matter of Balance

All of the food safety measures recommended by regulatory agencies and industry organizations–from a well-maintained refrigerated fleet to staff and driver training to inbound and outbound shipping standards–cost distributors both money and time.

"Food distribution is not just drayage–moving items from one point to another," Ferko says. "There's so much extra effort that we put into controlling the process to make sure product is safe."

Perhaps the most difficult question is, how do you put a value on doing the right thing? "What we do on the food safety front costs us time and money every day of the week," Ferko notes. "But it's all about delivering quality. The challenge is in choosing the right people and the right processes for the best reliability and safety, and negotiating a fair price that's acceptable to us and our customers. It's all about finding the right balance."

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INSIDE: GMA 2010 Logistics Benchmark Study Results Revealed

Food Logistics

Information For Grocery and Foodservice Distributors/Manufacturers

Issue No. 120 March 2010

2010 INNOVATORS
Ten Companies To Watch

GLOBAL STUDY
Food Fraud In The Supply Chain

PLUS: STATUS REPORTS
- Fleet Maintenance Made Easy
- Connecting With Technology
- Lift Truck Update

Cold Chain Champions

Don Ratliff, Jaymie Forrest and Harvey Donaldson (from left) head up the newly launched Georgia Tech Integrated Food Chain Center.

COLD CHAIN CHAMPIONS

The newly launched Georgia Tech Integrated Food Chain Center will bring high value and market power to participants in the cold chain. By April Terreri

COOL COLLABORATORS: Jane Griffith of Wawa and Nick Pacitti of Sterling Solutions helped to pioneer the establishment of the Integrated Food Chain Center.

Finally, the food logistics industry will have a research and resource center to utilize for questions about and solutions to every aspect of managing and monitoring the food cold supply chain. The Georgia Tech Integrated Food Chain Center—formed by The Georgia Tech Supply Chain & Logistics Institute (SCL) at The Georgia Institute of Technology and by Sterling Solutions LLC—will be housed within SCL in Atlanta.

The Center—integrating academia with seasoned industry experts—will launch this May and will operate as an international center for applicable knowledge in the fragile cold chain.

Operation Integration

While a few other organizations operate in the cold chain, they are composed primarily of trade associations. This is the first time the industry will ever have a research center that will integrate all cold supply chain and logistics participants, including distributors, retailers, foodservice companies, distributors and transportation providers.

"There is currently no one entity that studies, researches and applies economically feasible industry-wide cold chain solutions," notes Nick Pacitti, partner with Sterling Solutions LLC, Memphis. "So this will be a center of knowledge providing research into specific areas affecting these respective participants. It will serve as a center of knowledge providing research into tracing and protecting perishable foods as they move through the cold supply chain."

The Center will focus on a number of areas of concern to the industry, including product safety, product quality, environmental impact and economic benefit. Funding will come from industry members and sponsors and through government grants.

The goal of bringing together all of these various players is to establish an overarching understanding among cold chain participants of their respective responsibilities for maintaining the cold chain and how those responsibilities affect cold chain management of the other participants downstream in the cold chain.

"One of the reasons for the Center is to mitigate the risks we saw in dollars spent on product for development, manufacturing, consumer testing and regulatory compliance," explains Pacitti. "These costs are at risk throughout the cold chain from supply to delivery because if the cold chain is not managed right, brand integrity, customer confidence and market share are at risk."

Jane Griffith, senior director of quality assurance and food safety for Wawa Inc., based in Wawa, PA., notes that she and Pacitti have been pursuing getting this concept established for a number of years, talking with colleges and universities about the feasibility of such a center.

'The food supply chain is a lot more complex than any other supply chain and the cold chain is the most fragile; the quality of food is dependent on how food products are handled at every touch point throughout the food chain.' —Don Ratliff, SCL

"But many of them didn't have the ability to really move the needle and help us bring all these central partners together," says Griffith. "When we approached Georgia Tech, they immediately saw the value to the industry and to the entire food supply chain. And since they have a reputation of expertise and strength in the supply chain anyway, it was a natural fit for them to do this."

Bill Hudson, president and CEO of Alexandria, VA-based Global Cold Chain Alliance, weighs in on the value to the industry of the Center. "As the Center will integrate the examination of the cold supply chain and the operation of the chain, we see this as a tremendous opportunity in bringing together the industry, academia, government and food science in order to study the challenges in food logistics."

Hudson adds that his organization also strives for integrity of refrigerated foods throughout the distribution chain. "We look forward to aligning our programs and our members' needs with the Center's mission."

Georgia Tech: The Natural Choice

John Bartholdi is research director for the Integrated Food Cold Chain Center. He points out that Georgia Tech's Supply Chain and Logistics Institute (SCL) has long been a global leader in supply chain and logistics.

"Georgia Tech's SCL is the largest industry/academic collaborative in the world, with research offices globally," he says. So the fit was perfect as the home for the new Center. A number of centers focused on food science do operate currently, most having grown out of schools of agriculture, explains Donald Ratliff, Ph.D. at SCL. "But there is no center focusing on the food supply chain and food logistics. So we are bringing something new and necessary to the industry through this Center."

Jaymie Forrest notes that for the last consecutive 19 years, Georgia Tech has been rated the top industrial engineering school in the country. "So in leveraging our systems and design engineering processes, coupled with our expertise in the supply chain and logistics arena, we offer this sweet spot of ours that brings a lot of value to the industry," says Forrest, director of business development at SCL.

SCL already has been involved in studying the temperature control chain as it relates to international shipments, continues Forrest. In fact, the institute has established several research centers throughout Asia, South America and Latin America. "These centers focus on logistics strategies," she explains.

"We are leveraging the knowledge we gather in order to collaborate and integrate the entire food chain." This knowledge will help inform the Center's work as anticipated international regulations become law.

"Its time has come for something like this Center," notes Jane Griffith, senior director of quality assurance and food safety for Wawa Inc. "Everyone saw there was the need for this, but nobody really understood what the best approach should be. I am so grateful that Georgia Tech has seen the value of this by embracing the concept and becoming an owner of this, helping all of us in the industry to move this along quickly." —*A.T.*

TEAMWORK: From left, Ratliff, Forrest and Harvey Donaldson, SCL managing director.

Chain Reaction: The Fragile Cold Chain

There has been increasing recognition in the last few years of the uniqueness of the food cold chain and food logistics, says Don Ratliff, Ph.D., at SCL at Georgia Tech.

"Our goal is to make sure that everyone understands the food chains," explains Ratliff, executive director of SCL. "They differ depending on where they originate—by product and by type of processing, for example. So we are not talking about just one food chain; there are many different food chains involved. What we hope will happen is that the issues causing trouble in any of these chains will bubble up so that we can address problems around quality, safety, energy efficiency and economics. The food passing through these supply chains has to be safe and of the highest quality, while also being economically feasible for the operators and for consumers."

The U.S. imports about 60 percent of all of the fruits and vegetables that the nation consumes. "So there is an increasing focus on food safety relative to products that are imported as well," says Ratliff. "The food supply chain is a lot more complex than any other supply chain and the cold chain is the most fragile; the quality of food is dependent on how food products are handled at every touch point throughout the food chain."

Methods that work in a typical food supply chain do not work effectively in a cold chain because the food is highly perishable and fluctuations in temperature and humidity, mishandling or expired codes can wreak havoc on the quality of the products and, by extension, on customer loyalty, notes Sterling Solutions' Paciti. He adds that about 25 percent of product is wasted due to poor handling or the inability to track shelf life.

As to ownership of the cold chain, there is not a single owner, but many. So cold chain management throughout the chain becomes an exercise in integrating the processes required by each participant as the food passes through the participant's portion of the cold chain. "If you know what the processes are up and down the chain, you can integrate all the processes so there is continuity in cold chain management up and down the chain," says Ratliff.

The industry strives to deliver safe, fresh, high-quality food products cost-effectively to consumers. However, just one error at any touch point along the cold chain can jeopardize product quality, freshness, brand image and food safety, no matter how excellent the cold chain management practices are downstream from the error.

"Most of the focus of research has been on how you deal with these touches within a facility and they have been one-point solutions," explains Ratliff. "But every handoff point has to be perfect; for instance, the handoff between production and transportation and between transportation and storage. We felt there was a need in the industry for an entity that would pull all of these groups together to guide cold chain technologies, management processes and methodologies."

To assure quality throughout the chain, the approach must change from one of inspecting all the food—which is not a realistic solution—to instituting a process that will incorporate quality in the chain. Thus, safety and quality will be consistent, similar to the philosophy of total quality management employed in the

Enhancing Traceability

IBM will act as an industrial advisory board member to the Integrated Food Cold Chain Center, reports Jane Snowdon, Ph.D., senior manager, industry solutions and emerging business, smarter building research, for the IBM T.J. Watson Research Center in Yorktown Heights, NY.

Jane Snowdon

"We will provide guidance and ideas to direct the Center's research agenda," Snowdon says. "We also anticipate fostering interactions with Georgia Tech and with the international ecosystem of university partners and industrial partners in joint workshops and seminars."

Of course, consumer confidence is won or lost based on the capability of cold chain participants to deliver safe and fresh food to consumers. In a study conducted last year, shortly after the tragic peanut debacle, IBM found that consumer confidence and trust in retailers, manufacturers and grocers is increasingly declining. "So now is really the time for all the players in the food supply chain to rebuild consumer confidence by modernizing the global supply chain so the production, safety, and quality of food can be improved," says Snowdon.

"I think what Georgia Tech is doing to bring together these stakeholders will really make a positive difference," continues Snowdon. "Now companies will have a trusted source of updated information relating to traceability. Companies will have brand empowerment because this information will enable them to make claims that they have real-time information about where their products are along the chain."

Supply chain efficiencies will enable companies to accelerate their product flows, thereby allowing them to reduce their inventory levels through increased supply chain visibility, explains Snowdon. Companies will be better able to protect their brand through risk mitigation by identifying risks and isolating contaminated products. Companies can assure regulatory compliance with individual retailer mandates and government regulations. "So traceability plays a very critical role in creating transparency that allows companies to mitigate recalls and support product marketing claims."

A few of IBM's traceability projects can offer ideas to the Center to drive technologies to enhance traceability. For instance, IBM is working with a major German food retailer who is applying RFID smart labels to meat products.

"The meat is tracked by the date it was placed into a refrigerated display case and the date it is removed from the case by a consumer," explains Snowdon. "This helps provide workable information for the store to monitor the freshness of the products while controlling the environment in which the products are stored. It also helps manage inventory levels by matching sales data. This is one example of how we are teaming with food retailers to ensure that food in the freezer stays fresh."

For a Norwegian food retailer, IBM developed a smarter food-tracking solution using RFID technology to track and trace meat and poultry from the farm to the store shelf. "Offering transparency throughout the cold chain ensures that food is maintained in optimal condition," Snowdon explains. "It also helps suppliers and grocers reduce their costs and improve food safety, thereby increasing consumer confidence."

Another practice worth noting in food traceability advancements is the example of A&P, who is applying bar codes to every individual egg in egg cartons. "These are examples of the shift we are seeing in our foods that provides more accountability in the food chain. So there is more information available today to do analytics to be able to look for trends and to more quickly pinpoint and react to any type of problem in the food chain before it becomes a problem. The next wave will be to use information to help us make better business decisions that can help mitigate recalls." —*A.T.*

automotive industry. "Rather than randomly testing product as it is delivered, it is less expensive to develop and coordinate a cold chain standard upstream starting at the producer and ending downstream at the store," explains Sterling's Pacitti.

Common concerns in the industry will be on the Center's agenda, such as improving supply chain efficiencies, monitoring traceability and quality, minimizing waste and spoilage, and improving bottom-line performance. Cold chain management is evolving into a regulatory tool, notes Pacitti. "It must be done right or the stakes are high."

The repository of information and research the Center will contain on supply chain management technology and product quality characteristics will have market appeal to cold chain participants. The Center will also promote a deep understanding of the economics relative to the development, production and distribution of perishable foods.

Front And Center: Numerous Opportunities

The Center will collaborate with the industry, academia and the federal government in information sharing and in pilot studies. It will bring value to the industry as well as to all partners of the cold supply chain, Wawa's Griffith points out. "It will provide research on technologies and processes for us to monitor and improve cold chain efficiencies, which is really critical to the industry and it is something that we hadn't had before in the industry," she says.

'We will be looking for guidance from Georgia Tech as to where there is opportunity for value to occur as we move inventories of highly perishable products.'

—Chris Lofgren, Schneider National

It will be an important link in assuring safe, high-quality foods from sources throughout the globe. "Consumers expect strawberries in December, but they don't understand that we have to source foods from faraway places to be able to offer them year-round," says Griffith. "The only way we can provide consumers with safe, high-quality food is through a system assuring efficient and effective cold chain management."

The integrated philosophy brings enhanced value to the industry. "It's critical to our industry that the Center develop solutions in joint research projects involving industry players and academia who can offer recom-

Transportation: Critical Point In Cold Chain Management

Transportation is a critical element in the cold chain, notes Nick Pacitti, partner with Sterling Solutions LLC in Memphis. "The transportation piece in the food cold chain is referred to as 'the last mile' in the supply chain and it is the area in the cold chain that places food at its most vulnerable if temperature abuse occurs," he says.

Numerous environmental conditions can cause temperatures to fluctuate, including the number of times doors are opened to deliver products, the volume delivered, time of year (summer opposed to winter) and geographic area (south or north).

"Most carriers cannot tell you when there is an issue, except when there is a major reefer breakdown," continues Pacitti. "Some will say they do what their customers tell them to do, which in many cases relates to what the temperature of the trailer should be. Temperature abuse plays havoc on product and most of this happens in the final mile of delivery."

Carriers and logistics providers must manage temperatures in a more scientific way, asserts Pacitti. "The Center offers a resource for carriers and their customers to come to learn the best way to protect products and to recognize that product abuse is a cumulative process. Cold chain management is evolving into a regulatory tool, as well as into a supplier-retailer-specific requirement."

Jane Griffith notes that the Center's mission to integrate all participants in the cold chain will bring independent haulers into the fold. "This is a very large group that needs to understand their role and responsibility in maintaining the cold chain," says Griffith, senior director of quality assurance and food safety for Wawa Inc. "Many of us use them and sometimes they are not as aware of their responsibilities as they could be. So we see the educational opportunities the Center will offer helping greatly to improve this situation."

Risk management is a critical element for transportation providers to consider. Phil Dunavant notes that he expects the Center to bring discipline to the transportation process. "I believe it will help us raise the bar relative to the capabilities of independent haulers," says Dunavant, COO of Memphis-based ReTrans Inc. The company is a multi-modal transportation provider working with independent haulers nationwide.

Protecting the safety and quality of food is a major concern especially considering the number of participants in the cold chain, Dunavant continues. "So from a risk management perspective, we want to make sure that our carriers have the required controls in place to provide the proper environment for the food cold chain."

Phil Dunavant

He envisions guidance from the Center will help relative to establishing KPIs that measure carrier performance. "We expect that the Center will shed light on what is needed out there to ensure that carriers are responsible in making the cold chain even more efficient. It will offer carriers a better understanding of their responsibility to maintain the cold chain and it will also give them an exposure to what the rules are and what is expected of them."

Transportation is, after all, the integrating function of the cold chain, reminds Chris Lofgren, president and CEO of Schneider National in Green Bay, WI. "We will be looking for guidance from Georgia Tech as to where there is opportunity for value to occur as we move inventories of highly perishable products. I think the Center will help us leverage information and communication and how that relates to understanding how the information flows relative to the physical flow of goods. This information will help us learn how we can drive efficiencies even further as we identify additional opportunities."

Lofgren looks for guidance from the Center in how to balance backhauls with refrigerated equipment. "The value you generate across that asset is diminished if you are not using it to transport refrigerated or temperature-controlled products. So we hope to learn how to have these operations work a lot more efficiently." —*A.T.*

mendations in advancing the effectiveness of cold chain management," says John Owen, vice president of logistics for the Midwest/Southeast supply chain services region of Minneapolis-based Supervalu Inc.

Employing a multi-disciplinary role in cold chain management, the Center will bring numerous opportunities to the industry, including:

Ongoing research: Laboratory simulations of things such as how temperature and humidity fluctuations affect product quality and shelf life will provide the industry with actionable information.

"We will develop thresholds and trigger points across the cold chain," says Pacitti. "This will alert us hours before something goes wrong that there is a problem brewing so we can be proactive and fix the problem. Then we can begin to manage shelf life by integrating quality, traceability and replenishment strategies."

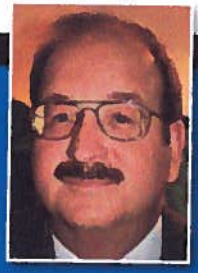
Next practices will direct methods of how to be more efficient in delivering perishable product from both a quality and economic perspective, Pacitti says.

SCL's Ratliff notes that industry will be a major participant in helping identify top problems. "Industry members will work with us to help resolve these problems. It is our desire to have regular ongoing projects that will monitor food as it moves through the chain as we examine things like temperature and humidity from end to end."

Supervalu's Owen looks to the Center to provide ongoing cold chain research to protect food throughout the chain. "The issue that any one particular company has is really an extension of the problems the industry faces," he says. "We deal with very sensitive products that need to be handled at critical temperatures and humidity. So anything that improves these processes helps all of us in the industry."

Suggesting technology solutions: The Center expects to determine how various technologies can be utilized effectively yet affordably, says Jaymie Forrest, director of business development for SCL. "We plan to work with companies who develop these technologies so we can determine how best to use their technologies," she says.

Griffith looks forward to emerging technology from the Center's research. "This is very essential to Wawa and we would like to see how this research can translate monitoring the cold chain into product traceability. If we can couple these two aspects—cold chain management and traceability—that will be a big win for many organizations in the food industry.



'Considering the ongoing regulatory activity focused on food safety, the industry must take the lead. The Center will be an important partner in this endeavor.'

—Frank Ferko, U.S. Foodservice

Traceability is something everyone needs to truly understand to be able to manage the cold chain properly."

These technology solutions should interface easily among participants and should be cost effective and affordable to everyone, she adds.

Another developing area relates to how to manage replenishment strategies while keeping very small inventories. "We are evaluating and understanding technologies that instantly capture data and report that your product sold so much of a percent of inventory on a particular day. This information converts into a production plan for the following day. So what happens at the cash register is critical in developing production and replenishment plans," notes Pacitti.

Assuring food safety: There is nothing more important to the strength of U.S. Foodservice's business than food safety, stresses Frank Ferko, director of distribution food safety and quality assurance for U.S. Foodservice headquartered in Rosemont, IL.

"As food safety leaders in the industry, we are acutely aware that the food cold chain really needs a world-class program like this Center," says Ferko. "The industry needs sophisticated educational and research programs that can provide analytical evidence to drive further development in the cold chain and distribution logistics."

Establishing standards: There are a number of organizations developing international standards for the food chain, SCL's Ratliff notes. While they focus primarily on providing services to their members (composed of a subset of service providers to the food chain), Ratliff explains the distinction of the Center is that it is focused on bringing together in an integrated approach to the chain all of the stakeholders, such as produc-

Continued Research And Development

The Georgia Tech Integrated Food Chain will address the following issues:

- **Temperature control (stability and challenge) testing:** Provides cumulative supply chain effects of time, temperature and other environmental effects on product quality.
- **Food and distribution engineering:** Provides abuse testing to determine product design and packaging and distribution methods.
- **Cold chain assessment and audit.**
- **Predictive modeling:** Provides predictions of the deterioration process.
- **Supply chain modeling:** Develops models and methodology for designing supply chains to optimize costs.
- **Automated data capture and processing:** Engineers onboard vehicle systems for automatic data capture.
- **Performance reporting and index:** Provides customer- and product-specific performance ratings.
- **Supply chain management technology:** Develops technologies and methodologies for visibility, tracking, and tracing.
- **Continuing education and certification:** Provides a learning center for cold chain participants.
- **Supply chain management technology showcase:** Demonstrates how technologies perform.
- **Sustainable energy management:** Assesses and correlates the impact to product quality of temperature management.
- **Risk and loss assessment and management:** Assesses vulnerabilities leading to product loss, quality deterioration and public health hazards.
- **Policy analysis:** Develops policies and models of success at regional, national and global levels for resilient and sustainable food chains.
- **Benchmarking and analytics:** Provides industry and best-in-class comparisons contributing to sustainable and resilient food chains. —*A.T.*

ers, processors, transportation providers, exporters, importers, wholesalers, distributors and retailers.

Currently, there are no cold chain standards to drive assurance and customer loyalty, adds Pacitti. "The costs of information have contributed to market failures in perishable product safety provisions, thus making the design of effective interventions difficult. Cold chain standards can reduce product safety risks and companies are seeking comprehensive answers to product integrity and supply chain effectiveness in light of the rapid rise in public health issues."

Pacitti reports that the Center will develop cold chain standards, processes and applications that will help overcome the expense of setting and monitoring levels of microbial food-borne pathogens and other product threats. "The Center will provide an economy of scale for solutions that the majority of perishable supply chain members would not be able to design or afford," he says.

Providing educational opportunities: Ferko at U.S. Foodservice reports his company intends to utilize the Center for educational opportunities and research partnerships.

"We have been looking for an academic partner for some time and the Center presents a solution for our team to enhance our performance. We would like to work with the Center to develop science-based metrics that measure food safety and quality within the cold chain," says Ferko. "We would also like to share some of the results of our own programs back to the Center, as I think there could be many valuable give-and-take opportunities between the industry and academia."

The Center expects to be on the cutting edge of advancing processes and technology, notes Owen at Supervalu. "We are always considering ways to further develop our associates, so the Center will offer us this great educational opportunity."

As a leader in supply chain and logistics, Georgia Tech also lends itself as a recruitment resource, he adds.

Griffith perceives the Center as an excellent source for educational opportunities for both herself and for members of her team at Wawa.

"We will use the Center as a resource for research on how to improve product quality throughout the cold chain. That might mean that they develop a standard for us of maximum temperature a product can reach before its quality begins to deteriorate or before we have a food safety issue," she says.

Informing regulations: The impact to the industry of government regulations will be another facet of the Center's research component, notes David Sterling, partner at Sterling Solutions.

"The amount of food safety regulations on the horizon could fundamentally impact how the industry does business. There is no true focal point for this kind of study today. The Center will be able to translate governmental regulations to indicate to the industry what the impact will be on their businesses," says Sterling. "Our goal is to be proactive and have a voice in governmental discussions as they relate to regulations."

Ferko at U.S. Foodservice notes: "Considering the ongoing regulatory activity focusing on food safety, it is especially important for the industry to take the lead. I think the Center will be an important partner in this endeavor."

Supervalu's Owen looks to the Center to examine best practices and best processes as they relate to regulations coming from various branches of the government. The industry can look to the Center to recommend regulations relative to food products sourced internationally, he adds.

Providing economical benefits: Of particular interest to Owen will be the methods the Center will develop to expand the cold life in the perishable portion of the grocery distribution business. "Applying these methods to our business and to the industry will be beneficial and will provide great economic value as well," he says.

'We deal with very sensitive products that need to be handled at critical temperatures and humidity. So anything that improves the process helps us all in the industry.'

—John Owens, Supervalu Inc.

Owen is also looking to the Center to discover ways for companies to lower their energy costs while maintaining cold chain integrity. "Many of our facilities of ours are very large and use a lot of electricity. We are always looking for ways to become more efficient."

Learning sustainability efficiencies: Ferko notes that sustainability aspects are a priority at U.S. Foodservice. He says the company was able to reduce the production of carbon dioxide by 22,000 metric tons in 2008. "We did this by simply reducing idle times, installing maximum speed controls, and routing deliveries more efficiently."

He adds that the company, involved in its own research projects, would like to work with the Center in developing other initiatives that reduce undesirable impacts on the environment. "We look forward to interactions between Georgia Tech, our company and the industry to find more of these kinds of environmental solutions."

Integration Articulation

Through the resources of the Center, improved applications can be brought to market a lot quicker. "Where you have consensus among different groups like government, private industry, and academia, this will provide a great resource for the industry to really be certain that we have the world's leading cold chain environment and that we are protecting food integrity all the way to the consumer," says Supervalu's Owen.

"I work very hard at Wawa to assure our cold chain is the very best we can provide, yet I know there are opportunities to improve," says Griffith. "Improvements will translate to increased shelf life, increased product quality, increased availability of products throughout the year to my consumers and increased consumer confidence that Wawa's products are high in quality. Of course, all of these things translate to a profit, which makes Wawa very happy."

The only other way to ensure safe food is to pasteurize or irradiate everything, notes Griffith. "But nobody wants to eat food that has been overprocessed. Going down that road is just not what the consumer wants. Everyone throughout the world wants the safest and freshest food possible. Having this Center as a resource will help us monitor and improve every aspect of the cold chain, and it will provide us with a deeper understanding of the processes that need to be implemented in order for the industry to manage and maintain an effective and efficient cold chain," she adds. ❀

For more information about the Georgia Tech Integrated Food Chain Center, go to www.sci.gatech.edu or call 404-894-2343. The Center can also be reached via email at ifc@sci.gatech.edu.

Conference for Food Protection
2012 Issue Form

Internal Number: 102
Issue: 2012 I-043

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Cottage Industry/Direct Producer to Consumer Sales

Issue you would like the Conference to consider:
Many states are adopting exceptions and special rules for cottage industries and direct producer to consumer sales. These types of sales include both packaged and unpackaged non PHF/TCS foods processed in residences and sold from the residence over the internet, at roadside stands, and at Farmer's Markets. The inconsistencies and in sometimes complete exemption from regulatory oversight are concerning from a safety persepective. We respectfully request that the Conference for Food Protection establish a Cottage Industry Committee to develop a proposal for the 2014 Conference that more completely addresses cottage industries and direct producer to consumer sales.

Public Health Significance:
States and local jurisdictions have adopted a variety of exemptions and policies with relationship to cottage industry/direct to consumer sales. The most significant public health issue is that jurisdictions without scientific input have developed a variety of standards, exception, and exemptions. This creates a system where a cottage industry/direct to consumer sales may or may not be regulated and inspected. From a state perspective, we see surrounding states that have exempted places from regulation, but the individuals are seeking to come to events and make sales in our State. For example, acidified foods, cheeses, eggs, and other processed foods are subject in some jurisidictions to these exceptions and exemptions. Furthermore, complete and thorough labeling is a concern to individuals with allergies or sensitivities.

Recommended Solution: The Conference recommends...:
creating a Committee to develop a proposal for the 2014 Biennial Meeting that more completely addresses cottage industries and direct producer to consumer sales. We respectfully suggest the Committee undertake the following charges:

- define Cottage Industries and Direct Producer to Consumer Sales
- identify exemptions from the Food Code
- establish labeling requirements
- write advisory statements as appropriate
- recommend Cottage Industry registration requirements

- require the Committee to submit a report at the 2014 Biennial Meeting along with Issues they identify.

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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.