

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-001

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report - Plan Review Committee (PRC)

Issue you would like the Conference to consider:

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

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

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Content Documents:

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

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

Conference for Food Protection – Committee Final Report

Template approved: 8/14/2013

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

COMMITTEE NAME: Plan Review Committee (P R C)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council 1

DATE OF REPORT: January 29, 2016

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

COMMITTEE CHARGE(s):

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

COMMITTEE ACTIVITIES AND RECOMMENDATIONS

Progress on Overall Committee Activities

As of July 24, 2014 we received confirmation from our initial list of committee participants August, 2014 we completed the list with as much a representation of constituency as possible.

In August, 2014 the Co-Chairs reviewed the Plan Review Guide (2008) and shared with our members.

We held a conference call on September 26, 2014 with a proposed agenda.

Conference Call held on Nov. 17 and Nov. 19, 2014 to continue updating the Plan Review Guide

Conference Calls were held on January 16th and February 18, 2015.

During the February 18th conference call our committee decided to have at least 2 members update each of the 12 Sections of the Guide and submit to our Group for discussion, consensus and final update. A webinar resource is requested to provide a VISUAL of the document during our Meetings. Dr. David McSwane later notified our Committee, a webinar resource was available to use.

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

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

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

Conference for Food Protection – Committee Final Report

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

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

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

We continued with conference calls every third Friday of the month from June to November,

2015 before submitting our updated Food Establishment Plan Review Manual

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

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

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

1. Recommendations for consideration by Council:

Conference for Food Protection – Committee Final Report

Template approved: 8/14/2013

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

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

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Report – Plan Review Committee Final Report
 - a. Acknowledgement of 2014-2016 Plan Review Committee Final Report
 - b. Thank the Committee members for their work on the guidance document
 - c. Disband the Committee
2. PRC 2- Food Establishment Plan Review Manual
 - a. Accept the updated Food Establishment Plan Review Manual and Appendix A through D

Attachments:

Content Documents:

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

COMMITTEE MEMBER ROSTER (attached)

Food Establishment Plan Review Manual

2016 Version

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

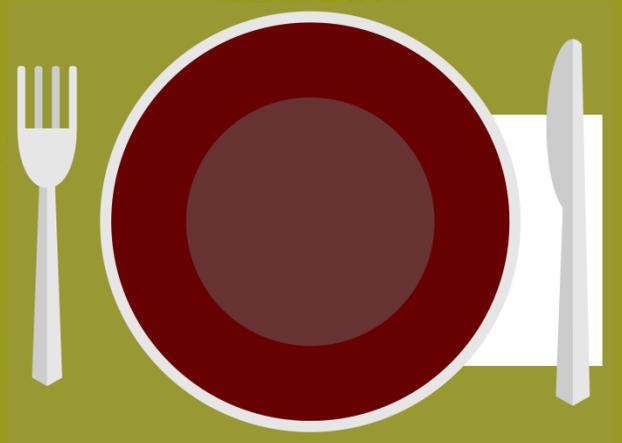


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PREFACE

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

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

INTRODUCTION

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

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

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

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

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

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

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

DEFINITIONS

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

Definitions found within the FDA Food Code have been identified in CAPS within this document. A link to the FDA Food Code is included for your reference.

<http://www.fda.gov/FOOD/GuidanceRegulation/RetailFOODProtection/FOODCode/ucm374275.htm>

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

- (1) Disassembling without the use of tools, or
- (2) Disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

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

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

CONTENTS AND FORMAT OF PLANS AND SPECIFICATIONS

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

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

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

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

MENU REVIEW AND FOOD FLOW

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

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

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

- **FOOD PROCESSES WITH NO COOK STEP**
 - **Receive – Store - Prepare – Hold – Serve**
(Other processes may occur, but there is **NO cooking step**)
 - Examples: Salads, deli meats, cheeses, sashimi, raw oysters

- **FOOD PREPARATION FOR SAME DAY SERVICE**
 - **Receive – Store - Prepare - Cook – Hold – Serve**
(Other processes may occur, including thawing)
 - Examples: Hamburgers, fried chicken, hot dogs

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

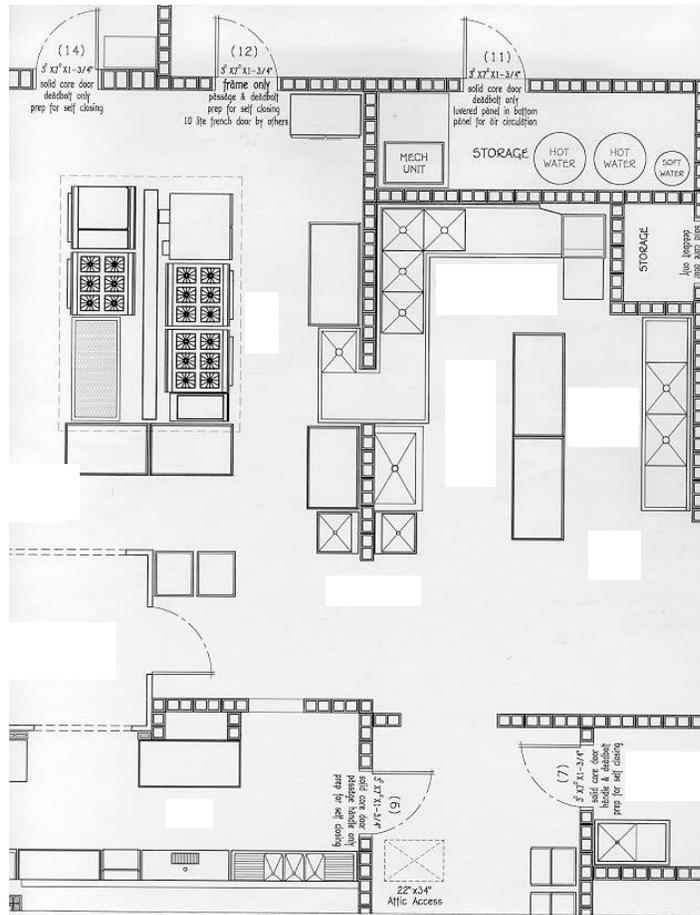
Knowledge of how the FOOD is intended to flow through the FOOD ESTABLISHMENT is very useful since the CRITICAL CONTROL POINTS for each process remain the same regardless of the individual menu ingredients.

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

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

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

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



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

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

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

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

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

FOOD Process and Steps Required

NO COOK

SAME DAY SERVICE

COMPLEX PROCESSES

Receive	Store	Prepare	Cook	Cool	Reheat	Hold	Service
X	X	X				X	X
X	X	X	X			X	X
X	X	X	X	X	X	X	X

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

Anticipated EQUIPMENT needs

PREVENTIVE TOOLS FOR THE FOOD ESTABLISHMENT

Active Managerial Control (AMC)

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

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

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

HACCP

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

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

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

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

FACILITIES TO MAINTAIN PRODUCT TEMPERATURE

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

Refrigeration and freezer storage involves five major areas:

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

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

A. Refrigeration Storage Calculations

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

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

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

B. Walk-in Cooler/Freezer Units

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

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

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

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

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

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

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

C. Reach-in Refrigerators

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

D. Reach-in Freezers

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

E. Blast Chillers/Rapid Chill Units

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

F. Refrigerated Worktables

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

G. Refrigerated Processing Rooms

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

H. Display Storage Refrigerators

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

I. Customer Service Display Units/ Cold Buffet Units

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

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

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

J. Ice Machines

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

K. General Cooking and Hot Holding

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

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

Units used to heat FOOD are divided into two categories:

1. Cooking/Reheating
2. Hot Holding

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

L. Stovetops and Grills

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

M. Ovens

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

N. Combination Oven/Steamer (Combi Oven)

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

O. Rice Cooker/Warmer

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

P. Kettle

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

Q. Rotisserie

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

R. Small Appliances

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

S. Fryers

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

T. Hot Tables

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

U. Customer Service Display Units/Hot Buffet Units

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

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

EQUIPMENT AND INSTALLATION

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

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

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

A. Floor Mounted Equipment

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

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

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

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

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

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

B. Counter-Mounted Equipment

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

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

C. Other

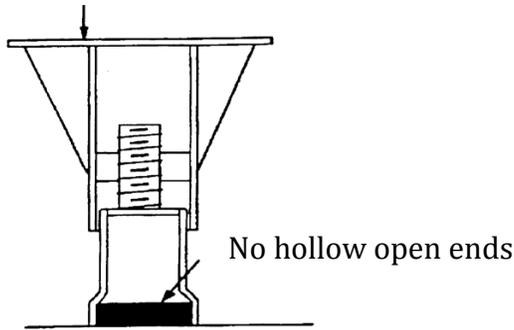
EQUIPMENT that is open underneath, such as drain boards, dish tables, and other tables that are not moveable should be spaced to allow for ease of cleaning or should be SEALED to the wall.

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

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

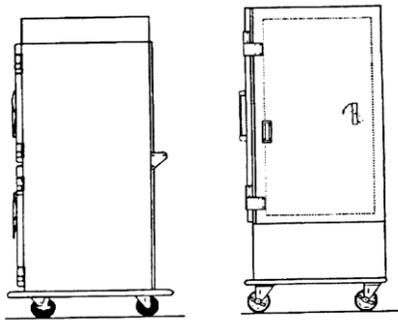
If running water dipper wells are installed, methods for filling and draining the units must be identified.

Equipment sealed to floor



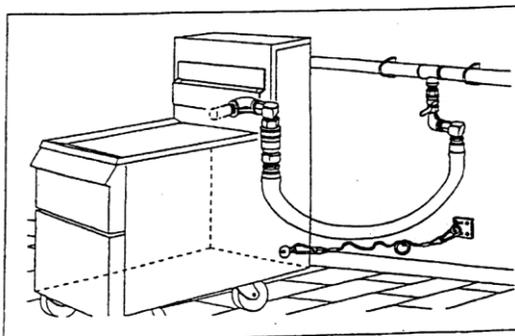
**Elevate
equipment for
effective cleaning.**

**Sanitary Leg
Example**



**Mobile Kitchen
equipment
mounted on
Castor**

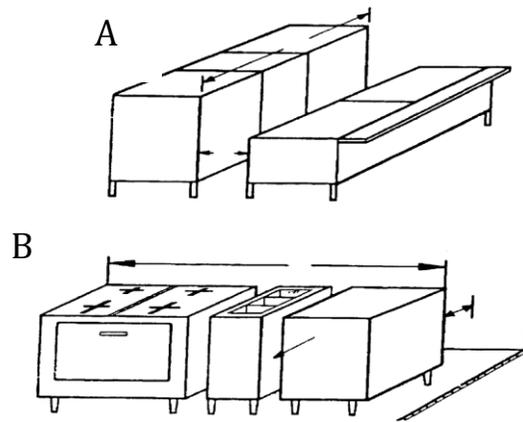
Holding Cabinet & a Reach-in Refrigerator



**Refer to your
Local Regulatory
Authority for Gas
Code
Requirements**

Flexible Gas Connection with Safety Chain

Equipment Spacing



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

EQUIPMENT Length (A)

Space From Walls and Adjacent EQUIPMENT (B)

4' or less

6"

4' - 8'

12"

8' or more

18"

WAREWASHING FACILITIES

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

A. Manual Ware washing

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

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

B. Mechanical Ware washing

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

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

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

PLUMBING

A. Water Supply

The primary concerns relative to the water supply in a FOOD ESTABLISHMENT are:

1. Ensure the facility is supplied with a safe and adequate water supply, including adequate supply of hot water; and
2. Verify that the water can remain safe while it is in the facility.

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

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

B. Hot Water Supply:

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

The temperature of the wash solution for manual WAREWASHING must be maintained to not be less than 110°F. The water temperature for manual hot water sanitization must be at least 171°F.

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

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

C. Sewage Disposal, Grease Interceptors/Traps

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

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

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

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

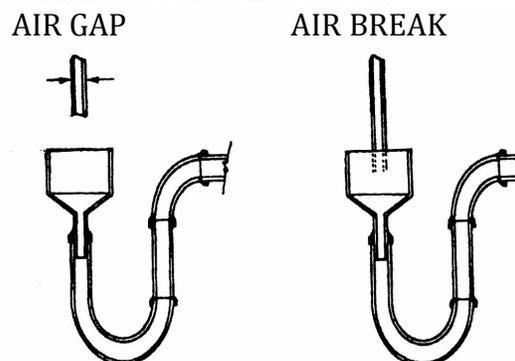
D. Backflow Protection

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

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

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

1. For a potable water supply, an **air gap** means the unobstructed, vertical air space that separates a potable system from a non-potable system.
2. An **air break** is a waste line from a fixture that discharges used water or liquid waste to a drain where the waste line terminates below flood level.



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

HYGIENE FACILITIES

A. Handwashing

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

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

Nothing must block the approach to a HANDWASHING SINK.

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

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

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

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

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

EQUIPMENT does not provide adequate protection.

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

B. Toilet Rooms

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

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

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

The minimum requirements for toilet facilities shall include:

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

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

STORAGE

A. Dry Storage-

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

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

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

B. Dry Storage Calculations

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

C. Poisonous or Toxic Materials Storage

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

D. Clean Equipment, Utensil and Linen Storage

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

will be protected from dust and splash.

LIGHTING

A. Intensity

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

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

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

B. Protective Light Shielding

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

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

FINISHES

A. Floors

Example floor materials are as follows:

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

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

B. Walls

Example wall materials are as follows:

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

Ceilings

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

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

C. Coving

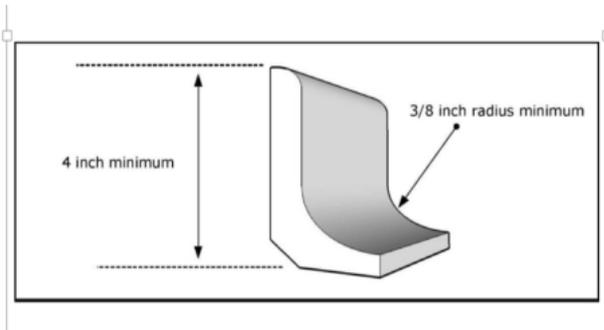
Coving is the floor material found at the base of walls (wall/floor junctures) and is required in most areas of the FOOD ESTABLISHMENT, such as:

FOOD preparation, storage, handling, and packaging areas

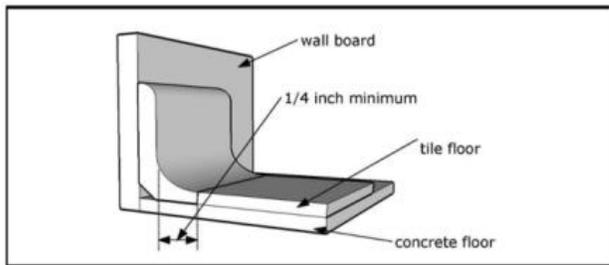
- UTENSIL washing and storage areas
- Interior waste disposal areas (garbage, REFUSE, grease)
- Restrooms
- Hand washing areas
- Janitorial facilities
- Walk-in refrigerator and freezer units (inside and outside)
- Bars (employee side)
- Customer self-serve areas where non-individually prepackaged FOODs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

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

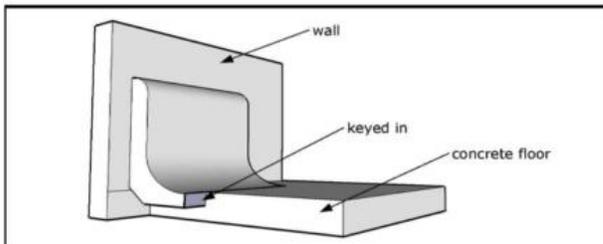
Floor Installation Diagrams



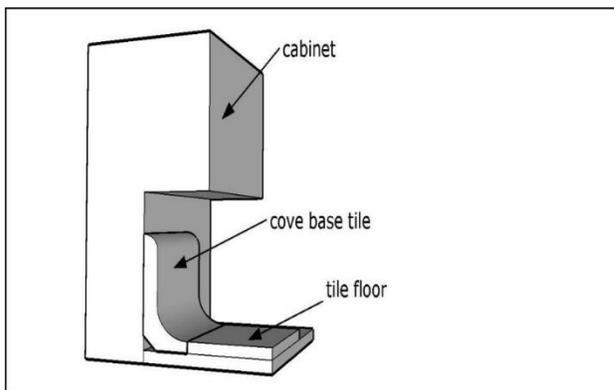
Example of quarry tile cove base.



Example of quarry tile cove base flush with floor.



Example of quarry tile cove base integral to concrete floor.



Example cove base; cabinet toe-kick

PEST CONTROL

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

Some examples of effective barriers include:

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

Example Air Curtain



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

A. Building

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

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

B. Windows

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

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

C. Delivery, Customer, and Toilet Room Doors

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

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

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

D. Insect Control Devices, Design and Installation

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

MECHANICAL VENTILATION

A. Mechanical Ventilation Requirements

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

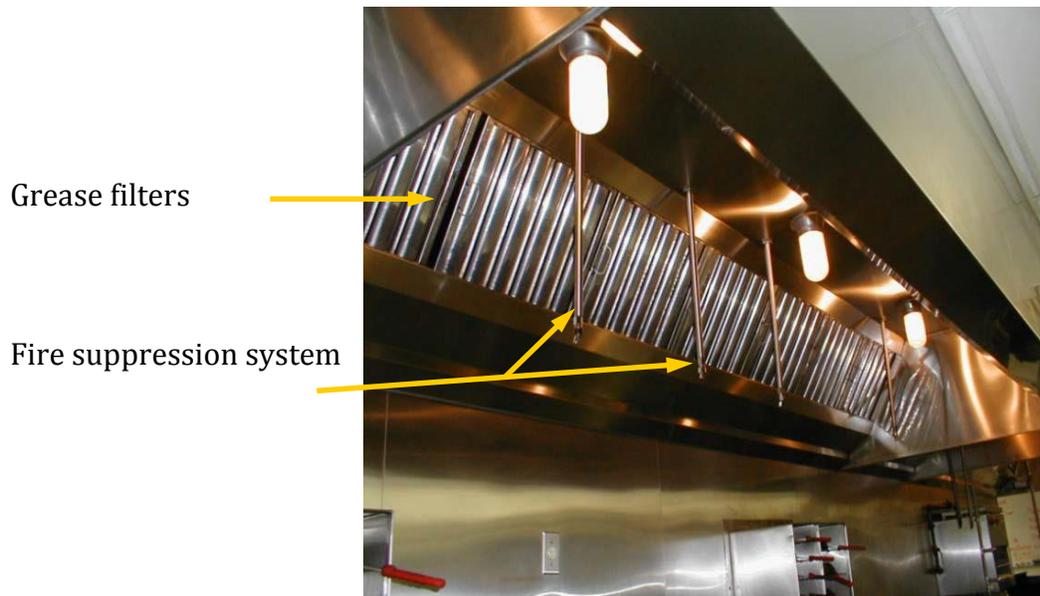
Hoods shall be designed and installed to prevent grease and condensation from collecting on walls, ceilings, and dripping into FOOD or onto FOOD contact surfaces. All hoods should comply with the current International Mechanical Code (IMC) and/or all local building and fire safety codes.

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

B. Mechanical Ventilation Hood Systems

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

Type I Hood over Cook Line



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

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

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

Type II Hood over WAREWASHING Machine

Vapor hood



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

Appendix A - MODEL PLAN REVIEW APPLICATION FOR FOOD ESTABLISHMENTS

TYPE OF APPLICATION: <input type="checkbox"/> New <input type="checkbox"/> Remodel <input type="checkbox"/> Conversion		Projected Start Date: _____ Projected Completion Date: _____	
TYPE OF FOOD OPERATION: <input type="checkbox"/> Restaurant <input type="checkbox"/> Institution <input type="checkbox"/> Daycare <input type="checkbox"/> Retail food store <input type="checkbox"/> Other: _____			
FOOD ESTABLISHMENT INFORMATION			
Name of Establishment: _____			
Establishment Address: _____	City: _____	State: _____	ZIP: _____
OWNERSHIP INFORMATION			
Name of Owner: _____			
Address: _____	City: _____	State: _____	ZIP: _____
Email: _____	Phone Number: _____		
APPLICANT INFORMATION (e.g., ARCHITECT/ENGINEER)			
Applicant Name: _____		Contact Person: _____	
Applicant Mailing Address: _____	City: _____	State: _____	ZIP: _____
Email: _____	Phone Number: _____		
FOOD OPERATION INFORMATION			
Hours/Days of Operation <input type="checkbox"/> Sun: _____ <input type="checkbox"/> Mon: _____ <input type="checkbox"/> Tues: _____ <input type="checkbox"/> Wed: _____ <input type="checkbox"/> Thurs: _____ <input type="checkbox"/> Fri: _____ <input type="checkbox"/> Sat: _____	Restaurant Seating Capacity # of Indoor Seats: _____ # of Outdoor Seats: _____ Square Feet of Facility: _____	Type of Service (check all that apply) <input type="checkbox"/> On-site consumption <input type="checkbox"/> Off-site consumption <input type="checkbox"/> Catering <input type="checkbox"/> Single-use utensils <input type="checkbox"/> Multi-use utensils <input type="checkbox"/> Other: _____	Employees Max per shift: _____ Maximum meals to be served <input type="checkbox"/> Breakfast _____ <input type="checkbox"/> Lunch _____ <input type="checkbox"/> Dinner _____
The following documents must be submitted along with this application:			
<input type="checkbox"/> Proposed menu or complete list of food and beverages to be offered (including seasonal, catering and banquet menus) – Standard Operating Procedures or HACCP plans may be required.			
<input type="checkbox"/> Plans must be clearly drawn to scale (minimum 11 x 14 inches in size) and include these items below:			
<ul style="list-style-type: none"> The floor plan must identify: food preparation, serving and seating areas, restrooms, office, employee change room, storage, warewashing, janitorial and trash area. Include location of any outside equipment or facilities (dumpsters, well, septic system-if applicable). Provide equipment layout and specifications, clearly numbered and cross-keyed with the equipment list. <i>Elevation drawings may be requested by the Regulatory Authority.</i> Identify handwashing, warewashing and food preparation sinks. Provide plumbing layout showing the sewer lines, cleanouts, floor drains, floor sinks, vents, grease trap or grease interceptor, hot and cold water lines, and direction of flow to sanitary sewer. Provide exhaust ventilation layout including location of hood and make-up air returns and ducts, if applicable. Lighting plan, indicating the exact foot candles for each area as required by the FDA Food Code (§6-303.11). Finish schedule showing floor, coved base, wall and ceilings for each area shown on the plans. 			
<i>Note: A color coded flow chart may be requested by the Regulatory Authority demonstrating flow patterns for: food (receiving, storage, preparation, service); dishes (clean, soiled, cleaning, storage); trash (service area, holding, storage, disposal).</i>			
Signature: _____		Date: _____	
Print Name: _____		Title: _____	

Appendix B – REGULATORY COMPLIANCE REVIEW LIST

FOOD PREPARATION PROCEDURES

FOOD DELIVERY

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

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

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

* Identify on plans where storage will be located.

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

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

FINISH SCHEDULE

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

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

Identify the finishes of cabinets, countertops, and shelving:

PHYSICAL FACILITIES

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

TOPIC	MINIMUM CRITERIA	MEETS CRITERIA (Circle and Initial)
Handwashing facilities	<ul style="list-style-type: none"> • Identify number of the handwashing sinks in food preparation and warewashing areas: _____ Food Preparation _____ Warewashing Area • Type of hand drying device? Disposable towels <input type="checkbox"/> Hand-drying device <input type="checkbox"/> 	YES/NO
Warewashing Facilities	<p>MANUAL DISHWASHING</p> <ul style="list-style-type: none"> • Identify the length, width, and depth of the compartments of the 3-compartment sink: _____ • Will the largest pot/ pan fit into each compartment of the 3-compartment sink? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, what will be the procedure for manual cleaning and sanitizing of items that will not fit into sink compartments? _____ • Describe size, location and type (drainboards, wall-mounted or overhead shelves, stationary or portable racks) of air drying space: _____ • What type of sanitizer will be used? <input type="checkbox"/> Chemical Type: _____ <input type="checkbox"/> Hot Water <p>MECHANICAL DISHWASHING</p> <ul style="list-style-type: none"> • Identify the make and model of the mechanical dishwasher: _____ • What type of sanitizer will be used? <input type="checkbox"/> Chemical Type: _____ <input type="checkbox"/> Hot Water • Will ventilation be provided? Yes <input type="checkbox"/> No <input type="checkbox"/> 	YES/NO

Water Supply	<ul style="list-style-type: none"> • Is the water supply public or non-public/private? public <input type="checkbox"/> non-public/private <input type="checkbox"/> • If private, has source been approved? Yes <input type="checkbox"/>* No <input type="checkbox"/> • Attach copy of written approval and/or permit. • Is ice made on premises or purchased commercially? Made on-site <input type="checkbox"/> Purchased <input type="checkbox"/> • Will there be an ice bagging operation? Yes <input type="checkbox"/> No <input type="checkbox"/> 	YES/NO
Sewage Disposal	<ul style="list-style-type: none"> • Is the sewage system public or non-public/private? public <input type="checkbox"/> non-public/private <input type="checkbox"/> • If private, has the sewage system been approved? Yes <input type="checkbox"/>* No <input type="checkbox"/> • Attach copy of written approval and/or permit. • Will grease traps/interceptors be provided? Yes <input type="checkbox"/>* No <input type="checkbox"/> *Identify location on plan. 	YES/NO
Backflow Prevention	<ul style="list-style-type: none"> • Will all potable water sources be protected for backflow? Yes <input type="checkbox"/> No <input type="checkbox"/> • Are all floor drains identified on the submit floor plan? Yes <input type="checkbox"/> No <input type="checkbox"/> 	YES/NO
Toilet Facilities	<ul style="list-style-type: none"> • Identify locations and number of toilet facilities: _____ • Hot and cold water provided? Yes <input type="checkbox"/> No <input type="checkbox"/> 	YES/NO
Dressing Rooms	<ul style="list-style-type: none"> • Will dressing rooms be provided? Yes <input type="checkbox"/> No <input type="checkbox"/> • Describe storage facilities for employee personal belongings _____ 	YES/NO
Linens	<ul style="list-style-type: none"> • Will linens be laundered on site? Yes <input type="checkbox"/> No <input type="checkbox"/> • If yes, what will be laundered and where? _____ • If no, how and where will linens be cleaned? _____ • Identify location of clean and dirty linen storage: _____ 	YES/NO

Poisonous/Cleaning Storage	<ul style="list-style-type: none"> • Identify the location and storage of poisonous or toxic materials • Where will cleaning and sanitizing solutions be stored at workstations? _____ • How will these items be separated from food and food-contact surfaces? _____ 	<p style="text-align: center;">YES/NO</p>
Pest Control	<ul style="list-style-type: none"> • Will all outside doors be self-closing and rodent proof? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA • Will screens be provided on all entrances left open to the outside? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA • Will all openable windows have a minimum #16 mesh screening? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA • Will insect control devices be used? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA • Will air curtains be used? If yes, where? _____ <p>Note: All pipes and electrical conduit chases must be sealed to prevent rodent access.</p>	<p style="text-align: center;">YES/NO</p>
Refuse, Recyclables, and Returnables	<ul style="list-style-type: none"> • Will refuse/garbage be stored inside? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, where _____ • Identify how and where garbage cans and floor mats will be cleaned? _____ • Will a dumpster or a compactor be used? <input type="checkbox"/> Dumpster <input type="checkbox"/> Compactor • Identify locations of grease storage containers: _____ • Will there be an area to store recyclables? <input type="checkbox"/> Yes <input type="checkbox"/> No • If yes, where _____ • Will there be an area to store returnable damaged goods? <input type="checkbox"/> Yes <input type="checkbox"/> No • If yes, where _____ 	<p style="text-align: center;">YES/NO</p>

Appendix C - Plan Review Model Calculations

Food Establishment Plan Review Formulas

Print this sheet and collect the following information from plans. Information will be used to perform calculations.

Facility Name & Address: _____

Hot Water

List each type of plumbing fixture that uses hot water # proposed

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Proposed Size: _____ KW or _____ BTU's

Proposed Storage capacity: _____ gallons Thermal Efficiency: _____%

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

Proposed dishmachine booster heater:

Refrigerated Storage

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

By # meals: # meals between deliveries: _____

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

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

Appendix C - Plan Review Model Calculations

Dry Storage

By seats: # seats: _____ # meal periods: _____

Drive-Up Window: Y N

By meals: # meals between deliveries: _____

Storage Rooms

Interior Length (ft)

Interior Width (ft)

Usable room height (ft)

Or

For full height shelves

Total Shelving Length (ft)

Shelving Width (ft)

Usable room height (ft)

Appendix C - Plan Review Model Calculations

Ventilation

Proposed make-up air (MUA) fan volume

MUA1= _____ cfm, MUA2=_____cfm, MUA3=_____ cfm

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

Required hood exhaust:

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

Hood 1 Equipment	Alternate Formula		Main Formula
	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Hood 2 Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Hood 3 Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Hood 4 Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)
_____	_____	_____	_____
_____	_____	_____	_____

Appendix C - Plan Review Model Calculations

Hood 5 Equipment	Vertical Distance (ft)	Open Perimeter (ft)	Area of hood over equip.(sq. ft.)

Appendix D Plan Review Web Links

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

Michigan Department of Agriculture and Rural Development

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

Wisconsin Department of Safety and Professional Services

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

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

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

North Carolina Public Health, Environmental Health Section

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

Minnesota Department of Agriculture

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

Conference for Food Protection, Plan Review for Food Establishments

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

Public Health – Seattle and King County

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

Harris County Public Health and Environmental Services

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

Florida Department of Health in Volusia County

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

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

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

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

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

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-002

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

PRC 2 – Food Establishment Plan Review Manual

Issue you would like the Conference to consider:

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

- 1) Approval of the Food Establishment Plan Review Manual (including the cover sheet) and Appendix A through D (2016) (documents attached to Issue titled: Report - Plan Review Committee Final Report)
- 2) Replacing the Plan Review Guide (2008) currently on the CFP website with the final compiled Food Establishment Plan Review Manual in PDF format.

Submitter Information 1:

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Submitter Information 2:

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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
2016 Issue Form**

Issue: 2016 I-003

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Outdoor equipment guidelines

Issue you would like the Conference to consider:

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

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

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

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

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

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

Submitter Information:

Name: Michael Capretta
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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-004

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

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

Title:

Report - Oyster Advisory Committee

Issue you would like the Conference to consider:

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

Public Health Significance:

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

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

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

(B) DISCLOSURE shall include:

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

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

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

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

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

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

Recommended Solution: The Conference recommends...:

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

Submitter Information 1:

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Ste 1301
City/State/Zip: Baltimore, MD 21202
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Submitter Information 2:

Name: Thomas McMahan
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3040 Remico St, SW
City/State/Zip: Grandville, MI 49418
Telephone: 616.249.6035
E-mail: thomas.mcmahan@meijer.com

Content Documents:

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

Supporting Attachments:

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

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Conference for Food Protection - Committee FINAL Report

Template rev: 06/21/2013

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

COMMITTEE NAME: *Oyster Advisory Committee*

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

DATE OF REPORT: November 6, 2015

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

COMMITTEE CHARGE(s):

1. Develop recommendations to update Food Code section 3-603.11 Consumer Advisory regarding raw molluscan shellfish that have not been treated by a process sufficient to reduce *Vibrio spp.* to an undetectable level, as detected by the *Vibrio vulnificus* testing method in the most current edition of the U.S. Food and Drug Administration Bacteriological Analytical Manual.
2. Report back to the 2016 Conference for Food Protection Biennial meeting on the committee's work and submit an issue amending the FDA Food Code as recommended by the committee.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

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

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

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

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

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

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

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

Conference for Food Protection - Committee FINAL Report

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

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

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

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

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

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Acknowledgement of the CFP 2014 - 2016 Oyster Advisory Committee Final Report and thanking the committee members for their work.
2. LIST OF SUPPORTING ATTACHMENTS
 - a. ISSC Letter dated July 7, 2014
 - b. Council 1, 2014-1-025
 - c. 3-603.11, 2013 FDA Food Code

COMMITTEE MEMBER ROSTER: See attached CFP Oyster Advisory Committee Roster

Committee Name: Oyster Advisory

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

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

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

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

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

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

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

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

Page 405 Annex 3 – Public Health Reasons/Administrative Guidelines

3-201.15 Molluscan Shellfish.

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

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

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

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

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

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

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

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

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

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

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

July 7, 2014

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

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

Dear Kevin Smith and Lori LeMaster

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

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

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

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

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

July 7, 2014

Page Two

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

Sincerely,



Maryanne Guichard
Executive Board Chair

/nsd/ccm

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

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-005

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report - Ice Maker Equipment Cleaning and Sanitizing Committee (IMC)

Issue you would like the Conference to consider:

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

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

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

Submitter Information:

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

Content Documents:

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

Supporting Attachments:

- "Attachment A: Ice Machine Manufacturers"

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

Conference for Food Protection – Committee FINAL Report

Template approved: 08/14/2013

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COMMITTEE NAME: Ice Maker Equipment Cleaning and Sanitizing Committee (IMC)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council I

DATE OF REPORT: January 10, 2016

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

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

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

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

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

PROGRESS ON OVERALL COMMITTEE ACTIVITIES:

REGULATORY ACTIVITIES

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

- c. 62 percent do not have a searchable database because they use paper forms.
 - d. Only 5 jurisdictions were able to provide inspection records associated with ice machines.
4. The committee reviewed the 5 sets of data provided by the regulatory agencies and came up with the following summary:
 - a. 3,763 violations were identified in 2014 related to mold or soil accumulation in the ice bin, bin walls, ice chute, door, and/or gaskets.
 - b. 1,427 violations were identified in 2014 related to the ice scoop, personal items being stored in the ice bin, and chemicals being stored over ice.
 - c. There were no violations identified regarding the internal components of the ice maker.
 5. Based on the findings described, it seems that regulatory agencies are only inspecting areas which could be seen at a quick glance with no ice maker disassembly. This could be attributed to both the design of the equipment and absence of tools needed to open ice makers in the field.

EQUIPMENT ACTIVITIES

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

RECOMMENDATIONS FOR CONSIDERATION BY COUNCIL:

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

- b. That the performance certification tests methods used for cleanability and sanitization of new equipment food contact surfaces has correlation to cleanability of those same surfaces when in use.
- 5. The Conference for Food Protection disband the Ice Maker Cleaning and Sanitizing Committee and form a new committee with to address the broader issue of design, cleaning, sanitizing and inspection of food process equipment with inaccessible food contact surfaces. The specific charges for the new committee are addressed in Issue Submittal 6 below.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE

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

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

- b. The Conference recommends that FDA update the Food Establishment marking instructions in Annex 7 of the 2013 FDA Food Code, Guide 3B under items 16 and 47 to specifically include references to ice making and storage components that may not be readily accessible. Proposed additions to existing language are underlined.
 - i. **16. Food-contact surfaces: cleaned and sanitized:** *This item must be marked OUT of compliance when manual and/or mechanical methods of cleaning and sanitizing food-contact surfaces of equipment and utensils are ineffective; or if one continuous-use piece of equipment such as an ice machine or one multiuse piece of equipment such as a slicer or can opener is visibly soiled and being used at the time of the inspection.*
 - ii. **47. Food and non-food-contact surfaces cleanable, properly designed, constructed and used.** *Equipment and utensils including ice machines must be properly designed and constructed, and in good repair to enable ready access to the internal food contact surfaces for cleaning, sanitization and inspection. Proper installation and location of equipment in the food establishment are important factors to consider for ease of cleaning in preventing accumulation of debris and attractants for insects and rodents. The components in a vending machine must be properly designed to facilitate cleaning and protect food products (e.g. equipped with automatic shutoff, etc.) from potential contamination. Equipment must be properly used and in proper adjustment, such as calibrated food thermometers...*
5. Working Group Formation to Update NSF/ANSI 12 Automatic Ice Making Equipment
 - a. The Ice Maker Equipment Cleaning and Sanitizing committee surveyed Ice Maker Original Equipment Manufacturers and Ice Vending manufacturers as to their specific cleaning and sanitizing procedures and any field study and laboratory test data supporting specific recommended cleaning and sanitizing procedures. The committee found that there was a general lack of uniformity and no test data available to validate the cleaning/sanitizing procedures. .
 - b. The Committee recommends the Conference for Food Protection send a letter to NSF International requesting the creation of a working group to review and update the existing NSF/ANSI 12 Automatic Ice Making Equipment Standard for cleaning and sanitizing certification with participation of academia and organizations such as Association of Official Analytical Chemists (AOAC), American Society for Testing and Materials (ASTM) with peer review process elements to ensure:
 - i. Food contact surfaces are readily accessible for inspection and effective cleaning and sanitation for new equipment.
 - ii. That the performance certification test methods used for cleanability and sanitation of new equipment food contact surfaces has correlation to cleanability of those same surfaces when in use
 6. The Conference for Food Protection CIP Committee Formation
 - a. The Ice Machine Cleaning and Sanitizing committee uncovered a significant discrepancy relating to cleanability of food contact surfaces. The FDA Food Code requires FOOD EQUIPMENT with inaccessible food contact surfaces that depend upon CIP processes for effective cleaning and sanitation to be designed to enable inspection access points for verification purposes, so it cannot be readily determined when cleaning is required. In addition, it is clear from a review of manufacturer's installation and service instructions that there is a lack scientific data for validation of the limited cleaning and sanitizing instructions that are provided.

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

Attachments – Content Documents:

- 1. Committee Report
- 2. Committee Roster

Committee Name:

Committee Name: Ice Maker Equipment Cleaning and Sanitizing Committee

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

Attachment A: Ice Machine Manufacturers

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

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-006

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

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Issue History:

This is a brand new Issue.

Title:

IMC 2 – Request Research on Microbial Contamination in Ice Machines

Issue you would like the Conference to consider:

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

Public Health Significance:

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

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

Recommended Solution: The Conference recommends...:

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

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

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-007

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

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Issue History:

This is a brand new Issue.

Title:

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

Issue you would like the Conference to consider:

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

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

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

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

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

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

Public Health Significance:

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

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

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

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

Recommended Solution: The Conference recommends...:

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

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

EQUIPMENT such as ice bins and BEVERAGE dispensing nozzles and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks and distribution lines, BEVERAGE and syrup dispensing lines or tubes, coffee bean grinders, and water vending EQUIPMENT:

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

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-008

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

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Issue History:

This is a brand new Issue.

Title:

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

Issue you would like the Conference to consider:

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

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

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

16. Food-contact surfaces: cleaned and sanitized

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

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

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

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-009

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

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Issue History:

This is a brand new Issue.

Title:

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

Issue you would like the Conference to consider:

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

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

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

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

Public Health Significance:

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

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

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

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

Recommended Solution: The Conference recommends...:

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

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

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-010

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

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Issue History:

This is a brand new Issue.

Title:

IMC 6 - Clean in Place (CIP) Committee Formation

Issue you would like the Conference to consider:

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

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

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

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

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

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

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

Public Health Significance:

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

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

Recommended Solution: The Conference recommends...:

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

1. Review ANSI sanitation standards for clean in place processes (CIP).
2. Report back to the CFP at the 2018 Biennial Meeting with specific recommendations for:
 - (a) Minimum criteria for CIP systems including suggested revisions to the FDA Food Code.
 - (b) A mechanism for on-going liaison with ANSI sanitation standards development organizations to reduce likelihood of future gaps in our national food safety, security and control programs.

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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
2016 Issue Form**

Issue: 2016 I-011

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report - Food Recovery Committee (FRC)

Issue you would like the Conference to consider:

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

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

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Content Documents:

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

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

Conference for Food Protection – Committee FINAL Report

Template approved: 08/14/2013

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

COMMITTEE NAME: Food Recovery Committee (FRC)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council I

DATE OF REPORT: January 29, 2016

SUBMITTED BY: Susie McKinley and John Marcy

COMMITTEE CHARGE(s):

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

Issue: 2014 I-035

Charge:

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

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

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

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

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

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

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

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

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

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

2. Recommendations for consideration by Council:

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

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Report – Food Recovery Committee

- a. Acknowledgement of 2014 – 2016 Food Recovery Committee Final Report.
- b. Thanking the Committee members for their work and efforts on the committee; and
- c. Disbanding the committee

2. FRC 2 – Comprehensive Resource for Recovery Programs

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

Lists of Attachments –

Content Documents

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

COMMITTEE MEMBER ROSTER (attached):

Attachment A - Summary Outline of Revisions to the Document

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

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

The following areas were deleted in total:

“About These Guidelines”

The following areas had much deleted:

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

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

“Appendix B”

The following areas were updated:

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

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

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

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

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

The “Food Donation” section was rewritten.

The “Foodborne Illness” section was updated and edited.

The “Food Allergens” section was updated and edited.

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

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

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

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

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

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

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

The following sections /content were added:

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

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

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

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

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

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

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

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

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

Comprehensive Resource for Food Recovery Programs

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

October 2000
Updated January 2004
Updated April 2006
Updated March 2007

This revision April 2016



CONFERENCE FOR FOOD PROTECTION

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Executive Summary

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

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

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

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

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

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

Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (1) **"Time/temperature control for safety (TCS) food"** is a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation. Most, but not all perishable food and prepared foods are TCS foods.
- (2) **"Time/temperature control for safety (TCS) food"** includes:
 - (a) An animal FOOD that is raw or heattreated; a plant FOOD that is heat treated or consists of raw seed sprouts, cut melons, or garlicinoil mixtures that are not modified in a way that results in mixtures that do not support pathogenic microorganism growth or toxin formation; and
 - (b) Except as specified in Subparagraph (3)(d) of this definition, a food that because of the interaction of its water activity (AW) and PH values is designated as Product Assessment Required (PA) in Tables A and B from the FDA Food Code and provided at the end of the Food Safety Procedures section.1
- (3) **"Time/temperature control for safety (TCS) food"** does not include:
 - (a) An aircooled hardboiled egg with shell intact, or an egg with shell intact that is not hardboiled, but has been pasteurized to destroy all viable salmonellae;
 - (b) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;
 - (c) A food that because of its PH or AW value, or interaction of AW and PH values, is designated as a nonTCS food in this definition;
 - (d) A food that is designated as Product Assessment Required (PA) in Table A or B of the Food Code definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:
 - (a.i) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,
 - (a.ii) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen-packaging (ROP), shelf life and use, or temperature range of storage and use, or

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

or

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

Introduction to Food Recovery

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

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

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

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

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

Food Recovery Activities

USDA and EPA Food Recovery Activities

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

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

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

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

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

Ongoing Food Recovery Activities

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

Legal Issues

Questions regarding legal issues may primarily be concerned with liability with the donation of food but there may also be other issues based upon both the state and health jurisdiction as well as other regulatory agencies. For a broader discussion, you can access “A Legal Guide to Food Recovery”

<http://law.uark.edu/documents/2013/06/Legal-Guide-To-Food-Recovery.pdf>

Bill Emerson Good Samaritan Food Donation Act

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

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

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

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

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

Implementing a Food Recovery Program

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

Major aspects of implementing a food recovery program include:

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

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

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

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

- b. The type of vehicle(s) to be used, temperatureholding equipment (e.g., insulated containers, refrigerated unit)
 - c. Backup or transportation contingency plan in case of vehicle breakdown or emergency
 - d. Distance in miles between the donor and the receiving facility
 - e. Anticipated time in minutes from the donor to receiving facility
 - f. Anticipated frequency of donations, and
 - g. Times/dates for pickup of donations;
4. The qualifications of the food manager or person in charge in the donor and receiving facilities such as training and experience;
 5. The training provided to staff on hygienic and safe food preparation, food defense procedures, storage, and transporting practices;
 6. Preferred time, means and frequency of communication;
 7. How unsatisfactory situations will be addressed; and
 8. Any other considerations raised by either party.

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

Donation Program Description

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

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

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

Food Safety and Food Recovery

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

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

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

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

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

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

Food Safety Procedures

Introduction

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

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

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

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

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

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

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

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

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

2. Cans that are dented in the top or side seams or are leaking or swollen;
3. Insect or rodent infested food e.g., droppings, gnawings, or nesting material. Infested foods, foods that are obviously compromised;
4. Foods of questionable safety should be discarded or isolated from wholesome foods until soundness is determined. In either case, the goal is to keep other foods wholesome and safe and physically separated to ensure sound condition.

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

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

Types of Foods

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

Understanding Product Code Dating

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

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

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

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

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

Foodhandlers - Good Hygienic Practices: Basic Essentials

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

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

Acceptable Foods and Labeling Requirements

Food Type	Prepared Foods	Packaged Foods	Fresh Produce
Sources	Hotels Restaurants Institutes Food Service Facilities Bakeries	National and local donors National and local vendors Retail store donations Reclaim and food drives	Any donor or vendor of fresh produce
Examples of foods	Prepared meat, poultry entrees, pasta, pizza, vegetables, chilled foods, etc.	Canned, boxed, or packaged foods Bagged cut produce Dairy Raw shell eggs Meat, poultry, and fish (fresh and frozen)	Whole produce in bins and bags
Label requirement	Fair Packaging and Labeling Act (FPLA) does not apply.	Fair Packaging and Labeling Act (FPLA) applies.	Fair Packaging and Labeling Act (FPLA) does not apply.
Recommended language for the label to state <small>*See sample labels in Appendix D</small>	<ol style="list-style-type: none"> 1. The name and location of FDO (pre-printed) 2. The name and location of donor 3. The food description 4. The date of donation 5. Allergen disclaimer statement (pre-printed) <p>WARNING! This container holds rescued food! This food may contain, have come into contact with, or have been produced in a facility which also produces milk, eggs, peanuts, tree nuts (walnuts, almonds, pecans, hazelnuts/filberts, pistachios, cashews, coconuts, pine nuts, macadamia nuts, and/or Brazil nuts), fish, shellfish (crab, crawfish, lobster, shrimp, mussels, and/or oysters), wheat, soybeans, and/or sesame seeds</p>	<ol style="list-style-type: none"> 1. The common or usual name of the product 2. The name and place of business of the manufacturer, packer, or distributor 3. The net quantity of the contents 4. The common or usual name of each ingredient, listed in descending order of prominence 	No label required
Comments	Label is applied to all containers.	These products are assumed to have the proper retail label already on the packaged product when they are received by the member.	

Foodborne Illness

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

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

Managing Ill Foodhandlers and Volunteers

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

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

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

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

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

Foodborne Illness Symptoms and Diagnoses:

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

Reporting

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

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

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

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

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

Especially Vulnerable Populations

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

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

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

Training of Foodhandlers or Volunteers

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

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

Controlling Biological Hazards Bacteria

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

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

- (1) **Nutrients:** foods that nourish bacterial growth, such as high protein foods, milk and dairy products, meat, fish, poultry, cooked pasta and cut produce such as cantaloupe, tomatoes or leafy greens.
- (2) **Moisture:** moisture in foods that is available for bacterial growth. This can be moisture that is intrinsically present or that is added to the food (e.g., milk, water, or juice).

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

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

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

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

Controlling Biological Hazards – Viruses and Parasites

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

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

Controlling Chemical and Physical Hazards

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

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

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

Food Allergens as Food Safety Hazards

According to the Food Allergy Research and Education (FARE) webpage¹, up to 15 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally occurring protein in a food or a food ingredient, which is referred to as an “allergen.” For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic response is commonly characterized by hives or other itchy rashes, nausea, abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.

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

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

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

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

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

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

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

Cross Contamination

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

Precautions to prevent cross-contamination include the following:

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

Keeping Food Safe

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Operator's Manual:

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

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

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

The Regulator's Manual:

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

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

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

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

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

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

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

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

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

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

Food Preparation Practices

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Time/Temperature Control for Safety (TCS) Food

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

Reduced Oxygen Packaging

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

Equipment

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

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

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

Maintaining Food Safety During Transportation

Loading for Transport

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

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

Maintaining Food Temperature

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

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

Cleaning of the Vehicle for Transport of Food

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

Receiving Food

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

Record Keeping for Food Safety

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

Emergency Readiness

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

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

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

Food Recovery Program Responsibilities

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

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

Guidelines for Monitoring Programs

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

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

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

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

Handling Donations of Wild Game Animals

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

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

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

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

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

Information for Processors:

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

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

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

Information for Recipients:

Receipt

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

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

Storage

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

Use

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

Safe Food Handling

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

Planning for Food Defense

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

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

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

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

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

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

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

APPENDIX A

Guidance Charts for Assessment of Food on Receipt

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

CHART: ASSESSMENT OF FOOD ON RECEIPT			
Food Products	Packaging	Storage Condition	NonAcceptable Conditions
Prepared Foods (Entrees, starches, side vegetables, chilled foods, homemeal replacements)	<ul style="list-style-type: none"> • Foodgrade packaging in direct contact with food. • Securely closed and separated by food type to avoid cross contamination. • Labeled and dated. 	Chilled at no more than 41°F or frozen at 0°F or less.	<ul style="list-style-type: none"> • Previously reheated foods. • Foods kept in danger zone more than 2 hours. • Food previously served.
Chilled Perishable Prepackaged Foods (Orange Juice)	<ul style="list-style-type: none"> • Original packaging or foodgrade packaging for all repacked product. 	Chilled at no more than 41°F.	<ul style="list-style-type: none"> • Foods kept in danger zone more than 2 hours. • Damaged or compromised packaging resulting in the loss of sanitary barrier protection. • Outside the “use by” date recommended from the manufacturer.
Meat, Poultry, Fish (Fresh product has a significant chance of leakage and potential cross-contamination therefore fresh animal proteins should be donated to a feeding program that is serving food immediately.)	<ul style="list-style-type: none"> • Original packaging. • Foodgrade packaging in direct contact with food. • Securely closed and separated by food type (e.g., beef, pork, poultry) to avoid cross contamination. • Labeled and dated as appropriate. 	Chilled at no more than 41°F.	<ul style="list-style-type: none"> • Foods kept in danger zone more than 2 hours. • Nonfoodgrade packaging in direct contact with food.
Meat, Poultry, Fish (Frozen)	<ul style="list-style-type: none"> • Original packaging. • Foodgrade packaging in direct contact with food. • Labeled and dated as appropriate. 	Frozen at 0°F or less.	<ul style="list-style-type: none"> • Defrosted product. • Damaged or compromised packaging resulting in discoloration of product. • Severe freezer burn.

APPENDIX A

Guidance Charts for Assessment of Food on Receipt

CHART: ASSESSMENT OF FOOD ON RECEIPT			
Food Products	Packaging	Storage Condition	NonAcceptable Conditions
Unprocessed Meats (Donated Wild Game)	<ul style="list-style-type: none"> • Custom exempt or state or federally inspected plant. • Foodgrade packaging. • Labeled and dated with name of game, name and location of plant, "Not an Inspected Product," "Keep Frozen," "Cook to 165°F." 	Frozen at 0°F or less.	<ul style="list-style-type: none"> • Source • Labeling • Defrosted product.
Dairy Products	<ul style="list-style-type: none"> • Original packaging. • Foodgrade packaging in direct contact with food. 	Chilled at no more than 41°F.	<ul style="list-style-type: none"> • Damaged or compromised packaging, resulting in the loss of sanitary barrier protection.

APPENDIX A

Guidance Charts for Assessment of Food on Receipt

CHART: ASSESSMENT OF FOOD ON RECEIPT			
Food Products	Packaging	Storage Condition	NonAcceptable Conditions
Raw Shell Eggs (unpasteurized)	<ul style="list-style-type: none"> • Original packaging. • Foodgrade packaging in direct contact with food. 	Chilled at no more than 41°F.	<ul style="list-style-type: none"> • Damaged or compromised packaging, resulting in the loss of sanitary barrier protection. • Cracked or broken eggs.
Fresh Produce (Whole)	<ul style="list-style-type: none"> • Original cartons and bags or foodgrade packaging for all repacked product. 	Cool, dry, clean area.	<ul style="list-style-type: none"> • Significant decay.
Fresh Produce (Chopped)	<ul style="list-style-type: none"> • Foodgrade packaging securely closed with each vegetable or fruit packed 	Chilled at 41°F.	<ul style="list-style-type: none"> • Food kept in danger zone more than 2 hours.
Frozen Foods (Entrees, starches, vegetables, fruit juices, baked goods)	<ul style="list-style-type: none"> • Original packaging or foodgrade packaging for all repacked product. 	Frozen at 0°F or less.	<ul style="list-style-type: none"> • Defrosted product. • Damaged or compromised packaging, resulting in the loss of sanitary barrier protection. • Severe freezer burn.
Baked Goods (Fresh or dayold bread, bagels, and other bakery items.)	<ul style="list-style-type: none"> • Foodgrade packaging in direct contact with food. • Securely closed. • Bread products separately packaged from other baked foods. 	Cool, dry, clean area.	<ul style="list-style-type: none"> • Stale products. • Mold. • Damaged or compromised packaging, resulting in the loss of sanitary barrier protection. • Not packaged in foodgrade packaging.
Prepackaged Foods Nonperishable (Canned)	<ul style="list-style-type: none"> • Fully intact <u>original cans</u> with labels that must show at a minimum: <ol style="list-style-type: none"> 1) Product identification 2) Ing redients 3) Net weight, and 4) Di stributor 5) Food source for each major food allergen 	Cool, dry, clean area.	<ul style="list-style-type: none"> • Opened, punctured, bulging, or serious can damage, including evidence of leakage, side seam dent, topseam dent, and/or significant rust. • Homecanned products.

APPENDIX A

Guidance Charts for Assessment of Food on Receipt

CHART: ASSESSMENT OF FOOD ON RECEIPT			
Food Products	Packaging	Storage Condition	NonAcceptable Conditions
Prepackaged Foods Nonperishable (Shelf-stable boxed/packageged foods)	<ul style="list-style-type: none"> • Original packaging, boxes or cases. • Foodgrade packaging for all repacked foods. • Labels that must show at a minimum: <ol style="list-style-type: none"> 1) Product identification 2) Ingredients 3) Net weight, and 4) Distributor 	Cool, dry, clean area.	<ul style="list-style-type: none"> • Opened, punctured, or damaged packing, resulting in the loss of sanitary barrier protection and/or unfavorable environmental exposure. • Damp or stained packages.

Illness

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

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

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

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

Name of Foodhandler / Volunteer

FDO Representative

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12. "Food Defense," US Food and Drug Administration, Web. 26 October 2015.FDA
www.fda.gov/Food/FoodDefense
13. "Food Defense and Emergency Response," US Department of Agriculture, Web. 26 October 2015.
www.fsis.usda.gov/wps/portal/fsis/to

EDUCATIONAL RESOURCES

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

Appendix D

Sample Forms for Food Recovery Programs

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

8) Keep these records for 2 years.

REFRIGERATED STORAGE DAILY TEMPERATURE LOG

Cooler/Freezer Number _____ Month _____ Year _____

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

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

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

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

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

2012-2014 Issues Committee Roster

Committee Name: 2014 - 2016 Food Recovery Committee								
Last Name	First Name	Position	Constituency	Employer	City	State	Telephone	Email
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Mellichar	Wayne	at-large	Food Service Industry	Feeding America	Chicago	IL	(312) 629-7263	wmelichar@feedingamerica.org
Mello	Wayne	at-large	Retail Food Industry	Delhaize America/Hannaford	Scarborough	ME	(207) 885-2126	wamello@hannaford.com
Moore	Eric	Member	Retail Food Industry	ACME Markets	Malvern	PA	(610) 889-4005	eric.moore@acmemarkets.com
Oswald	Steve	at-large	Retail Food Industry	Wakefern Food Corporation	Elizabeth	NJ	(908) 527-3624	steve.oswald@wakefern.com
Pasley	Dianna	at-large	Retail Food Industry	Schnuck Markets, Inc.	St. Louis	MO	(314) 994-4346	dpasley@schnucks.com
Pohjola	Carrie	Member	State Regulator	State of WI-DHS	Madison	WI	(715) 579-9487	carrie.pohjola@wi.gov
Roberson	Michael	Member	Retail Food Industry	Publix Super Markets, Inc.	Lakeland	FL	(863) 688-1188	michael.roberson@publix.com
Smith	Aaron	at-large	Retail Food Industry	Ahold USA	Assonet	MA	(508) 977-5201	aaron.smith@stopandshop.com
Spriggs	Sherry	Ex-officio	Federal Regulator	FDA/CFSAN/OFS	College Park	MD	(240) 402-1876	sherry.spriggs@fda.hhs.gov
Sturdivant	Steven	Ex-officio	Regulator	EPA	Dallas	TX	(214) 665-6673	sturdivant.stephen@epa.gov
Wagner	Jim	Member	Retail Food Industry	McClement Management Group	Wheaton	IL	(630) 789-7228	jimwagner123@gmail.com
Williams	Janet	Ex-officio	Federal Regulator	FDA/ORL/DHRD	Rockville	MD	(301) 796-4534	Janet.Williams@fda.hhs.gov
Wilson	Nancy	Member	Food Service Industry	Wawa Inc.	Media	PA	(610) 812-3934	nancy.wilson@wawa.com
Zimmerman	John	Member	Food Service Industry	Sysco	Nashville	TN	(615) 350-1976	zimmermann.john@corp.sysco.com

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-012

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

FRC 2 - Comprehensive Resource for Food Recovery Programs

Issue you would like the Conference to consider:

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

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

Submitter Information 1:

Name: John Marcy
Organization: Food Recovery Committee Co-Chair
Address: University of Arkansas O-203 POSC
City/State/Zip: Fayetteville, AR 72701
Telephone: (479) 575-2211
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Submitter Information 2:

Name: Susie McKinley

Organization: Food Recovery Committee Co-Chair
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*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name
or a commercial proprietary process.*

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-013

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Report - Unattended Food Establishment Committee (UFE)

Issue you would like the Conference to consider:

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

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

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

Submitter Information:

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

Organization: Virginia Department of Health
Address: 109 Governor Street 13th Floor-Office of the Commissioner
City/State/Zip: Richmond, VA 23219
Telephone: 804-864-7011
E-mail: Christopher.Gordon@vdh.virginia.gov

Content Documents:

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

Supporting Attachments:

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

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Conference for Food Protection - Committee FINAL Report

Template approved: 08/14/2013

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

COMMITTEE NAME: Unattended Food Establishments

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council I

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

SUBMITTED BY: Co-Chairs Ric Mathis and Larry Eils

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

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

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

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

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

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

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

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

Conference for Food Protection - Committee FINAL Report

Template approved: 08/14/2013

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

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

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

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

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

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

2. Recommendations for consideration by Council:

The Co-chairs, on behalf of the members of the Conference for Food Protection Unattended Food Establishment Committee, recommends:

1. Acknowledging the work of the Unattended Food Establishment Committee; and
2. Re-creating the Unattended Food Establishment Committee following the CFP 2016 Biennial Meeting to develop a guidance document and recommendations on how the Food Code should be modified to address Unattended Food Establishments and present their findings at the 2018 CFP Biennial Meeting.

Conference for Food Protection - Committee FINAL Report

Template approved: 08/14/2013

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

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Issues to be submitted:

a. Title: Report - Unattended Food Establishments

b. Title: Re-create - Unattended Food Establishments

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

1. Develop recommendations on how the FDA Food Code addresses Unattended Food Establishments;
2. Continue to review the “Guidance Document for Unattended Food Establishments” and any existing guidance from FDA and others to update the CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet section 2-101.11 and 2-103.11 of the 2013 Food Code;
3. Present their findings at the 2018 CFP Biennial Meeting.

c. Title: Guidance Document for Unattended Food Establishments

1. Approval of the Unattended Food Establishment Committee document titled *Guidance Document for Unattended Food Establishments*
2. Posting the approved document in PDF format on the Conference for Food Protection website.

COMMITTEE MEMBER ROSTER (attached):

Committee Name:

CFP Unattended Foodservice Establishment 2014-16

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

Committee Name:

Narvaez	Nona	Member	Consumer	AFFA	St Paul	MN	(651) 644-5937	nona@minnesotafoodallergy.org
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Patel	Jaymin	Members	Vending & Distrib.	Aramark	Philadelphia	PA	(215) 409-7343	patel-jaymin@aramark.com
Powell	Terrance	Member	Local Regulator	LA County Health	Baldwin Park	CA	(626) 430-5330	tpowell@ph.lacounty.gov
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Saunders	Doug	Member	Food Industry Support	Coca Cola	Atlanta	GA	(404) 676-5229	ricsaunders@coca-cola.com
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Walker	Cynthia	Member	State Regulator	FL Dept Bus	Tampa	FL	(813) 748-9721	cynthia.walker@myfloridalicense.com
Wanucha	Donna	Member Consultant	Alternate Consultant	FDA	College Park	MD	678-616-6500	donna.wanucha@fda.hhs.gov
Whiting	Kelli	Member	Local Regulator	Marion CO IN	Indianapolis	IN	(317) 221-2256	kwhiting@hhcorp.org

Guidance Document For Unattended Food Establishments

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

Preface

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

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

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

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

Introduction

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

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

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

Guidance Document
Unattended Food Establishment

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

Minimum Requirements for an Unattended Food Establishment

- A) Definitions
 - (1) Unattended Food Establishment means an operation that provides packaged foods or whole fruit using an automated payment system; and has controlled entry not accessible by the general public.
 - (2) Controlled Entry means selective restriction or limitation of access to a place or location.
- B) The plan review and food safety operating permit shall be in accordance with the requirements of the local authority having jurisdiction.
- C) Unattended Food Establishment Location
 - (1) The unattended food establishment shall be located in the interior of a building that is not accessible by the general public. Access to the unattended food establishment shall be limited to a defined population (e.g., employees or occupants of the building where the establishment is located).
- D) Nature and Source of Food and Beverages Offered for Sale
 - (1) Only commercially packaged foods properly labeled for individual retail sale (per Food Code definition of packaged and labeled per section 3-201.11(C) are offered).
 - (2) No unpackaged food is permitted except as provided by section 3-302.11(B) (1), of the Food Code.
 - (3) Food preparation by consumers is limited to heating/reheating food in a microwave oven.
 - (4) No dispensing of bulk food.
- E) Refrigerated Display Equipment
 - (1) An unattended food establishment shall be equipped with refrigeration or freezer units that have the following features:
 - (a) Self-closing doors that allow food to be viewed without opening the door to the refrigerated cooler or freezer; and
 - (b) Automatic self-locking mechanism that prevents the consumer from accessing the food upon the occurrence of any condition that results in the failure of the refrigeration unit to maintain the internal product temperature specified under section 3-501.16(A) (2) or freezer unit to maintain the product frozen.
- F) Food Service Equipment Limitations
 - (1) Dispenses beverages by individual serving only.
 - (a) Beverage dispensers connected to the building water supply must be properly equipped with backflow prevention per section 5-203.14, of the Food Code.

Guidance Document
Unattended Food Establishment

- (2) Food Contact Surfaces
 - (a) Multi-use food-contact surfaces shall be cleaned on the frequency consistent with the-service per section 4-202. 11, of the Food Code or can be easily removed and replaced with cleaned surfaces.
 - (b) No multi-use food-contact surfaces intended for use with TCS foods.
- G) Security
 - (1) An unattended food establishment shall provide continuous video surveillance of areas where consumers view, select, handle and purchase products that provides sufficient resolution to identify situations that may compromise food safety or food defense.
 - (a) Video surveillance recordings shall be maintained and made available for inspection upon request by a representative of a regulatory agency within 24 hours of a request.
 - (b) Video surveillance recordings shall be held by the establishment for a minimum of fourteen (14) days after the date of the surveillance.
 - (2) The permit holder takes reasonable steps necessary to discourage individuals from returning food and/or beverages that not have been selected for purchase.
- H) Routine Maintenance at an Unattended Food Establishment:
 - (1) The permit holder shall service the unattended food establishment on a scheduled basis and at a frequency acceptable to the regulatory agency. Service may include, but is not limited to the following:
 - (a) Checking food supplies and equipment for signs of product damage and/or tampering.
 - (b) Verifying refrigeration equipment is operating properly including the temperature display and self-locking mechanism.
 - (c) Rotating foods to better ensure first in/first out of food items.
 - (d) Cleaning food service equipment and food display areas.
 - (e) Stocking food and disposable single-use and single-service supplies.
 - (f) Checking inventory for recalled foods.
 - (2) Permit holder shall assure:
 - (a) Food is from an approved source.
 - (b) Packaged food is provided in tamper-evident packaging.
 - (c) Food is protected from potential sources of cross contamination.
 - (d) Food is maintained at safe temperatures during transport and display.
- I) Unattended Food Establishment Oversight
 - (1) Each unattended food establishment shall have a sign readily visible at the automated payment station stating:
 - (a) The name and mailing address of the business entity responsible for the establishment and to whom complaints and comments should be addressed.

Guidance Document
Unattended Food Establishment

- (b) The telephone, email or web information for the responsible business entity, when applicable.
- J) Designation of Responsibilities:
- (1) The permit holder bears all responsibilities for the operation of the food establishment. Where the permit holder is not the owner or operator of the building where the food establishment is located, a mutual agreement that outlines the responsibilities for cleaning and maintenance of all surfaces and equipment, provision of supportive facilities/services such as janitorial and restroom facilities, pest control and removal of solid waste may be approved by the regulatory agency. This agreement should also outline what actions must be taken by both parties to maintain the establishment in compliance with all requirements.

To: FDA National Retail Food Team
From: Director, Retail Foods and Cooperative Program Coordination Staff - CFSAN
Date: 12/12/2014
Re: Considerations for Permitting Unattended Food Establishments

At the 2014 Biennial Meeting in Orlando, the Conference for Food Protection established an *Unattended Food Establishments Committee* (see Issue 2014-I-019). The Committee is charged with reporting back to the 2016 meeting with recommendations on “*whether and how the Food Code should be modified to address unattended food merchandising operations*” and to “*consider existing guidance from FDA and others and develop a CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet Sections 2-101.11 and 2-103.11 of the 2013 Food Code.*” FDA has appointed a member (Girvin Liggans) and an alternate (Donna Wanucha) to that Committee. We anticipate that the Committee will fulfill its charge and provide sound recommendations to CFP for consideration at the 2016 biennial meeting. FDA will consider all recommendations from the CFP.

Currently, Part 2-1 of the FDA Food Code requires that a food establishment have an appropriate person-in-charge present during all hours of operation. The FDA Food Code does not define specific criteria for the safe operation of unattended food merchandising operations other than those that apply to vending machine locations.

With regard to the potential changes to the Food Code and/or the development of guidance documents for regulatory authorities considering the issuance of a variance or waiver (to Sections 2-101.11 and 2-103.11 of the 2013 Food Code) for unattended food merchandising operations, FDA is recommending that the *CFP Unattended Food Establishments Committee* consider a number of characteristics of unattended food establishments that could impact food safety. FDA is requesting that the Committee consider what, if any, criteria for safe operation should be established with regard to:

1. The nature and source of food and beverages being offered for sale

Food safety risks are dependent on the types of foods being offered for sale.

Considerations include:

- Extent to which sales are limited to packaged foods
- Extent to which sales are limited to commercially prepared foods
- Extent to which sales are limited to foods that do not require temperature control for safety
- Extent to which foods may require on-site preparation by the customer
- Extent to which foods that are date-labeled for safety or quality are merchandised

2. Display equipment and facility design

The nature of the equipment and the facility design may impact food safety risks.

Considerations include:

- Extent to which display equipment is designed and constructed to limit customer access to TCS foods that have been subject to temperature abuse as the result of mechanical failure or other unintended condition
- Extent to which equipment requires connection to a water supply or wastewater connections
- Size and mobility of equipment used in the establishment
- Overall size of the operation
- Availability of seating and other facilities (e.g. restrooms, sinks) for use by customers in the establishment

3. Facility location, oversight and security

The nature of customer access to the location and the level of oversight provided by the operator and others may impact food safety risks.

Considerations include:

- Extent to which the facility is located in a "controlled location" such that access to the food establishment is restricted to a defined group of individuals (e.g. places of employment)
- Extent to which the permit holder or designee is available to service the site, the frequency at which the individual will assess food safety and sanitation and how the permit holder is alerted to problems in the facility that may warrant an immediate response
- Extent to which individuals, including those who may not be employed by the permit holder, are available and authorized to take action if a potential food safety hazard is created in the food establishment (e.g., food spills, cross contamination, vomiting)
- Extent to which surveillance is provided to detect and/or discourage intentional or unintentional acts that may create a food safety hazard
- Extent to which the location is protected from exposure to the outdoors or uncontrolled environments.

Please note that regulatory authorities in some states have already established requirements, either via rulemaking or policy directives, to better define the conditions under which self-service food merchandising operations may operate without the presence of an employee.

Person in Charge as it relates to Unattended Food Service Establishments - October, 2015

2-103.11	Duty of the Person-In-Charge	Applicable to Unattended Market?	Risk Level	Action, Prevention, or Reduction of Risk
(A)	Food operations not conducted in private home, living or sleeping quarters	No		Prepackaged food obtained from commercial, licensed suppliers
(B)	Persons unnecessary to operation are not allowed in food preparation area	No		All foods prepackaged. No food production at unattended market. Only "open" food may be beverages dispensed into a single-use cup.
(C)	People entering the food preparation, storage and warewashing areas comply with the Code.	No		Food is not prepared on-site. Food is stored in secured areas (locked cabinets) or on display in area under continuous electronic surveillance. Entry to unattended market is secured. Warewashing is not done at the unattended market.
(D)	Employees are effectively cleaning their hands. PIC is routinely monitoring the employees' handwashing.	Yes	Low	All food is prepackaged. Hand contact with any food contact surface can be eliminated or minimized. Filling single-service, disposable article dispensers (coffee cups, coffee stirrers, straws) may be accomplished with gloved hands or by using the plastic sleeve wrapping on the cups.
(E)	Employees are visibly observing foods as they are received for <ul style="list-style-type: none"> • Approved source • Delivered at required temperatures • Protected from contamination • Unadulterated • Accurately presented PIC is to routinely monitor employee observations and periodically evaluate food upon receipt	Yes	Medium	Food is obtained from a safe source (vending branch, commercial, licensed suppliers). Route driver/merchandiser must protect the cold chain of the food from receipt, during transportation, and to the display refrigerator. All foods must be pre-packaged (tamper-resistant or tamper-evident packaging). All foods must be protected from all potential sources of contamination from receipt, transportation and storage.

				All packages of food must be properly labeled for individual retail sale. In all likelihood, the route driver/merchandiser is the person in charge and will not be evaluating other employees.
(F)	Verifying that foods delivered during non-operating hours are from approved sources and are placed into appropriate storage locations, maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented	No		N/A Food is not drop shipped at unattended markets. All food is delivered by the route driver/merchandiser.
(G)	Employees are properly cooking TCS foods and using thermometers	No		N/A Food is not cooked at the unattended market
(H)	Employees are properly cooling TCS foods	No		N/A TCS foods are not prepared using a cooling step at the unattended market
(I)	Consumer advisory is provided	Yes	Low	Any raw animal foods offered for sale (prepackaged sushi) must be properly labeled, including the consumer advisory statement on the individual package label.
(J)	Employees are properly sanitizing cleaned multi-use equipment and utensils before they are reused	Maybe	Low	(1) No multi-use utensils or equipment allowed OR (2) any multi-use utensils or equipment is cleaned and sanitized on a frequency in compliance with applicable sections of the Food Code (either Clean-In-Place or parts are removed during the service visit and replaced with clean parts – soiled parts are properly washed-rinsed-sanitized at the vending branch location)
(K)	Consumers are notified	No		No multi-use tableware is

	that clean tableware is to be used when they return to self-service areas such as salad bars and buffets			provided. <i>If there is a concern of customers re-using single-service articles, a sign may be recommended....</i>
(L)	Employees are preventing bare hand contact with ready-to-eat foods	No		All food is prepackaged
(M)	Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties	Maybe	Low	Minimum food safety training for employees of unattended markets would need to be specified. Current Food Code definition of FOOD EMPLOYEE: "Food employee" means an individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.
(N)	Food employees and conditional employees are informed in a verifiable manner of their responsibility to report in accordance with law, to the person in charge, information about their health and activities as they related to diseases that are transmissible through food	Maybe	Low	Employee health reporting agreement forms (vending companies can use model Forms 1-A, 1-B, 1-C in Annex 7). "RESTRICT" already states that the FOOD EMPLOYEE does not work with exposed FOOD, clean EQUIPMENT, UTENSILS, LINENS, or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.
(O)	Written procedures and plans, where specified by this Code and as developed by the food establishment, are maintained and implemented as required.	No		HACCP plans would not be required for unattended markets.

Micro Market – NAMA Technical Bulletin

A New Innovation in Automatic Merchandising

Introduction

Technology is making possible great changes in the food and beverage vending industry. Today you can purchase a Latte or a Cappuccino from a hot beverage machine and enjoy many of the new bottle drinks from a glass front beverage dispenser. You can also make your purchase using a credit/debit card in addition to using bills or coins.

However, the biggest change has been the introduction of the Micro Market. A Micro Market is a self-checkout retail food establishment that replaces a bank of vending machines. In a Micro Market a customer picks up a product from an open rack display, a reach-in refrigerated cooler or freezer or open air cooler, than scans the UPC bar code or an RFID tag for each product at a payment kiosk. The customer pays with a single payment, be it cash, credit card or stored value card. Another unique feature of the Micro Market is that it operates without an employee present, just like vending machines. All Micro Markets are equipped with a 24 hour a day security system monitoring customers as they make their selections and checkout. Micro Markets are designed to be in “closed locations.” This refers to a business that has a moderately secured facility for a known group of employees where the Micro Market can be located in a designated area away from heavy public traffic.

Micro Market Products Available

In a typical Micro Market you will find:

- Fresh crisp salads and fruit
- Deli sandwiches, subs, soups and meal options
- Premium beverages, sparkling drinks and juice varieties
- Popular snacks, candies, gum and mints
- Low-calorie, low-fat healthy alternatives
- Breakfast sandwiches, pastries and cereals
- Ice cream and other frozen treats
- Some over the counter medicine and sundry items

Micro Market Equipment

To merchandise all the products available in a Micro Market you will typically find:

- Shelving, be it wall or free standing for popular snacks, candies, gum, mints, low-calorie, low-fat healthy alternative snacks and sundry items
- Single or double door glass front reach-in refrigerators for premium beverages, sparkling drinks and juice varieties
- Single door glass front reach-in refrigerator or open air cooler for fresh crisp salads and

fruit; deli sandwiches, subs, soups and other meal options; breakfast sandwiches, pastries and cereals

Single door glass front reach-in freezer for ice cream and other frozen treats.

Equipment Specification for Handling Potentially Hazardous Foods

All glass front reach-in refrigerators and freezers and open air coolers shall be Listed by the National Sanitation Foundation.

How a Micro Market Works

A Micro Market is serviced on a pre-set schedule by a route driver. The route driver arrives at a location, checks the equipment to be sure it is working correctly, cleans the equipment on a set schedule, check products to be sure they are still “in date” and will be until the next service date, pulls any products that will be “out of date” and then stocks the product shelves and refrigerated and/or freezer units with new product. Through the use of on-line software, the route driver brings only what products are actually needed. The “out of date” products are returned to the warehouse for accountability and proper disposal at the end of day.

Today, government agencies at all levels along with businesses are requesting or mandating that healthier food options be available to their employees. Traditional vending has come a long way to improve its’ offerings but is still very limited by column or shelf space size and selections as to what items can be sold in a typical vending machine. A Micro Market expands the number of products that can be sold in the same floor space a typical bank of vending machine would occupy. In addition, a customer can read all the nutrition information on the label of a food product because they can hold it before purchasing.

Public Health Safeguards

Food Safety - Since Micro Markets sell potentially hazardous foods reach-in refrigerated refrigerators maintain a temperature of 41°F and reach-in freezers maintain a temperature of 0°F. All refrigeration equipment have self-closing doors to help maintain the correct temperatures. In addition all refrigeration equipment are equipped with automatic shut-off controls that prevents the equipment from selling food by locking the door when there is a power failure, mechanical failure or other condition that results in an internal temperature greater than 41°F for longer than 30 minutes. Only an authorized service technician or the route driver has the ability to reset the equipment after it is has been determined what caused the temperature failure.

Food Security - Micro Markets are designed to be located in a closed location serving a known set of employees. As mentioned earlier, Micro Markets operate without an employee present. To prevent theft and tampering of food products Micro Markets are equipped with 24/7 surveillance cameras. The time and date products were purchased can

be traced back and matched to the person who made the purchase.

General Sanitation - To perform routine cleaning of the Micro Market the route driver does have access to potable water and a sanitation kit consisting of a cleaning pail, disposable towels, detergent in a spray bottle, sanitizer in a spray bottle and window cleaner.

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-014

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

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014 I-019; new or additional information has been included or attached.

Title:

UFE 2 - Guidance Document for Unattended Food Establishments

Issue you would like the Conference to consider:

At the 2014 Biennial Meeting, the Conference created the Unattended Food Establishments Committee with the following charges:

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

The committee recommends that the new guidance document for Unattended Food Establishments be approved.

Public Health Significance:

Industry representatives estimate that thousands of unattended food establishments have replaced traditional vending machine operations in the US. However since many jurisdictions do not routinely regulate vending operations, it is not clear how many unattended food establishments would be subject to regulation as a food establishment. Many of the unattended food establishments operations exist in closed environments, such as factories, with a known employee population and with restricted access reducing the threats of accidental or intentional contamination. If the unattended food establishments have installed and are using video surveillance this further reduces the public health impact. Additional precautions need to be implemented, such as failsafe systems for a cooler that cannot maintain TCS product at the required temperature. If none of these

measures exist then the risk to the consumer increases to unacceptable levels and should not be allowed.

Recommended Solution: The Conference recommends...:

1. Approval of the Unattended Food Establishment Committee document titled *Guidance Document for Unattended Food Establishments* (attached to the Issue titled: Report - Unattended Food Establishment Committee); and
2. Posting the approved document in PDF format on the Conference for Food Protection website.

Submitter Information 1:

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E-mail: rpeonygarden@gmail.com

Submitter Information 2:

Name: Ric Mathis
Organization: Co-chair Unattended Food Establishment Committee
Address: FL Dept of Health4052 Ba;d Cypress Way Bin A08
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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-015

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

UFE 3 - Re-create the Unattended Food Establishment Committee

Issue you would like the Conference to consider:

Re-creating the Unattended Food Establishment Committee to continue work on charges set forth in Issue 2014-I-019.

Public Health Significance:

Continuing work on the Unattended Food Establishment Committee is required to meet the charges set forth by Issue 2014-I-019.

Recommended Solution: The Conference recommends...:

Re-create the Unattended Food Establishment Committee to complete the following charges:

1. Develop recommendations on how the FDA Food Code addresses Unattended Food Establishments;
2. Continue to review the "Guidance Document for Unattended Food Establishments" and any existing guidance from FDA and others to update the CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet section 2-101.11 and 2-103.11 of the 2013 Food Code; and
3. Present their findings at the 2018 CFP Biennial Meeting.

Submitter Information:

Name: Chris Gordon, Council I Chair, on behalf of UFE Committee
Organization: Virginia Department of Health
Address: 109 Governor Street
City/State/Zip: Richmond, VA 23219
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E-mail: Christopher.Gordon@vdh.virginia.gov

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-016

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Food Establishments With Robotic Operations

Issue you would like the Conference to consider:

New innovative technology is entering the retail food service industry in the form of automated food preparation and process "robots" that not only cook raw foods to ready-to-eat, but combine, garnish, assemble, wrap, package and dispense them. These robots are installed inside of building spaces specifically designed to accommodate their processes. The FDA Food Code should be changed to provide criteria to enable these safe and optimized operational platforms to exist.

Public Health Significance:

New, fully automated *raw* to ready-to-eat (R-RTE) "robotic" food operations in retail food facilities present several critical risk reductions as compared to traditional manual food preparation methods. 1. There are no hands touching R-RTE foods - therefore, no ill employee's are in contact with foods that are being prepared. 2. Every step of the process is continuously controlled, monitored and data logged for time and temperature, along with supervisory analytics and identification of food and ingredient lots, responsible personnel, etc.. 3. R-RTE systems enable automated trace-back and record review of each critical control point (CCP) associated with its hazard analysis critical control point (HACCP) or hazard analysis risk based preventative control (HARPC) program, including corrective action execution, time, date, personnel, etc. and record keeping.

Products begin as raw and are prepared, cooked, garnished, assembled, wrapped, packaged and "dispensed" to a server or to the consumer directly. These new R-RTE food operations that are housed within purpose designed, engineered and built building spaces. They present extreme uniformity and precision for everything from portion size, cook time and temperature and overall quality and their continuous data logs meet evidentiary rule requirements. So too do these systems provide for real time event notification. One of the pioneers for robotic food facilities and the co-presenter of this issue has their food products packed into reusable, sealed, sanitary cassettes (eg., removable, reusable cylindrical

"hoppers") at a licensed food processing facility. These American National Standards (ANSI) sanitation listed cassettes have radio frequency Identification tags (RFID) and track time, temperature and location as products are moved under refrigeration from the food processor through transportation to the food facility. Cassettes that are short-term stored on-site use First-in-First Out (FIFO) control methods and are loaded directly into the robot which opens the hermetically sealed cassette internally, removing the meat cubes, produce, sauce or other food items, ready for preparation and assembly.

Some RTE time/temperature control for safety (TCS) food items may use TIME alone as a public health control. Because of the extreme accuracy of food handling records, time alone as a public health control is easily managed. Products that left temperature control four hours ago are automatically discharged to waste and recorded as such. All of the clean and sanitize in place processes (CSIP) are recorded (logged) some of which are fully automated. A complete flow chart for the flow of food through robotic operation (robop?) is presented to the licensing authority upon application for permit. In addition, a list of the approved sources and the overall food safety plan with standard sanitary operating procedures are provided, including both clean and sanitize in place (CSIP) operations and various manual in place cleaning (IPC) and clean out of place (COP) procedures. In addition to maintenance of an automatic, continuous log of collected critical control point data, there is an overlay to enable supervisory notes from the person in charge relating to the data. Detailed, High Definition (HD) 24/7/365 video surveillance data is over-layered providing a unique data set for each and every daily food operation. The intent of this mechanized process is to provide the safest complex food operation in the world.

Recommended Solution: The Conference recommends...:

1. that a letter be sent to the FDA requesting the 2013 Food Code be amended to include a definition in Section 1-201.11 of the FDA Food Code for food establishments with robotic operations;

and

2. the Conference further recommend that a committee be formed:

A. to establish reasonable criteria and guidance for the new and emerging field of robotic food service operations; and

B. report back with their findings and recommendations to the 2018 Biennial Meeting.

Submitter Information 1:

Name: Thomas Johnson
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E-mail: tomj@jdpinc.com

Submitter Information 2:

Name: Steve Frehn
Organization: Momentum Machines, LLC
Address: 977 Howard St.

City/State/Zip: San Francisco, CA 94103
Telephone: 651-906-7058
E-mail: steve@momentummachines.com

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-017

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Revised Term for Animal Foods

Issue you would like the Conference to consider:

The Food Code uses the term "animal food" in several places. This term could be misunderstood as pet food.

Public Health Significance:

Revising the term "animal food" to "animal-origin food" would reduce confusion.

Recommended Solution: The Conference recommends...:

a letter be send to FDA requesting that the term "animal food" be replaced by the term "animal-origin food" throughout the Food Code.

Submitter Information:

Name: Adam Inman
Organization: Kansas Department of Agriculture
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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-018

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Defining Food Establishments—Amend Section 1-201.10(B)

Issue you would like the Conference to consider:

The FDA Food Code recognizes that food establishments should be maintained to ensure sanitary conditions free of rodents, insects, and other pests. The 2013 Food Code, however, defines "food establishments" subject to the code to exclude establishments that offer only prepackaged, shelf-stable foods. States that have adopted the 2013 Food Code's definition of food establishments may not ensure that stores selling only prepackaged, shelf-stable foods meet basic sanitation requirements.

Public Health Significance:

Proper handling, storage, and display of prepackaged foods is necessary to safeguard public health. Establishments that are typically not in the business of selling food -- *such as home goods, hardware, clothing, party supply, and office supply stores* -- should be defined as "food establishments" and required to meet basic sanitation standards. Jurisdictions that inspect such stores have found numerous sanitation violations including the presence of insects, rat and mouse droppings, the presence of a trapped mouse, gnawed food bags, the presence of live birds and a pet dog, improper storage of toxic chemicals, and spoiled food (documentation attached).

Risks posed to consumers may be high for ready-to-eat foods, such as candy bars and chips. These foods are typically eaten directly out of the packaging, with consumers' hands touching both the packaging and the food itself, increasing the likelihood that excrement or toxic chemicals present on the packaging could contaminate the food consumed.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the definition of Food Establishments in the 2013 Food Code section 1-201.10(B) be amended as follows (new language is underlined; language to be deleted is in strikethrough format):

1-201.10 Statement of Application and Listing of Terms

(B) Terms Defined. As used in this Code, each of the terms listed in ¶ 1-201.10(B) shall have the meaning stated below.

Food Establishment.

(3) "Food establishment" does not include:

~~(a) An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;~~

~~(ba) A produce stand that only offers whole, uncut fresh fruits and vegetables;~~

~~(eb) A FOOD PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT~~

~~(ec) A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;~~

~~(ed) An area where FOOD that is prepared as specified in Subparagraph (3)(ec) of this definition is sold or offered for human consumption;~~

~~(fe) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; or~~

~~(gf) A private home that receives catered or home-delivered FOOD.~~

Submitter Information 1:

Name: David W. Plunkett
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City/State/Zip: Washington, DC 20005
Telephone: 2027778319
E-mail: dplunkett@cspinet.org

Submitter Information 2:

Name: Jessica Almy
Organization: Center for Science in the Public Interest
Address: 1220 L Street NW Suite 300
City/State/Zip: Washington, DC 20005
Telephone: 2027778358
E-mail: jalmy@cspinet.org

Supporting Attachments:

- "Clothing Store 1"
- "Clothing Store 2"
- "Hardware Store 1"
- "Hardware Store 2"
- "Home Goods Store 1"
- "Home Goods Store 2"
- "Home Goods Store 3"
- "Office Supply Store 1"
- "Office Supply Store 2"
- "Party Store 1"
- "Party Store 2"

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

Establishment Name [REDACTED]

Establishment Address [REDACTED]

OBSERVATIONS	25 DCMR	CORRECTIVE ACTIONS
36 - Rodent droppings and gnawed food product bags observed at areas where food products are sold	3210 1	The premises shall be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by: (a) Routinely inspecting incoming shipments of food and supplies; (b) Routinely inspecting the premises for evidence of pests; (c) Using methods, if pests are found, such as trapping devices or other means of pest control as specified in sections 3402, 3410 and 3411; and (d) Eliminating harborage conditions
53 - Cracks and holes observed throughout the walls of the receiving/storage area of establishment	3200 1	The physical facilities shall be maintained in good repair

TEMPERATURES							
Item/Location	Temp	Item/Location	Temp	Item/Location	Temp	Item/Location	Temp
Hot Water (Handwashing Sink)	105.0F						

Inspector Comments:
SUMMARY SUSPENSION: IN ORDER FOR LICENSE TO BE RESTORED, A RE-INSPECTION FEE OF \$100 [DURING NORMAL BUSINESS HOURS] OR \$400 [DURING NON-BUSINESS HOURS] MUST BE PAID PRIOR TO REQUEST AND ALL VIOLATIONS MUST BE ABATED AND APPROVED BY THE DC DOH.
NOTE: AFTER CORRECTING ALL VIOLATIONS, PLEASE HAVE PEST CONTROL SERVICE ESTABLISHMENT AND PROVIDE THE INVOICE/SERVICE REPORT AT THE RESTORATION INSPECTION.
IF YOU HAVE ANY QUESTIONS, CONTACT AREA SUPERVISOR MR. TAYLOR AT (202)442-9037.

Person-in-Charge (Signature) [REDACTED] (Print) [REDACTED] Date 04/28/2015

Inspector (Signature) Jaime Hernandez (Print) Badge # 607 Date 04/28/2015

Establishment Name [REDACTED]

Establishment Address [REDACTED]

OBSERVATIONS	25 DCMR	CORRECTIVE ACTIONS
26 - CHEMICALS NOT STORED PROPERLY (Corrected On Site)	3400 1	Poisonous or toxic materials shall be stored so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by: (a) Separating the poisonous or toxic materials by physically separating or partitioning by a wall or structure; and (b) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This paragraph does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

TEMPERATURES							
Item/Location	Temp	Item/Location	Temp	Item/Location	Temp	Item/Location	Temp
(Refrigerator - beverage)	38.9F						

Inspector Comments:
 NO CRITICAL VIOLATIONS WERE OBSERVED. IF YOU HAVE ANY QUESTIONS PLEASE CALL AREA SUPERVISOR MR. RONNIE TAYLOR AT 202-442-9037.

Person-in-Charge (Signature) [REDACTED] (Print)	05/11/2015 Date
Inspector (Signature) VICTOR CURRIE (Print)	088 Badge #
	05/11/2015 Date



INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health

1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

Hardware Store #1

[REDACTED]
LAKE FOREST, CA 92630

Record ID: [REDACTED]
Inspection Date: 05/03/2013
Reinspection Date:

Type of Facility: 0390-LIMITED PRE-PACKAGED FOOD
25-299 SQ FT-NO PHF
Service: A01-ROUTINE INSPECTION
V Kenekeo, REHS
ENVIRONMENTAL HEALTH SPEC I
(714) 659-4036
7:30-8:30 a.m.

Mailing Address:

ON FILE

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

MINOR VIOLATIONS

FC38 - Unsanitary Equipment/Utensil/Linen/Plumbing

Remove dust from the fan covers from the following coolers:
a. Vitamin water
b. Coca Cola
c. Coca Cola at Lawn and Garden
Maintain these areas clean on a regular basis.

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects

Observed a customer with a dog in the facility.
Live animals, birds, and fowl shall not be kept or allowed in any food facility except those that are exempt from California Retail Food Code as described in Section 114259.

COMMENTS

FC99 - NOTES

This inspection report was reviewed with [REDACTED] (Assistant manager).
It was agreed that a copy of this report will be e-mailed to the address provided. The person in charge was directed to call this office if the report is not received within 2 business days. Reports and other valuable information can be found at www.ocfoodinfo.com. SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.

Change of Ownership: No
Food Temperatures:
NO potentially hazardous foods

Hot water recorded at 120F at the mop sink
Dish/Utensil Sanitation method: N/A
Sanitizer level for wiping cloths: N/A

The "PASS" Notification Seal was posted today in a prominent location.

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____

Date _____



INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health

1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

Hardware Store #2

[REDACTED]
BREA, CA 92821

Record ID: [REDACTED]
Inspection Date: 06/20/2014
Reinspection Date:

Type of Facility: 0390-LIMITED PRE-PACKAGED FOOD
25-299 SQ FT-NO PHF
Service: A01-ROUTINE INSPECTION
L Arellano, REHS
ENVIRONMENTAL HEALTH SPEC I
(714) 823-7046

Mailing Address:
ON FILE

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

OPENING COMMENTS

FC00 - OPENING COMMENT

Observed 25-199 sq ft of pre packaged non potentially hazardous foods on this date.

MINOR VIOLATIONS

FC38 - Unsanitary Equipment/Utensil/Linen/Plumbing

Clean the tracks inside the soda coolers. Maintain all equipment, utensils and facilities clean, fully operative and in good repair.

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects

Observed live birds inside the facility. Construct, equip, maintain, and operate the food facility so as to prevent the entrance and harborage of insects and rodents. Use any approved method for eliminating insects (i.e. flies, cockroaches) and/or rodents from the facility. A thorough inspection for vermin activity was conducted and no further evidence was observed.

FC40 - Facility not Fully Enclosed/Open Door/Air Curtain

Observed the front doors to be propped open. Maintain the door closed at all times except during immediate passage. Alternatively, if ventilation is desired, provide an approved screen door. Maintain the food facility fully enclosed to prevent the entrance and harborage of animals and insects.

COMMENTS

FC99 - NOTES

The report violations were reviewed with: [REDACTED]
It was agreed that a copy of this report will be sent to the e-mail address provided. The person in charge was directed to call this office if the report is not received within 2 business days. Reports and other valuable information can be found at www.ocfoodinfo.com. SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.
Change of Ownership: No
Food Temperatures: N/A

F100 - "PASS" SEAL POSTED

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____

Date _____

Restaurant Name (optional)

Near (Address, City & State, or Zip)

HOME

ABOUT

CONTACT

Home Goods Store #1



Downey, CA 90242-2659



3/16/2011 **Violation 58**

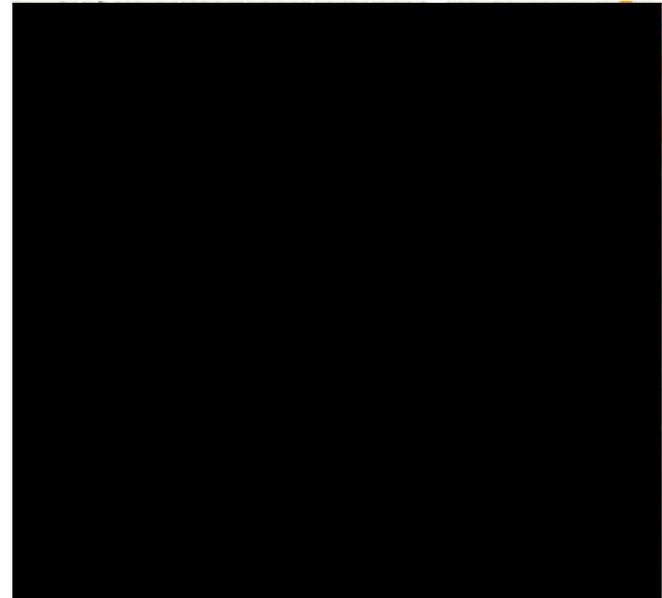
OTHER INSECTS (MINOR) Examples Include: Flies in the delivery staging area only, Gnats in the warewashing area or around floor sink, Flies in a pre-packaged food facility, Ants found on the kitchen floor

Violation 60

SINKS & FIXTURES / SUPPLY LINE - LEAKING / NOT CLEAN / DISREPAIR / UNAPPROVED Examples Include: Leaking faucet at the ware washing sink, Dirty sinks / fixtures, Unapproved rubber hose used as a faucet extension at 3-compartment sink, Faucet unable to reach all compartments of the sink, Cracked sink or sink not secured to wall, Automatic pre-mixing faucet does not stay on for the required minimum 15 seconds, Back flow prevention device is leaking, Hose used to clean floor mats is also used to supply water at wok stove faucet, Leaking water supply line (e.g., inlet valves)

Violation 62

LOW RISK HOT / WARM WATER VIOLATIONS Examples Include: Water throughout the restaurant is measured at 110-119°F, chemically sanitizing multi-use utensils (24 hours to abate), All non critical sinks not meeting the required minimum hot water temperatures (120°F for food prep / mop OR 100°F for handwash sink), Water is less than 120°F at a pre-packaged food facility (24 hours to abate), Water temperature measured at a critical food preparation or mop sink is between 110-119°F or 90-99°F at a critical handwash sink, Manual warewashing solution between



NEARBY RESTAURANTS

Within 2 Miles

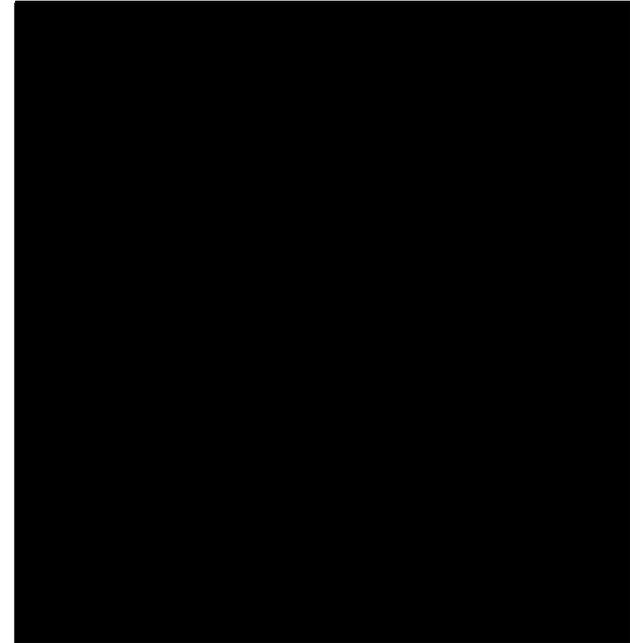


100-110°F (Unless otherwise specified by detergent manufacturer's instruction label)

5/18/2010 **Violation 48**

NON-FOOD-CONTACT SURFACES NOT CLEAN (MINOR)

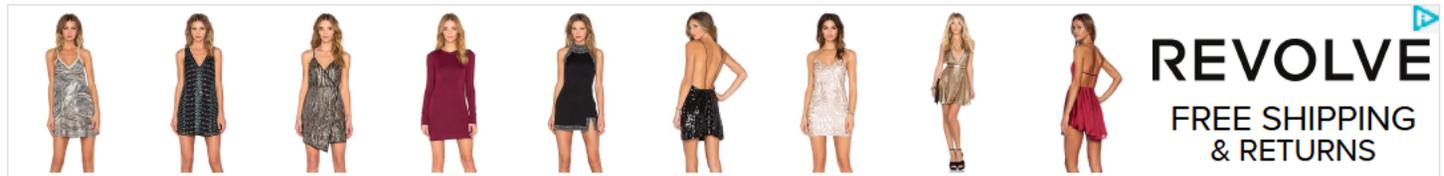
Examples Include: Accumulated grease or food debris on the non-food contact surfaces of equipment, shelving, or cabinets, Dirty fan guards or door gaskets in walk-in refrigerator, Dirty shelving in refrigeration unit with no direct food contact



DATA SOURCE

This data was downloaded from the local health department for this restaurant. See our **FAQ** for a full list of our data sources.

Last Updated 3/16/2011 4:00:00 AM





Food Establishment Inspection Report

Pursuant to Title 25-A of the District of Columbia Municipal Regulations



Bureau of Community Hygiene • Food Safety & Hygiene Inspection Services Division • 899 North Capitol Street, NE-8th Floor • Washington, DC 20002 • food.safety@dc.gov

Establishment Name: _____
 Address: _____
 City/State/Zip Code: WASHINGTON, DC 20010
 Telephone: _____ E-mail address: _____
 Date of Inspection: 02 / 26 / 2015 Time In: 01 : 32 PM Time Out: 02 : 35 PM
 License Holder: _____
 License/Customer No.: _____
 License Period: 04 / 01 / 2013 - 03 / 23 / 2015 Type of Inspection: Routine

Critical Violations	0	COS	0	R	0
Noncritical Violations	2	COS	0	R	0
Certified Food Protection Manager (CFPM)					
CFPM #: _____					
CFPM Expiration Date: ____ / ____ / ____					
D.C. licensed trash or solid waste contractor: Building: _____					
D.C. licensed sewage & liquid waste transport contractor: n/a					
D.C. licensed pesticide operator/contractor: _____					

Establishment Type: Food Products Risk Category 1 2 3 4 5

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS				
Compliance Status			COS	R
Demonstration of knowledge				
IN	OUT	N/A	1. Correct response to questions	<input type="checkbox"/> <input type="checkbox"/>
Employee Health				
IN	OUT		2 Management awareness; policy present	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT		3 Proper use of restriction and exclusion	<input type="checkbox"/> <input type="checkbox"/>
Good Hygienic Practices				
IN	OUT	N/O	4 Proper eating, tasting, drinking, or tobacco use	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/O	5 No discharge from eyes, nose, and mouth	<input type="checkbox"/> <input type="checkbox"/>
Preventing Contamination by Hands				
IN	OUT	N/O	6 Hands clean and properly washed	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	7 No bare hand contact with ready-to-eat foods or approved	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT		8 Adequate handwashing sinks properly supplied and accessible	<input type="checkbox"/> <input type="checkbox"/>
Approved Source				
IN	OUT	N/A N/O	9 Food obtained from approved source	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	10 Food received at proper temperature	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT		11 Food in good condition, safe, unadulterated	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	12 Required records available: shellstock tags, parasite destruction	<input type="checkbox"/> <input type="checkbox"/>
Protection from Contamination				
IN	OUT	N/A N/O	13 Food separated and protected	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A	14 Food-contact surfaces: cleaned & sanitized	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT		15 Proper disposition of returned, previously served, reconditioned, and unsafe food	<input type="checkbox"/> <input type="checkbox"/>
Potentially Hazardous Food (TCS Food)				
IN	OUT	N/A N/O	16 Proper cooking time and temperatures	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	17 Proper reheating procedures for hot holding	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	18 Proper cooling time & temperatures	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	19 Proper hot holding temperatures	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	20 Proper cold holding temperatures	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	21 Proper date marking & disposition	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A N/O	22. Time as a public health control: procedures & records	<input type="checkbox"/> <input type="checkbox"/>
Consumer Advisory				
IN	OUT	N/A	23. Consumer advisory provided for raw or undercooked foods	<input type="checkbox"/> <input type="checkbox"/>
Highly Susceptible Populations				
IN	OUT	N/A	24 Pasteurized foods used; prohibited foods not offered	<input type="checkbox"/> <input type="checkbox"/>
Chemical				
IN	OUT	N/A	25 Food additives: approved & properly used	<input type="checkbox"/> <input type="checkbox"/>
IN	OUT	N/A	26. Toxic substances properly identified, stored, used	<input type="checkbox"/> <input type="checkbox"/>
Conformance with Approved Procedures				
IN	OUT	N/A	27. Compliance with variance, specialized process, and HACCP plan	<input type="checkbox"/> <input type="checkbox"/>

GOOD RETAIL PRACTICES				
Compliance Status			COS	R
Safe Food and Water				
N	OUT	N/A	28. Pasteurized eggs used where required	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		29. Water & Ice from approved source	<input type="checkbox"/> <input type="checkbox"/>
N	OUT	N/A	30. Variance obtained for specialized processing methods	<input type="checkbox"/> <input type="checkbox"/>
Food Temperature Control				
N	OUT		31. Proper cooling methods used; adequate equipment for temperature control	<input type="checkbox"/> <input type="checkbox"/>
N	OUT	N/A N/O	32. Plant food properly cooked for hot holding	<input type="checkbox"/> <input type="checkbox"/>
N	OUT	N/A N/O	33. Approved thawing methods used	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		34. Thermometers provided & accurate	<input type="checkbox"/> <input type="checkbox"/>
Food Identification				
N	OUT		35. Food properly labeled; original container	<input type="checkbox"/> <input type="checkbox"/>
Prevention of Food Contamination				
N	OUT		36. Insects, rodents, & animals not present	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		37. Contamination prevented during food preparation, storage, & display	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		38. Personal cleanliness	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		39. Wiping cloths: properly used & stored	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		40. Washing fruits & vegetables	<input type="checkbox"/> <input type="checkbox"/>
Proper Use of Utensils				
N	OUT		41. In-use utensils: properly stored	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		42. Utensils, equipment & linens: properly stored, dried, & handled	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		43. Single-use/single-service articles: properly stored & used	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		44. Gloves used properly	<input type="checkbox"/> <input type="checkbox"/>
Utensils, Equipment, and Vending				
N	OUT		45. Food and nonfood-contact surfaces cleanable, properly designed, constructed, & used	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		46. Warewashing facilities: installed, maintained, & used; test strips	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		47. Nonfood-contact surfaces clean	<input type="checkbox"/> <input type="checkbox"/>
Physical Facilities				
N	OUT		48. Hot & cold water available; adequate pressure	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		49. Plumbing installed; proper backflow devices	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		50. Sewage & waste water properly disposed	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		51. Toilet facilities: properly constructed, supplied, & cleaned	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		52. Garbage & refuse properly disposed, facilities maintained	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		53. Physical facilities: installed, maintained, & clean	<input type="checkbox"/> <input type="checkbox"/>
N	OUT		54. Adequate ventilation & lighting; designated areas used	<input type="checkbox"/> <input type="checkbox"/>

IN = in compliance OUT = not in compliance N/O = not observed
 N/A = not applicable COS = corrected on-site R = repeat violation

Establishment Name [REDACTED]

Establishment Address [REDACTED]

OBSERVATIONS	25 DCMR	CORRECTIVE ACTIONS
36 - There is no pest service invoice available (CORRECT VIOLATION WITHIN 5 CALENDAR DAYS)	3210 2	The licensee shall maintain a copy of the establishment's professional service contract and service schedule, which documents the following information: (a) Name and address of its licensed pest exterminator / contractor; (b) Frequency of pest extermination services provided under the contract; and (c) Date pest extermination services were last provided to the establishment
36 - Mice droppings and one trapped mice observed (CORRECT VIOLATION WITHIN 5 CALENDAR DAYS)		The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by: (c) Using methods, if pests are found, such as trapping devices or other means of pest control as specified in sections 3402, 3410 and 3411
37 - Prepackaged foods are stored less than six inches above the ground (CORRECT VIOLATION WITHIN 45 CALENDAR DAYS)	816 1	Except as specified in sections 816 2 and 816 3, food shall be protected from contamination by storing the food: (a) In a clean, dry location; (b) Where it is not exposed to splash, dust, or other contamination; and (c) At least fifteen centimeters (15 cm) or six inches (6 in) above the floor

TEMPERATURES

Item/Location	Temp	Item/Location	Temp	Item/Location	Temp	Item/Location	Temp
Hot Water (Handwashing Sink - toilet room)	102.0F						

Inspector Comments:
 CORRECT ITEMS STATED WITHIN 5-DAYS
 CORRECT ITEMS STATED WITHIN 45-DAYS
 If you have any questions, please call area supervisor Mr. Ronnie Taylor at 202-442-9037.

Person-in-Charge (Signature) [REDACTED] 02/26/2015
Date
(Print)

Inspector (Signature) Douglas Dalier 082
(Print) Badge # 02/26/2015
 Date



INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health

1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

Home Goods Store #3

PREPACKAGED FOOD ONLY
HUNTINGTON BEACH, CA 92647

Record ID: [REDACTED]
Inspection Date: 01/09/2013
Reinspection Date: 01/22/2013

Mailing Address:
ON FILE

Type of Facility: 0391-PKGD FOOD MKT OR
CONFECTIONARY 1-1999 SQ FT
Service: A01-ROUTINE INSPECTION
B Freeman, REHS
ENVIRONMENTAL HEALTH SPEC II
(714) 981-9070
7:30-8:30 a.m.

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

OPENING COMMENTS

FC00 - OPENING COMMENT

A review of this facility's program element was conducted. This facility was observed not to be selling or storing potentially hazardous food of unpackaged foods. The program element of this facility will be changed to prepackaged non-potentially hazardous food between 25 and 300 feet of food displat.

MINOR VIOLATIONS

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects

Rat droppings were observed on the storage shelving in the storeroom where the prepackaged food is stored. Construct, equip, maintain, and operate the food facility so as to prevent the entrance and harborage of rodents. Use any approved method for eliminating rodents from the facility.

A thorough inspection for vermin activity and contaminated food was conducted and no further evidence was observed.

COMMENTS

FC99 - NOTES

This inspection report was reviewed with: The manager [REDACTED]
The management of this facility has provided a current e-mail address and has agreed to receive a copy of this report via e-mail. This report will be sent via e-mail. The person in charge was instructed to contact this office if they do not receive the e-mail.

Change of Ownership: No

Hot water at the mop-sink was good at above 120 F

Retain a copy of the most recent inspection report on the premises available for review at the request of the public.

SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.

The "Reinspection Due-Pass" Notification Seal was posted today in a prominent

FCC0 - REINSPECTION SCHEDULED

A reinspection is scheduled on the date noted at top of the inspection report. A reinspection notification seal was posted today in a prominent location.

REINSPECTION FEES:

Fees are assessed for second or greater reinspections. The purpose of these fees is to shift costs away from compliant operators and impose fees on those facilities that fail to readily comply with the applicable laws and

I declare that I have examined and received a copy of this inspection report.



INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health

1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

PREPACKAGED FOOD ONLY
HUNTINGTON BEACH, CA 92647

Record ID: [REDACTED]
Inspection Date: 01/09/2013

regulations. The amount of the fee is to cover all of the costs associated with the service and the time charged includes travel time. The fees until June 30, 2013 are as follows:

- 1st Reinspection: NO FEE
- 2nd Reinspection or Greater, during normal work hours:
\$25.75 per quarter-hour or fraction thereof
- 2nd Reinspection or Greater, during other hours, including weekends and holidays:
\$38.63 per quarter-hour or fraction thereof
- Notice of Violation Reinspection: \$305.00

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____

Date _____

Restaurant Name (optional)

Near (Address, City & State, or Zip)

HOME

ABOUT

CONTACT

Office Supply Store #1



Bellflower, CA 90706-6202



Exclusive Offer
 Double all your cash back at the end of your first year. No annual fee*
 THIS AND MORE >
 *For new cardmembers only. See Terms.

11/10/2011 Violation 37

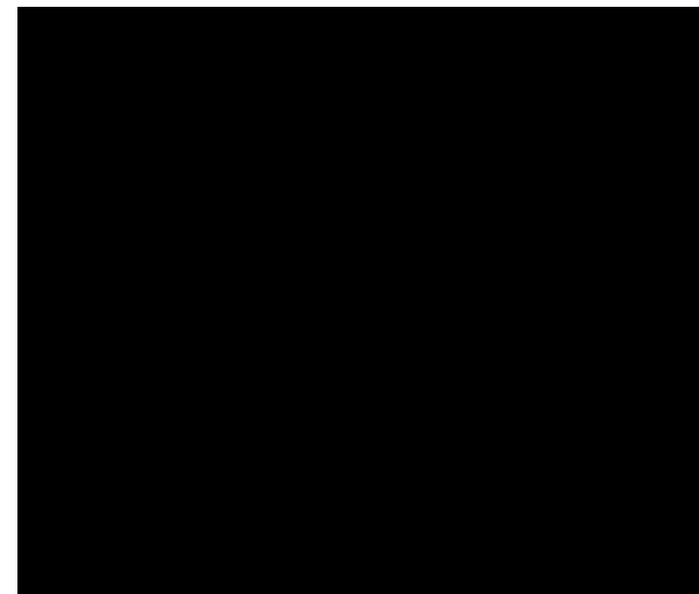
PURE FOOD / SPOILAGE (MINOR) Examples Include: Meat, fish or poultry products that have the appearance of spoilage (), PHF oxygen reduced package exceeds a "use by" date, Food-infesting insects (e.g., grain beetles, meal moths, gnats, ants) are observed in food or fruit flies in liquor bottle, Unopened soda can stored in ice bin (customer edible ice), Swollen can or significantly dented can at the rim / seam, Condensate from refrigerator dripping onto raw meat / poultry / uncut fruits and vegetables, Hair found in food, Lining food containers with newspaper*

Violation 54

DETERIORATED / UNAPPROVED MATERIALS Examples Include: Missing base coving, floor tiles or grout between tiles, Unapproved floor material (carpet / vinyl tiles) in food areas, Damaged walls (peeling paint / plaster / not smooth / loose FRP / metal flashing), Missing electrical or light-switch cover, Missing or unapproved type of ceiling panels, Deteriorated caulking at the wall and sink junction, Deteriorated floors / walls / ceilings in the walk-in refrigerator(s) (aggregate / gravel exposed), Cardboard or unapproved floor boards used on floors, Holes / cracks in the wall or ceiling that may promote a vermin harborage

Violation 55

NOT CLEAN Examples Include: Accumulated food debris, grease, mold, or dirt on floors, walls, ceilings including inside of walk-in, Make-up air vent / ceiling vent / ceiling fan accumulated



NEARBY RESTAURANTS

Within 2 Miles



with grease or dust, Cockroaches (live or dead) / rodent droppings or urine on floors, walls or ceilings

Violation 67

TOILETS / TOILET ROOM DISREPAIR / INADEQUATE # / DOOR NOT SELF-CLOSING / NOT CLEAN / TOILET TISSUE

Examples Include: One of the available toilets is damaged, leaking, clogged or inoperative, Urinal is missing in toilet room of a facility that has on-site liquor consumption, Separate men's and women's toilets are not available in a facility that serves alcohol for on-site consumption, No toilet tissue or missing toilet tissue dispenser, Door removed or propped open at the toilet room, Missing or damaged self-closing device, Unclean toilet facilities

[REDACTED]

7/6/2010

Violation 54

DETERIORATED / UNAPPROVED MATERIALS Examples Include: Missing base coving, floor tiles or grout between tiles, Unapproved floor material (carpet / vinyl tiles) in food areas, Damaged walls (peeling paint / plaster / not smooth / loose FRP / metal flashing), Missing electrical or light-switch cover, Missing or unapproved type of ceiling panels, Deteriorated caulking at the wall and sink junction, Deteriorated floors / walls / ceilings in the walk-in refrigerator(s) (aggregate / gravel exposed), Cardboard or unapproved floor boards used on floors, Holes / cracks in the wall or ceiling that may promote a vermin harborage

DATA SOURCE

This data was downloaded from the local health department for this restaurant. See our **FAQ** for a full list of our data sources.

Last Updated 11/10/2011 5:00:00 AM

Try it on before you pay it off.
 With Pay after Delivery, your payment won't leave your bank account for 14-days after you check out. [Terms Apply.](#)

Sign up for Free

Restaurant Name (optional)

Near (Address, City & State, or Zip)

HOME

CONTACT

Office Supply Store #2



[REDACTED] Huntington Park, CA 90255-3138



9/25/2009 **Violation 37**

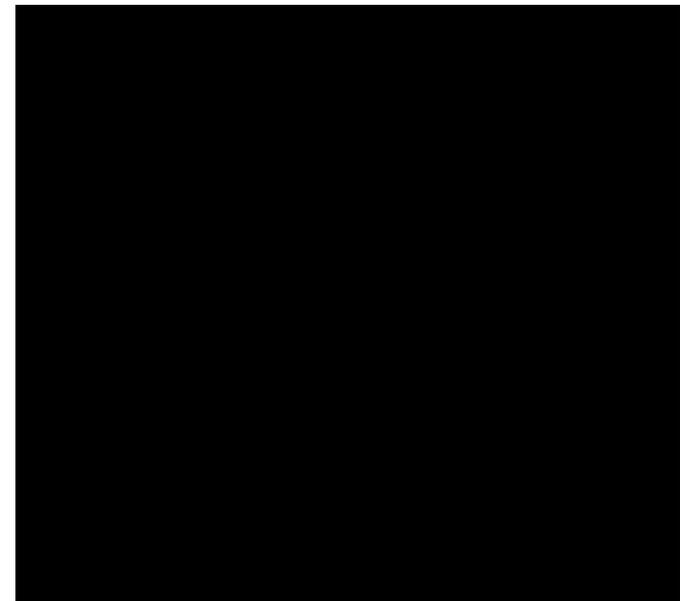
PURE FOOD / SPOILAGE (MINOR) Examples Include: Meat, fish or poultry products that have the appearance of spoilage (), PHF oxygen reduced package exceeds a "use by" date, Food-infesting insects (e.g., grain beetles, meal moths, gnats, ants) are observed in food or fruit flies in liquor bottle, Unopened soda can stored in ice bin (customer edible ice), Swollen can or significantly dented can at the rim / seam, Condensate from refrigerator dripping onto raw meat / poultry / uncut fruits and vegetables, Hair found in food, Lining food containers with newspaper*

Violation 48

NON-FOOD-CONTACT SURFACES NOT CLEAN (MINOR) Examples Include: Accumulated grease or food debris on the non-food contact surfaces of equipment, shelving, or cabinets, Dirty fan guards or door gaskets in walk-in refrigerator, Dirty shelving in refrigeration unit with no direct food contact

Violation 62

LOW RISK HOT / WARM WATER VIOLATIONS Examples Include: Water throughout the restaurant is measured at 110-119°F, chemically sanitizing multi-use utensils (24 hours to abate), All non critical sinks not meeting the required minimum hot water temperatures (120°F for food prep / mop OR 100°F for handwash sink), Water is less than 120°F at a pre-packaged food facility (24 hours to abate), Water temperature measured at a critical food preparation or mop sink is between 110-119°F or 90-99°F at a critical handwash sink, Manual warewashing solution between



NEARBY RESTAURANTS

Within 2 Miles



100-110°F (Unless otherwise specified by detergent manufacturer's instruction label)

[REDACTED]

[MORE...](#)

DATA SOURCE

This data was downloaded from the local health department for this restaurant. See our [FAQ](#) for a full list of our data sources.

Last Updated 1/1/2000 5:00:00 AM

	\$21.99	\$29.99	\$35	\$52.59	\$53.99	
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INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health

1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

Party Store #1

PREPACKAGED FOOD ONLY
HUNTINGTON BEACH, CA 92647

Record ID: [REDACTED]
Inspection Date: 01/07/2013
Reinspection Date: 01/14/2013

Mailing Address:
ON FILE

Type of Facility: 0391-PKGD FOOD MKT OR
CONFECTIONARY 1-1999 SQ FT
Service: A01-ROUTINE INSPECTION
B Freeman, REHS
ENVIRONMENTAL HEALTH SPEC II
(714) 981-9070
7:30-8:30 a.m.

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

OPENING COMMENTS

FC00 - OPENING COMMENT

This facility seems to have changed ownership from [REDACTED]. Please fill out and provide the new Health Permit application to this Agency.
This facility has on display under 300 feet of non-potentially hazardous food. This facility will have a program element designated as limited Prepackaged food.

MINOR VIOLATIONS

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects

Multiple Rodent droppings were observed on the floor of the storeroom where packaged food is stored. Construct, equip, maintain, and operate the food facility so as to prevent the entrance and harborage of rodents. Use any approved method for eliminating rodents from the facility.

NOTE: A thorough inspection for vermin activity was conducted and no further evidence was observed.

FC40 - Facility not Fully Enclosed/Open Door/Air Curtain

Discontinue propping open the front door to the outside. Maintain the door closed at all times except during passage. Construct, equip, maintain and operate the food facility so as to prevent the entrance and harborage of animals, birds and vermin, including, but not limited to, rodents and insects.

FC43 - Lack of/Improper Handwashing/Handwashing Sup.

No warm water was available from the sink in one of the new restrooms. Handwashing facilities shall be equipped to provide warm water under pressure for a minimum of 15 seconds through a mixing valve or combination faucet.

COMMENTS

FC99 - NOTES

This inspection report was reviewed with: The manager, [REDACTED].
The management of this facility has provided a current e-mail address and has agreed to receive a copy of this report via e-mail. This report will be sent via e-mail. The person in charge was instructed to contact this office if they do not receive the e-mail.

Change of Ownership: Yes

All food is prepackaged and non-potentially hazardous.

The "PASS" Notification Seal was posted today in a prominent location.

Retain a copy of the most recent inspection report on the premises available for review at the request of the public.

SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.

FCC0 - REINSPECTION SCHEDULED

I declare that I have examined and received a copy of this inspection report.



INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
 1241 EAST DYER ROAD, SUITE 120
 SANTA ANA, CA 92705-5611
 (714) 433-6000
 ochealthinfo.com/eh

PREPACKAGED FOOD ONLY
 [REDACTED]
HUNTINGTON BEACH, CA 92647

Record ID: [REDACTED]
 Inspection Date: 01/07/2013

A reinspection is scheduled on the date noted at top of the inspection report. A reinspection notification seal was posted today in a prominent location.

REINSPECTION FEES:

Fees are assessed for second or greater reinspections. The purpose of these fees is to shift costs away from compliant operators and impose fees on those facilities that fail to readily comply with the applicable laws and regulations. The amount of the fee is to cover all of the costs associated with the service and the time charged includes travel time. The fees until June 30, 2013 are as follows:

- 1st Reinspection: NO FEE
- 2nd Reinspection or Greater, during normal work hours:
 \$25.75 per quarter-hour or fraction thereof
- 2nd Reinspection or Greater, during other hours, including weekends and holidays:
 \$38.63 per quarter-hour or fraction thereof
- Notice of Violation Reinspection: \$305.00

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____ Date _____



INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health

1241 EAST DYER ROAD, SUITE 120
SANTA ANA, CA 92705-5611
(714) 433-6000
ochealthinfo.com/eh

Party Supply Store #2

[REDACTED]
SANTA ANA, CA 92703

Record ID: [REDACTED]
Inspection Date: 02/26/2014
Reinspection Date:

Type of Facility: 0391-PKGD FOOD MKT OR
CONFECTIONARY 1-1999 SQ FT
Service: A01-ROUTINE INSPECTION
L Adourian
ENVIRONMENTAL HEALTH SPEC I
(657) 600-7783

Mailing Address:

ON FILE

THE ITEMS NOTED BELOW WERE OBSERVED DURING THE COURSE OF A SITE VISIT. ANY VIOLATIONS OBSERVED MUST BE CORRECTED.

MINOR VIOLATIONS

FC39 - Evidence of Vermin Activity/Presence of Animals/Insects

A bird in a bird cage was observed to be kept in the employee area in front of the candy aisle. Live animals, birds, and fowl shall not be kept or allowed in any food facility except those that are exempt from California Retail Food Code as described in Section 114259.

FC40 - Facility not Fully Enclosed/Open Door/Air Curtain

Observed the front doors to be propped open. Maintain the door closed at all times except during immediate passage. Alternatively, if ventilation is desired, provide an approved screen door. Maintain the food facility fully enclosed to prevent the entrance and harborage of animals and insects.

FC46 - Unapproved Pesticides/Chemicals/Labeling

An insecticide not approved for use in a commercial food facility was observed to be stored in the customer area near the front entrance. Store and use all poisonous substances, detergents, bleach, cleaning compounds, and all other injurious or poisonous materials in a manner that is not likely to cause contamination or adulteration of food.

FC47 - Lack of/Unsanitary/Condition Walls/Floors/Ceilings

1. Accumulated dust, trash, and/or grime was observed beneath the upright cooler. Thoroughly clean and maintain the floors (including the floor sinks and drains), walls, and ceilings in a clean and sanitary manner.
2. A hole was observed in the ceiling in the janitorial room. Effectively seal all crevices (i.e. gaps and cracks) throughout the facility to eliminate potential vermin (including insects) harborage.
3. Sections of base coving were observed to be missing in the janitorial room. Provide an integrally designed base coving with a 3/8-inch radius at the juncture of the floor and wall. The coving must extend up the wall at least 4 inches.

FC49 - Signs/Labels/Menu Board/Trans Fat-Missing/Incorrect/Lack of Food Handler Card

A handwashing sign was not observed to be posted at the handwashing sink in the restroom. Post a legible sign in a conspicuous location at each handwashing sink directing attention to the need to thoroughly wash hands.

*A handwashing sticker was provided on this date.

FC51 - Last Report Unavailable/Consumer Access

The last inspection report was unavailable for review at the public's request. Retain a copy of the most recent inspection report on the premises available for review at the request of the public. A copy of the most recent Health Inspection Report is available at www.ocfoodinfo.com.

COMMENTS



INSPECTION REPORT
County of Orange, Health Care Agency, Environmental Health
 1241 EAST DYER ROAD, SUITE 120
 SANTA ANA, CA 92705-5611
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[REDACTED]
SANTA ANA, CA 92703

Record ID: [REDACTED]
 Inspection Date: 02/26/2014

FC99 - NOTES Effective January 1, 2014, California Assembly Bill No. 1252 requires the food employees to use suitable utensils, such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment, when contacting ready-to-eat food. For more details, please visit our website at www.ocfoodinfo.com or contact your Environmental Health Specialist.

This inspection report was reviewed with [REDACTED], owner.

It was agreed that a copy of this report will be mailed to the address provided. The person in charge was directed to call this office if the report is not received within 7 business days. Reports and other valuable information can be found at www.ocfoodinfo.com. A copy of the most recent routine inspection report conducted shall be maintained at the food facility and be made available to a consumer upon request. SIGNATURE IS NOT REQUIRED; PLEASE RETAIN THIS COPY FOR YOUR FILES.

Change of Ownership: No

Food Temperatures:

-upright cooler: packaged milk 45F

Hot water recorded at 120F

Dish/Utensil Sanitation method: n/a

Sanitizer level for wiping cloths: n/a

F100 - "PASS" SEAL POSTED

I declare that I have examined and received a copy of this inspection report.

Print Name and Title _____

Signature _____ Date _____

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-019

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Clean in place (CIP) definition

Issue you would like the Conference to consider:

Clean-in-Place (CIP) is common in liquid food and beverage processing, but is poorly defined and understood in the retail and food service industries. New and novel dispensing equipment and systems being introduced to the industry both in the U.S. and internationally create the need to better define and characterize hazards and reasonable interventions for liquid food preparation and dispensing systems. The process involves more than just rinsing wetted surfaces; it is not just "cleaning" - as the current CIP acronym infers. Chemicals used to clean and sanitize require kinetics in one or many forms to improve efficacy. When food contact surfaces are cleaned and sanitized in a dishwasher, or a three compartment sink, kinetics are added in the forms of high pressure sprays, or scrubbing, or turbulent flows in a power wash type sink. Kinetics (in some form) is also required for plumbed systems that handle liquid foods. Cleaning and sanitizing are discrete sequential steps, where cleaning precedes the application of an approved food contact surface sanitizer on the food contact surface of the equipment. The process is better defined as clean *and* sanitize in place (CSIP), as one cannot sanitize an unclean surface. Pronounced "sea-sip" (two syllables instead of three), CSIP systems are plumbed systems that typically use valves, pumps and control logic to sequentially wash and then sanitize food contact surfaces that are essentially, plumbing lines for liquid foods and beverages.

Public Health Significance:

Due to their plumbing line form, their internal wetted surfaces cannot be readily accessed for inspection or for manual cleaning and sanitizing. This presents a unique hazard to food safety and requires focused safety criteria to ensure reasonable continuous food safety. Using an acronym that has the first letter for each critical sequential step, yet fewer pronounceable syllables can add clarity to its unique safety function without any additional cost to industry or consumers. Further, it is well known that you cannot effectively sanitize contaminated surfaces. Consequently, food contact surfaces must be cleaned before sanitizers are applied. In food and beverage processing, surfactants that may not be

categorized as detergents are often used for the initial cleaning step. Accordingly, instead of calling cleaners "detergents", it is more appropriate use the genus solutions that have reduced surface tensions, known to be more effective than water by itself; *surfactants*. Further, "rinsing" is only needed when the listing and or label instructions indicate it is needed. Some surfactants (and now sanitizers too) are GRAS and others have K1's or are secondary food additives or ingredients and accordingly, require no rinsing after use and before introduction of liquid foods.

References link: <https://www.yousendit.com/download/ZWJWR0IVNXZGR0V3anNUQw>
CSIP processes comprise a PRIORITY ITEM (P) risk categorization.

Recommended Solution: The Conference recommends...:

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

Section 1-201.10

Clean and sanitize in place (CSIP)^P

(1) "CSIP" means cleaned and sanitized in place by the sequential circulation or forceful flowing by mechanical means through a piping system, of a ~~detergent~~ surfactant solution, water rinse (when required), and SANITIZING solution onto ~~or over~~ EQUIPMENT or through wetted food contact surfaces that require cleaning and sanitizing, such as the method used, in part, to clean and SANITIZE wetted liquid food contact surfaces of food equipment that feature liquid food plumbing lines such as dispensing freezers a frozen-dessert machine or milk or juice dispensers and similar equipment.

(2) "CSIP" does not include the cleaning of EQUIPMENT such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CSIP system.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-020

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Add a definition for In-place cleaning (IPC)

Issue you would like the Conference to consider:

In-place cleaning (IPC) is not the same as clean in place (CIP) or clean and sanitize in place (CSIP). Section 1-201.10 of the 2013 FDA Food Code has a definition for CIP. Section 4-501.112 Part (B) of the FDA Food Code makes reference to in-place cleaning (IPC) which is otherwise not defined in the code. Rather, there is a circular reference made back to CIP. Because they are different processes, IPC needs its own definition.

Public Health Significance:

Having clear, unambiguous definitions for food safety systems is critical to ensuring that everyone has the same idea of what is needed for reasonable safety. This is the reason that section 1-201.10 of the food code is so important and why a new definition needs to be added to the FDA Food Code to differentiate two completely separate concepts that (unfortunately) are known to use the same three words, albeit, in different order.

An *in-place cleaning* (IPC) process is a *manual* cleaning and sanitizing process that is carried out without moving the food equipment or food contact surfaces to a sink or into a dishwasher. Examples here include motorized meat slicers, band saws and grinders, whether for meat or coffee. Another example is a large cutting board or a large food display tray that does not fit into a sink or dishwasher, thus requiring IPC.

Clean in place (CIP) systems have integral plumbing lines for the conveyance of liquid foods. If the internal surfaces of these liquid food or beverage plumbing lines do not have access (inspection) openings to enable inspection, and access to enable manual cleaning and sanitization of its surfaces, then a sequential clean and sanitize in place (CSIP or CIP) system is required. A more accurate description of these system is a *clean and sanitize in place* systems, or CSIP (pronounced "*sea-sip*" using only two syllables as compared to three syllables for *C.I.P.*). CSIP systems are similar to IPC only in the sense that the food contact surfaces are cleaned and sanitized without moving them to the scullery or into a dish machine. CSIP systems are *plumbed* systems designed to *automatically* or *semi-*

automatically clean and disinfect internal food contact surfaces that are otherwise inaccessible using process validated cleaning and sanitizing protocols. Some equipment can have CSIP integrated into its design and is comprised of a series of valves, pumps and/or control logic with the sequential application of cleaning and then sanitizing solutions, and are free draining. Other CSIP systems depend upon connection to ancillary CSIP equipment that will flush throughout the (food contact surface) plumbing system of the food/beverage equipment, cleaners and sanitizers in sequence, to remove accumulated soils and/or biofilms. These systems are self-draining to carry away dislodged food soils and other contaminants along with the cleaning and sanitizing process solutions. Examples include the internal plumbing and other food contact surfaces in dispensing freezers for soft-serve ice cream, yogurt and similar equipment with inaccessible multi-use food contact surfaces in the form of internal beverage lines, fittings and valves and energy transfer surfaces. Additional examples include internal surfaces of ice machines such as its feed water lines, harvest plates and sumps, and internal and external plumbed beverage lines for food equipment that prepares, processes, packages and/or dispenses milk or milk products, juices, soda, beer, wine and spirits.

IPC comprises a PRIORITY foundation (Pf) item.

Recommended Solution: The Conference recommends...:

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

Section 1-201.10

"In-place cleaning" (IPC) means the manual cleaning of Food Equipment and Food Contact surfaces without moving the equipment or food contact surface to the scullery, a dish washer or sink.^{Pf}

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-021

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

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Change abbreviation for CIP to CSIP (clean and sanitize in place)

Issue you would like the Conference to consider:

The acronym "CIP" as defined in section 1-201.10 of the 2013 FDA Food Code could be improved to better articulate the process by reducing one syllable and adding a letter. Instead of having to say each letter aloud, readers can refer to the process with greater descriptive precision by referring to the clean and sanitize in place process as "sea-sip" (CSIP).

Public Health Significance:

Having clear, unambiguous definitions for food safety systems is critical to ensuring that everyone has the same idea of what is needed for reasonable safety. This is the reason that section 1-201.10 of the Food Code is so important and why more descriptive index words should be used whenever possible.

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 FDA Food Code modified language be incorporated as follows:

Section 1-201.10 of the FDA food Code is modified to change the index word from CIP to CSIP for the descriptive process of cleaning and then sanitizing the internal liquid food plumbing lines in food equipment.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-022

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Update the definition of Vending Machines

Issue you would like the Conference to consider:

New payment transaction technology is available whereby products can be dispensed by a vending machine upon completion of a digital transaction. The current definition for "Vending Machines" in the 2013 FDA Food Code section 102.10 (B) needs an update to remain current.

Public Health Significance:

Old-fashioned coin and currency based vending transactions are being replaced with "smart" digital transactions. Safety and convenience conscious consumers are often "cashless" and rely upon new technology for their purchase of goods including food and beverage. Revising the definition to include new payment technologies will reduce confusion as to its acceptability.

Recommended Solution: The Conference recommends...:

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

Section 1 201.10

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or upon completion of a digital transaction or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-023

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

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Issue History:

This is a brand new Issue.

Title:

Shellfish Retail Record Keeping

Issue you would like the Conference to consider:

Enhancing record keeping at retail establishments.

Public Health Significance:

The incidence of *Vibrio parahaemolyticus* (Vp) illness associated with molluscan shellfish consumption is on the increase and continues to be a significant challenge to state and federal health authorities. In 2013 the Interstate Shellfish Sanitation Conference (ISSC) incorporated language into the National Shellfish Sanitation Program requiring increased state regulatory action in response to *V.p.* illnesses. The regulatory response outlined in these new requirements is directly linked to the number of reported *V.p.* illnesses. This approach requires timely investigation of *V.p.* cases by State health officials to determine product source. In many cases, States have been unable to determine the source of the shellfish due to inadequate record keeping as required by Section 3-203.12 of the 2013 FDA Food Code. The National Shellfish Sanitation Program (NSSP) recognizes this requirement as a critical violation. This change would create consistency between the Food Code and the NSSP.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending:

1) Modification of Section 3-203.12(A) of the 2013 FDA Food Code as indicated below from a Priority Foundation to a Priority Violation (language to be added is underlined; language to be deleted is in strikethrough format).

3-203.12 Shellstock, Maintaining Identification.

(A) Except as specified under Subparagraph (C) (2) of this section, SHELLSTOCK tags or labels shall remain attached to the container in which the SHELLSTOCK are received until the container is empty. P~~f~~ P

2) The FDA begin discussions with the ISSC and Conference for Food Protection to identify steps that can be taken to enhance implementation and enforcement of shellfish record keeping at retail establishments.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-024

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Alignment of the Food Code with the FDA Juice HACCP Retail Definition

Issue you would like the Conference to consider:

The sale of packaged, raw, untreated, or cold pressed juices is allowed under the 2013 FDA Food Code by a retail food establishment. However, the FDA Food Code does not address where a retail food establishment may sell untreated packaged juice. The FDA Juice Hazard Analysis and Critical Control Point (HACCP) regulation and associated guidance does have specific conditions under which packaged untreated juice may be sold under the retail exemption, specifically that any offsite sales must be conducted at a location owned by the retail establishment. Retail regulators operating under FDA Food Code are being challenged by food establishments that want to package untreated juice and then sell it "offsite" via a cooperative arrangement with a health club, health food store or a vending unit as an extension of the retail establishment. A clear link needs to be established in the Food Code & 21 Code of Federal Regulations (CFR) 120 Juice HACCP sections regarding retail sales.

Public Health Significance:

Providing a link between the FDA Food Code and 21 CFR part 120 Juice HACCP requirements for the sale of packaged juice allows for regulators to apply the same criteria when evaluating the safety of a proposed packaged juice process in regards to the retail exemption. Industry benefits from the uniform application of the retail exemption for treated juice by not having differing sets of standards from jurisdiction to jurisdiction. The need to treat packaged juice and the public health risk associated with consumption of untreated packaged juice has been cited in many studies.

Annex 3 of the FDA Food Code in Section 3-801.11 states: There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as *Cryptosporidium*, Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Vibrio cholera*.

The Summary in *the Federal Register / Vol. 66, No. 13 / Friday, January 19, 2001 / Rules and Regulations for Juice* states the need for the treatment of packaged juice.

"The Food and Drug Administration (FDA or the agency) is adopting final regulations to ensure the safe and sanitary processing of fruit and vegetable juices. The regulations mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of these foods. HACCP is a preventive system of hazard control. FDA is taking this action because there have been a number of food hazards associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products are safe."

In a September 22, 2005 *Guidance for Industry Letter to State Regulatory Agencies and Firms That Produce Treated (but not Pasteurized) and Untreated Juice and Cider*, the FDA stated the concern regarding continuing outbreaks of foodborne illness associated with the consumption of treated (but not pasteurized) and untreated juice and cider. The letter reminds regulators and industry of actions that the FDA recommends processors take to enhance the safety of these products with the following reason:

"Recent illness outbreaks due to treated (but not pasteurized) and untreated apple cider occurred in Ohio in 2003, and in New York state in 2004. In addition, a multi-state illness outbreak associated with treated (but not pasteurized) orange juice occurred this year. These outbreaks highlight the need for processors to ensure that they are taking all appropriate steps to comply with applicable food safety requirements."

References:

Federal Register CFR 21 Part 120:

<https://www.federalregister.gov/articles/2001/01/19/01-1291/hazard-analysis-and-critical-control-point-haccp-procedures-for-the-safe-and-sanitary-processing-and>

Guidance for Industry Letter to State Regulatory Agencies and Firms:

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm072508.htm>

Hazard Analysis Critical Control Point (HACCP), National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Recommendations:

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm073540.htm>

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the 2013 FDA Food Code be amended to include the following (new language is in underline format):

3-404.11 Treating Juice.

JUICE PACKAGED in a FOOD ESTABLISHMENT shall be:

(A) Treated under a HACCP PLAN as specified in ¶¶ 8-201.14(B) -(E) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; ^P or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance: ^{Pf}

(1) As specified under § 3-602.11, ^{Pf} and

(2) As specified in 21 CFR 101.17(g) Food labeling, warning, notice, and safe handling statements, JUICES that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and person with weakened immune systems." ^{Pf}

(C) And only at locations that are considered to be retail by the definition of a retail establishment as specified in 21 CFR 120.3 (l) and qualify for the retail exemption as specified in 21 CFR 120.3 (j) (2) (ii).

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Supporting Attachments:

- "CFR 120.3"

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§120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, §101.9(j)(18)(vi) of this chapter, and parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part. The following definitions shall also apply:

- (a) *Cleaned* means washed with water of adequate sanitary quality.
- (b) *Control* means to prevent, eliminate, or reduce.
- (c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.
- (d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.
- (e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
- (f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with §120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.
- (g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
- (h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.
- (i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.
- (j)
 - (1) *Processing* means activities that are directly related to the production of juice products.
 - (2) For purposes of this part, processing does not include:
 - (i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and
 - (ii) The operation of a retail establishment.
- (k) *Processor* means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.
- (l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending.
- (m) *Shall* is used to state mandatory requirements.
- (n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.
- (o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.
- (p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.
- (q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-025

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Amend Food Code – Nutrition Labeling of Standard Menu Items in Restaurants

Issue you would like the Conference to consider:

The 2013 FDA Food Code should be amended to be consistent with 2010 federal nutrition labeling requirements for foods served or offered for sale in restaurants and similar retail food establishments. The Food, Drug, and Cosmetic Act now requires chain retail food establishments with 20 or more locations to provide calorie and other information for standard menu items (21 U.S. Code § 343(q)(5)(H)(i) to (iii)). Updating the Food Code will encourage state and local food regulatory agencies to implement the law.

Public Health Significance:

Nearly two thirds of adults and one third of children are overweight or obese.¹ Americans consume, on average, one-third of their calories from eating out.² Studies link eating out with obesity, higher caloric intake, higher intake of calories, saturated fat and fewer nutrients.³ Children typically eat almost twice as many calories when they eat out compared to at home.

Studies show that providing nutrition information at restaurants can help Americans make lower calorie choices and spur the reformulation of existing food items and the introduction of nutritionally improved items. A recent Harvard study found restaurant menu calorie labeling could prevent up to 41,000 cases of childhood obesity and could save over \$4.6 billion in healthcare costs over ten years.⁴

Americans need nutrition information to manage their weight and reduce the risk of or manage heart disease, diabetes, or high blood pressure, which are leading causes of death, disability, and high health-care costs.

Trade groups, restaurant chains, other food establishments, and over 100 nutrition and health organizations and professionals support menu labeling.

Covered food establishments will be required in 2016 to provide calorie labeling on the menu and menu board for standard menu items, along with a succinct statement on general nutrition advice, and provide additional written nutrition information.

Incorporating this provision in the Food Code will assist regulatory authorities in adding to their restaurant inspections a quick check to determine if the required information is available and presented in a manner that is easy for consumers to see and read (i.e., that it is provided in the required format).

References

¹ CDC/NCHS, National Health and Nutrition Examination Survey, 2012.
<http://www.cdc.gov/nchs/nhanes.htm>

² Todd J, et al. The Impact of Food Away from Home on Adult Diet Quality USDA, 2010.
http://www.ers.usda.gov/media/136609/err90_1_.pdf

³ Center for Science in the Public Interest. Research Review: Effects of Eating Out on Nutrition and Body Weight, updated October 2008. https://cspinet.org/new/pdf/lit_rev_eating_out_and_obesity.pdf

⁴ Gortmaker SL, et al. Three Interventions That Reduce Childhood Obesity Are Projected to Save More Than They Cost to Implement. November 2015, *Health Affairs*, 34, no. 11 (2015):1304-1311. <http://content.healthaffairs.org/content/34/11/1932.full?ijkey=InFXpx4AIM506&keytype=ref&siteid=healthaff>

Recommended Solution: The Conference recommends...:

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

Section 3-602.11 Food Labels

(E) FOODS served or offered for sale in restaurants or similar retail FOOD ESTABLISHMENTS not otherwise exempted in the Federal Food, Drug, and Cosmetic Act § 403(q)(5)(H) be labeled according to 21 CFR 101.11.

Annex 3 - Public Health Reasons/Administrative Guidelines

Nutrition Labeling

I. The following foods need not comply with nutrition labeling in the CFR referenced in subparagraph 3-602.11(B)(6) if they do not bear a nutrient claim, health claim, or other nutrition information:

~~(C) Foods served in food establishments with facilities for immediate consumption such as restaurants, cafeterias, and mobile food establishments; and foods sold only in those establishments;~~

~~(D) Foods similar to those specified in the preceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:~~

~~(1) Ready-to-eat but not necessarily for immediate consumption;~~

~~(2) Prepared primarily in the food establishment from which it is sold, and~~

~~(3) Not offered for sale outside the food establishment;~~

~~(E) Foods of no nutritional significance such as coffee;~~

~~(D)(F)~~ Bulk food for further manufacturing or repacking; and

~~(E)(G)~~ Raw fruits, vegetables, and fish.

Annex 7 - Model Forms, Guides, and Other Aids

Form 3-A, Food Establishment Inspection Report

37. Food properly labeled; original container; nutrition labeling

Guide 3-B, Instructions for Marking the Food Establishment Inspection....

Food Identification

37. Food properly labeled; original container; nutrition labeling

Packaged foods and foods served or offered for sale in restaurants or similar retail food establishments are required to conform to specific labeling laws unless otherwise exempted.

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Supporting Attachments:

- "CSPI Menu Labeling Fact Sheet (Redacted)"
- "Nutrition Labeling on Menus Final Rule 21 CFR Part 101.11"
- "Sample Menu Board 1"
- "Sample Menu Board 2 (Redacted)"

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.

Nutrition Labeling at Restaurants, Supermarkets & Other Food Service Establishments

Congress passed a national law in March 2010 requiring calories to be posted on menus, menu boards, and for food on display at restaurants, supermarkets, convenience stores, and other food service establishments with 20 or more outlets [21 U.S.C. 343(q)(5)(H)].

Menu labeling allows Americans to exercise personal responsibility and make informed choices for a growing part of their diets.

People want nutrition information from food service establishments: **80% of Americans support menu labeling in chain restaurants; 77% want calorie labeling at convenience stores; and 81% favor having supermarkets provide calorie information for their prepared, restaurant-type foods.**¹

Eating out is a big and problematic part of Americans' diets

Americans consume, on average, one-third of their calories from eating out.² Studies link eating out with obesity and higher caloric intakes.³

Children typically eat almost twice as many calories when they eat a meal at a restaurant compared to a meal at home.⁴ **When eating out, people eat more saturated fat and fewer nutrients**, such as calcium and fiber, than at home.^{2,3}

People need nutrition information to manage their weight and reduce the risk of or manage heart disease, diabetes, or high blood pressure, which are leading causes of death, disability, and high health-care costs.

SIGNATURE SIDES			
RED BEANS & RICE	230	680	
COLE SLAW	220	570	
CAJUN FRIES	260	770	REG \$2.39
MASHED POTATOES	110	450	
GREEN BEANS	40	120	LG \$4.29
CAJUN RICE	170	450	
ONION RINGS	280	560	
CORN ON THE COB	190	380	
BISCUITS			
(1)	\$5.89	260	(6) \$4.99 1560 (12) \$7.99 3120



Without nutrition information, it is difficult to compare options and make informed decisions.

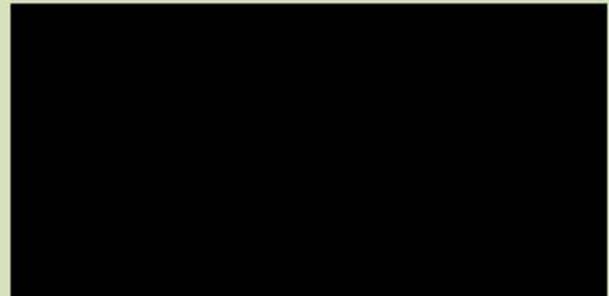
2,000 calories per day is used for general nutrition advice. Who would guess...

Large movie theater popcorn from [redacted] without "buttery" topping has over 1,200 cal and 60 g (three days' worth) of saturated fat



A regular order of cheese fries with ranch dressing from [redacted] contains almost 1,800 cal

A pecan roll from [redacted] has almost double the calories of a chocolate pastry (410 cal)



A side order of jalapeno corn bread from [redacted] has 690 cal, a side order of fries has 390 cal

A grande hot chocolate from [redacted] contains 320 cal while a cappuccino contains 120 cal



A regular oriental chicken salad from [redacted] contains 1,400 cal while the [redacted] Chicken and Shrimp contains 620 cal

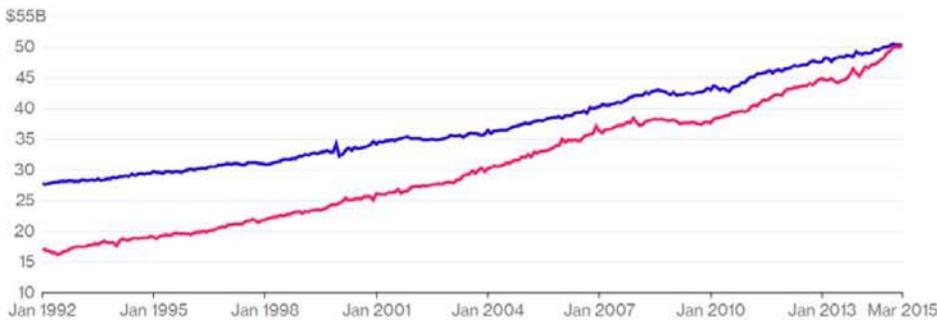


[redacted] red hot beef burrito contains 340 cal

Pass the Menu, Please

Spending on dining out has overtaken grocery store purchases for the first time ever

■ Groceries ■ Restaurants & Bars



Source: Commerce Department

Bloomberg

In March 2015, sales at restaurants and bars surpassed spending at grocery stores for the first time, making it half of food dollars spent.⁵

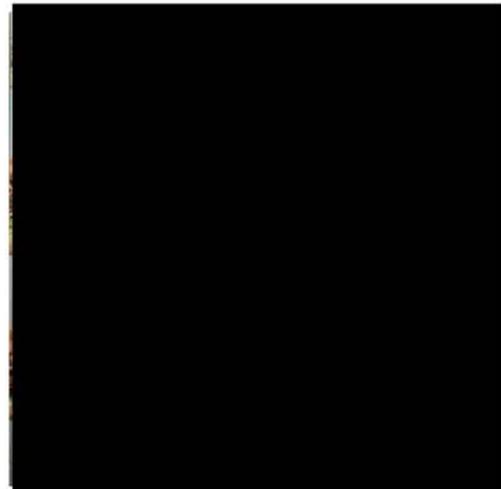
On a typical day, 33% of children, 41% of adolescents, and 36% of adults eat at a fast-food restaurant.⁶

A health impact assessment from Los Angeles County estimated that menu labeling could avert 40% of the 6.75 million pound average annual weight gain in the county (population aged 5 years and older).⁷

Menu labeling

Though not all studies are able to measure an effect of menu labeling, many show that providing nutrition information at restaurants can help people make lower calorie choices and spur the reformulation of existing food items and the introduction of nutritionally improved items.

- A New York City study found **15% of customers reported using menu labeling and purchased 106 fewer calories in a fast-food lunch** than customers who did not see or use the calorie information.⁸
- A study conducted in New York City ██████████ restaurants found that menu labeling had little effect on beverage calories, but reduced calories in food purchases by 14%. **Together, this is a 6% decrease in calories on average per transaction.** For people buying more calories, the effect was bigger, a 26% decrease.⁹
 - A 6% decrease in calories purchased at chain restaurants would mean a **30 calorie per person per day decrease in intake population-wide.**⁹ Keeping in mind that the obesity epidemic is explained by a **less than 100 calorie per day imbalance,**¹⁰ such a change could have a meaningful impact on public health.
- In a restaurant study conducted in Philadelphia, displaying calorie and nutrient labels next to all food-item descriptions and prices resulted in **an average purchase of 151 fewer calories, 224 mg less sodium, and 4 g less saturated fat** relative to unlabeled sites.¹¹
- Parents of children 3–6 years old presented with a ██████████ menu with calorie labeling **ordered an average of 100 fewer calories for their children** than did parents who did not receive calorie information.¹²
- A study in King County, Washington found a **significant decrease in calories (41 calories) in entrée items** at 37 chain restaurants after implementation of menu labeling.¹³
- From 2012 to 2013, **newly introduced menu items in the largest U.S. restaurants were 56 calories lower on average** (a decline of 12%).¹⁴
- Between spring 2010 and spring 2011, **fast-food restaurants decreased children's menu entrees by 40 calories.**¹⁵
- Between the years of 2005 and 2011, **healthier food options increased from 13% to 20%** at five fast-food chains subject to menu labeling.¹⁶



For more information, contact the Center for Science in the Public Interest at 202-777-8352 or nutritionpolicy@cspinet.org or visit www.menulabeling.org

Updated July 2015

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§ 101.10 Nutrition labeling of restaurant foods.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., “low fat, this meal provides less than 10 grams of fat”) may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

[61 FR 40332, Aug. 2, 1996]

EFFECTIVE DATE NOTE: At 79 FR 71253, Dec. 1, 2014, § 101.10 was revised, effective Dec. 1, 2015. For the convenience of the user, the revised text is set forth as follows:

§ 101.10 Nutrition labeling of restaurant foods whose labels or labeling bear nutrient content claims or health claims.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., “low fat, this meal provides less than 10 grams of fat”) may serve as the functional equivalent of complete nutrition information as described in § 101.9. For the purposes of this section, restaurant food includes two categories of food. It includes food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments. It also includes food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in the previous sentence, and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. For standard menu items that are offered for

sale in covered establishments (as defined in § 101.11(a)), the information in the written nutrition information required by § 101.11(b)(2)(ii)(A) will serve to meet the requirements of this section. Nutrient levels may be determined by nutrient databases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

§ 101.11 Nutrition labeling of standard menu items in covered establishments.

(a) *Definitions.* The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this section. In addition, for purposes of this section:

Authorized official of a restaurant or similar retail food establishment means the owner, operator, agent in charge, or other person authorized by the owner, operator, or agent in charge to register the restaurant or similar retail food establishment, which is not otherwise subject to section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act, with FDA for the purposes of paragraph (d) of this section.

Combination meal means a standard menu item that consists of more than one food item, for example a meal that includes a sandwich, a side dish, and a drink. A combination meal may be represented on the menu or menu board in narrative form, numerically, or pictorially. Some combination meals may include a variable menu item or be a variable menu item as defined in this paragraph where the components may vary. For example, the side dish may vary among several options (e.g., fries, salad, or onion rings) or the drinks may vary (e.g., soft drinks, milk, or juice) and the customer selects which of these items will be included in the meal.

Covered establishment means a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, e.g., individual franchises) and offering for sale substantially the same menu items, as well as

a restaurant or similar retail food establishment that is registered to be covered under paragraph (d) of this section.

Custom order means a food order that is prepared in a specific manner based on an individual customer's request, which requires the covered establishment to deviate from its usual preparation of a standard menu item, *e.g.*, a club sandwich without the bacon if the establishment usually includes bacon in its club sandwich.

Daily special means a menu item that is prepared and offered for sale on a particular day, that is not routinely listed on a menu or menu board or offered by the covered establishment, and that is promoted by the covered establishment as a special menu item for that particular day.

Doing business under the same name means sharing the same name. The term "name" refers to either:

(i) The name of the establishment presented to the public; or

(ii) If there is no name of the establishment presented to the public (*e.g.*, an establishment with the generic descriptor "concession stand"), the name of the parent entity of the establishment. When the term "name" refers to the name of the establishment presented to the public under paragraph (i) of this definition, the term "same" includes names that are slight variations of each other, for example, due to the region, location, or size (*e.g.*, "New York Ave. Burgers" and "Pennsylvania Ave. Burgers" or "ABC" and "ABC Express").

Food on display means restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption.

Food that is part of a customary market test means food that appears on a menu or menu board for less than 90 consecutive days in order to test consumer acceptance of the product.

Location means a fixed position or site.

Menu or *menu board* means the primary writing of the covered establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch, and dinner

menus; dessert menus; beverage menus; children's menus; other specialty menus; electronic menus; and menus on the Internet. Determining whether a writing is or is part of the primary writing of the covered establishment from which a customer makes an order selection depends on a number of factors, including whether the writing lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a customer to make an order selection at the time the customer is viewing the writing. The menu may be in different forms, *e.g.*, booklets, pamphlets, or single sheets of paper. Menu boards include those inside a covered establishment as well as drive-through menu boards at covered establishments.

Offering for sale substantially the same menu items means offering for sale a significant proportion of menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies, (*e.g.* "Bay View Crab Cake" and "Ocean View Crab Cake"). "Menu items" in this definition refers to food items that are listed on a menu or menu board or that are offered as self-service food or food on display. Restaurants and similar retail food establishments that are part of a chain can still be offering for sale substantially the same menu items if the availability of some menu items varies within the chain. Having the same name may indicate, but does not necessarily guarantee, that menu items are substantially the same.

Restaurant or similar retail food establishment means a retail establishment that offers for sale restaurant-type food, except if it is a school as defined by 7 CFR 210.2 or 220.2.

Restaurant-type food means food that is:

(i) Usually eaten on the premises, while walking away, or soon after arriving at another location; and

(ii) Either:

(A) Served in restaurants or other establishments in which food is served for immediate human consumption or

which is sold for sale or use in such establishments; or

(B) Processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in paragraph (ii)(A) of this definition, and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.

Self-service food means restaurant-type food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility and that is served by the customers themselves. Self-service food also includes self-service beverages.

Standard menu item means a restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display.

Temporary menu item means a food that appears on a menu or menu board for less than a total of 60 days per calendar year. The 60 days includes the total of consecutive and non-consecutive days the item appears on the menu.

Variable menu item means a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item.

(b) *Requirements for nutrition labeling for food sold in covered establishments—*

(1) *Applicability.* (i) The labeling requirements in this paragraph (b) apply to standard menu items offered for sale in covered establishments.

(ii)(A) The labeling requirements in this paragraph (b) do not apply to foods that are not standard menu items, including:

(1) Items such as condiments that are for general use, including those placed on the table or on or behind the counter; daily specials; temporary menu items; custom orders; food that is part of a customary market test; and

(2) Self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance.

(B) The labeling requirements of paragraph (b)(2)(iii) of this section do not apply to alcoholic beverages that

are foods on display and are not self-service foods.

(2) *Nutrition information.* (i) Except as provided by paragraph (b)(2)(i)(A)(β) of this section, the following must be provided on menus and menu boards:

(A) The number of calories contained in each standard menu item listed on the menu or menu board, as usually prepared and offered for sale. In the case of multiple-serving standard menu items, this means the calories declared must be for the whole menu item listed on the menu or menu board as usually prepared and offered for sale (e.g., “pizza pie: 1600 cal”); or per discrete serving unit as long as the discrete serving unit (e.g., pizza slice) and total number of discrete serving units contained in the menu item are declared on the menu or menu board, and the menu item is usually prepared and offered for sale divided in discrete serving units (e.g., “pizza pie: 200 cal/slice, 8 slices”). The calories must be declared in the following manner:

(1) The number of calories must be listed adjacent to the name or the price of the associated standard menu item, in a type size no smaller than the type size of the name or the price of the associated standard menu item, whichever is smaller, in the same color, or a color at least as conspicuous as that used for the name of the associated standard menu item, and with the same contrasting background or a background at least as contrasting as that used for the name of the associated standard menu item.

(2) To the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.

(3) The term “Calories” or “Cal” must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item. If the term “Calories” or “Cal” appears as a heading above a column of calorie declarations, the term must be in a type size no smaller than the smallest type size of the name or price of any menu item on that menu or menu board in the same color or a color at least as conspicuous

as that used for that name or price and in the same contrasting background or a background at least as contrasting as that used for that name or price. If the term “Calories” or “Cal” appears adjacent to the number of calories for the standard menu item, the term “Calories” or “Cal” must appear in the same type size and in the same color and contrasting background as the number of calories.

(4) Additional requirements that apply to each individual variable menu item:

(i) When the menu or menu board lists flavors or varieties of an entire individual variable menu item (such as soft drinks, ice cream, doughnuts, dips, and chicken that can be grilled or fried), the calories must be declared separately for each listed flavor or variety. Where flavors or varieties have the same calorie amounts (after rounding in accordance with paragraph (b)(2)(i)(A)(2) of this section), the calorie declaration for such flavors or varieties can be listed as a single calorie declaration adjacent to the flavors or varieties, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amounts for each individual flavor or variety.

(ii) When the menu or menu board does not list flavors or varieties for an entire individual variable menu item, and only includes a general description of the variable menu item (*e.g.* “soft drinks”), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.*, “150/250 calories”) or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(7) of this section where more than two options are available (*e.g.*, “100–250 calories”).

(iii) When the menu or menu board describes flavors or varieties for only part of an individual variable menu item (such as different types of cheese offered in a grilled cheese sandwich (*e.g.*, “Grilled Cheese (Cheddar or Swiss)”), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (*e.g.*, “450/500 calories”) or as a range in accordance with the requirements of paragraph

(b)(2)(i)(A)(7) of this section where more than two options are available (*e.g.*, “450–550 calories”).

(5) Additional requirements that apply to a variable menu item that is offered for sale with the option of adding toppings listed on the menu or menu board. When the menu or menu board lists toppings that can be added to a menu item (such as pizza or ice cream):

(i) The calories must be declared for the basic preparation of the menu item as listed (*e.g.*, “small pizza pie,” “single scoop ice cream”).

(ii) The calories must be separately declared for each topping listed on the menu or menu board (*e.g.*, pepperoni, sausage, green peppers, onions on pizza; fudge, almonds, sprinkles on ice cream), specifying that the calories are added to the calories contained in the basic preparation of the menu item. Where toppings have the same calorie amounts (after rounding in accordance with paragraph (b)(2)(i)(A)(2) of this section), the calorie declaration for such toppings can be listed as a single calorie declaration adjacent to the toppings, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amount for each individual topping.

(iii) The calories for the basic preparation of the menu item must be declared for each size of the menu item. The calories for each topping listed on the menu or menu board must be declared for each size of the menu item, or declared using a slash between the two calorie declarations for each topping where only two sizes of the menu item are available (*e.g.*, “adds 150/250 cal”) or as a range for each topping in accordance with the requirements of paragraph (b)(2)(i)(A)(7) of this section where more than two sizes of the menu item are available (*e.g.*, “adds 100–250 cal”). If a slash between two calorie declarations or a range of calorie declarations is used, the menu or menu board must indicate that the variation in calories for each topping arises from the size of the menu item to which the toppings are added.

(iv) If the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the

menu item (such as is sometimes the case with pizza toppings), the calories for each topping must be declared as single values representing the calories for each topping when added to a one-topping menu item, specifying that the calorie declaration is for the topping when added to a one-topping menu item.

(6) Additional requirements that apply to a combination meal. Except as provided in paragraph (b)(2)(i)(A)(6)(iv) of this section:

(i) When the menu or menu board lists two options for menu items in a combination meal (*e.g.*, a sandwich with a side salad or chips), the calories must be declared for each option with a slash between the two calorie declarations (*e.g.*, “350/450 calories”).

(ii) When the menu or menu board lists three or more options for menu items in a combination meal (*e.g.*, a sandwich with chips, a side salad, or fruit), the calories must be declared as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(7) of this section (*e.g.*, “350–500 calories”).

(iii) When the menu or menu board includes a choice to increase or decrease the size of a combination meal, the calorie difference must be declared for the increased or decreased size with a slash between two calorie declarations (*e.g.*, “Adds 100/150 calories,” “Subtracts 100/150 calories”) if the menu or menu board lists two options for menu items in the combination meal, or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(7) of this section (*e.g.*, “Adds 100–250 calories,” “Subtracts 100–250 calories”) if the menu or menu board lists three or more options for menu items in the combination meal.

(iv) Where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price (*e.g.*, “Combine Any Sandwich with Any Soup or Any Salad for \$8.99”), and the calories for each standard menu item, including each size option as described in paragraph (b)(2)(i)(A)(6)(iii) of this section if applicable, available for the consumer to combine are declared elsewhere on the menu or menu board, the requirements of paragraphs (b)(2)(i)(A)(6)(i), (ii), and (iii) of this section do not apply.

(7) Additional format requirements for declaring calories for an individual variable menu item, a combination meal, and toppings as a range, if applicable. Calories declared as a range must be in the format “xx–yy,” where “xx” is the caloric content of the lowest calorie variety, flavor, or combination, and “yy” is the caloric content of the highest calorie variety, flavor, or combination.

(8) Exception for a variable menu item that has no clearly identifiable upper bound to the range of calories: If the variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, *e.g.*, all-you-can-eat buffet, then the menu or menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, *e.g.*, “See buffet for calorie declarations.” This statement must appear in a type size no smaller than the type size of the name or price of the variable menu item, whichever is smaller, and in the same color or a color at least as conspicuous as that used for that name or price, with the same contrasting background or a background at least as contrasting as that used for that name or price.

(9) Additional requirements that apply to beverages that are not self-service. For beverages that are not self-service, calories must be declared based on the full volume of the cup served without ice, unless the covered establishment ordinarily dispenses and offers for sale a standard beverage fill (*i.e.*, a fixed amount that is less than the full volume of the cup per cup size) or dispenses a standard ice fill (*i.e.*, a fixed amount of ice per cup size). If the covered establishment ordinarily dispenses and offers for sale a standard beverage fill or dispenses a standard ice fill, the covered establishment must declare calories based on such standard beverage fill or standard ice fill.

(B) The following statement designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards:

“2,000 calories a day is used for general nutrition advice, but calorie needs vary.” For menus and menu boards targeted to children, the following options may be used as a substitute for or in addition to the succinct statement: “1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years, but calorie needs vary.”; or “1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years and 1,400 to 2,000 calories a day for children ages 9 to 13 years, but calorie needs vary.”

(1) This statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest type size of any calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as that used for the calorie declarations and with the same contrasting background or a background at least as contrasting as that used for the calorie declarations.

(2) For menus, this statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement required by paragraph (b)(2)(i)(C) of this section, this statement must appear immediately above, below, or beside the statement required by paragraph (b)(2)(i)(C) of this section.

(3) For menu boards, this statement must appear on the bottom of the menu board, immediately above, below, or beside the statement required by paragraph (b)(2)(i)(C) of this section.

(C) The following statement regarding the availability of the additional written nutrition information required in paragraph (b)(2)(ii) of this section must be on all forms of the menu or menu board: “Additional nutrition information available upon request.”

(1) This statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest type size of any calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as that used for the caloric declarations, and with the same contrasting background or a background at least as contrasting as that used for the caloric declarations.

(2) For menus, the statement must appear on the bottom of the first page with menu items immediately above, below, or beside the succinct statement required by paragraph (b)(2)(i)(B) of this section.

(3) For menu boards, the statement must appear on the bottom of the menu board immediately above, below, or beside the succinct statement required by paragraph (b)(2)(i)(B) of this section.

(ii) The following nutrition information for a standard menu item must be available in written form on the premises of the covered establishment and provided to the customer upon request. This nutrition information must be presented in the order listed and using the measurements listed, except as provided in paragraph (b)(2)(ii)(B) of this section. Rounding of these nutrients must be in compliance with §101.9(c). The information must be presented in a clear and conspicuous manner, including using a color, type size, and contrasting background that render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Covered establishments may use the abbreviations allowed for Nutrition Facts for certain packaged foods in §101.9(j)(13)(ii)(B):

- (A)(1) Total calories (cal);
- (2) Calories from fat (fat cal);
- (3) Total fat (g);
- (4) Saturated fat (g);
- (5) *Trans* fat (g);
- (6) Cholesterol (mg);
- (7) Sodium (mg);
- (8) Total carbohydrate (g);
- (9) Dietary fiber (g);
- (10) Sugars (g); and
- (11) Protein (g).

(B) If a standard menu item contains insignificant amounts of all the nutrients required to be disclosed in paragraph (b)(2)(ii)(A) of this section, the establishment is not required to include nutrition information regarding the standard menu item in the written form. However, if the covered establishment makes a nutrient content claim or health claim, the establishment is required to provide nutrition information on the nutrient that is the subject of the claim in accordance with §101.10. For standard menu items that

contain insignificant amounts of six or more of the required nutrients, the declaration of nutrition information required by paragraph (b)(2)(ii)(A) of this section may be presented in a simplified format.

(1) An insignificant amount is defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrates, dietary fiber, and protein, it must be an amount that allows a declaration of “less than one gram.”

(2) The simplified format must include information, in a column, list, or table, on the following nutrients:

(i) Total calories, total fat, total carbohydrates, protein, and sodium; and

(ii) Calories from fat, and any other nutrients identified in paragraph (b)(2)(ii)(A) of this section that are present in more than insignificant amounts.

(3) If the simplified format is used, the statement “Not a significant source of _____” (with the blank filled in with the names of the nutrients required to be declared in the written nutrition information and calories from fat that are present in insignificant amounts) must be included at the bottom of the list of nutrients.

(C) For variable menu items, the nutrition information listed in paragraph (b)(2)(ii)(A) of this section must be declared as follows for each size offered for sale:

(1) The nutrition information required in paragraph (b)(2)(ii)(A) of this section must be declared for the basic preparation of the item and, separately, for each topping, flavor, or variable component.

(2) Additional format requirements for toppings if the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the menu item (such as is sometimes the case with pizza toppings). The nutrients for such topping must be declared as single values representing the nutrients for each topping when added to a one-topping menu item, specifying that the nutrient declaration is for the topping when added to a one-topping menu item.

(3) If the calories and other nutrients are the same for different flavors, vari-

eties, and variable components of the combination meal, each variety, flavor, and variable component of the combination meal is not required to be listed separately. All items that have the same nutrient values could be listed together with the nutrient values listed only once.

(D) The written nutrition information required in paragraph (b)(2)(ii)(A) of this section may be provided on a counter card, sign, poster, handout, booklet, loose leaf binder, or electronic device such as a computer, or in a menu, or in any other form that similarly permits the written declaration of the required nutrient content information for all standard menu items. If the written nutrition information is not in a form that can be given to the customer upon request, it must be readily available in a manner and location on the premises that allows the customer/consumer to review the written nutrition information upon request.

(iii) The following must be provided for a standard menu item that is self-service or on display.

(A) Calories per displayed food item (*e.g.*, a bagel, a slice of pizza, or a muffin), or if the food is not offered for sale in a discrete unit, calories per serving (*e.g.*, scoop, cup), and the serving or discrete unit used to determine the calorie content (*e.g.*, “per scoop” or “per muffin”) on either: A sign adjacent to and clearly associated with the corresponding food; (*e.g.*, “150 calories per scoop”); a sign attached to a sneeze guard with the calorie declaration and the serving or unit used to determine the calorie content above each specific food so that the consumer can clearly associate the calorie declaration with the food, except that if it is not clear to which food the calorie declaration and serving or unit refers, then the sign must also include the name of the food, *e.g.*, “Broccoli and cheese casserole—200 calories per scoop”; or a single sign or placard listing the calorie declaration for several food items along with the names of the food items, so long as the sign or placard is located where a consumer can view the name, calorie declaration, and serving or unit of a particular item while selecting that item.

(1) For purposes of paragraph (b)(2)(iii)(A) of this section, “per displayed food item” means per each discrete unit offered for sale, for example, a bagel, a slice of pizza, or a muffin.

(2) For purposes of paragraph (b)(2)(iii)(A) of this section, “per serving” means, for each food:

(i) Per serving instrument used to dispense the food offered for sale, provided that the serving instrument dispenses a uniform amount of the food (*e.g.*, a scoop or ladle);

(ii) If a serving instrument that dispenses a uniform amount of food is not used to dispense the food, per each common household measure (*e.g.*, cup or tablespoon) offered for sale or per unit of weight offered for sale, *e.g.*, per quarter pound or per 4 ounces; or

(iii) Per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the description of the cup size (*e.g.*, “140 calories per 12 fluid ounces (small)”).

(3) The calories must be declared in the following manner:

(i) To the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories except that amounts less than 5 calories may be expressed as zero.

(ii) If the calorie declaration is provided on a sign with the food’s name, price, or both, the calorie declaration, accompanied by the term “Calories” or “Cal” and the amount of the serving or displayed food item on which the calories declaration is based must be in a type size no smaller than the type size of the name or price of the menu item whichever is smaller, in the same color, or a color that is at least as conspicuous as that used for that name or price, using the same contrasting background or a background at least as contrasting as that used for that name or price. If the calorie declaration is provided on a sign that does not include the food’s name, price, or both, the calorie declaration, accompanied by the term “Calories” or “Cal” and the amount of the serving or displayed food item on which the calorie declaration is based must be clear and conspicuous.

(iii) For self-service beverages, calorie declarations must be accompanied by the term “fluid ounces” and, if ap-

plicable, the description of the cup size (*e.g.*, “small,” “medium”).

(B) For food that is self-service or on display and is identified by an individual sign adjacent to the food itself where such sign meets the definition of a menu or menu board under paragraph (a) of this section, the statement required by paragraph (b)(2)(i)(B) of this section and the statement required by paragraph (b)(2)(i)(C) of this section. These two statements may appear on the sign adjacent to the food itself; on a separate, larger sign, in close proximity to the food that can be easily read as the consumer is making order selections; or on a large menu board that can be easily read as the consumer is viewing the food.

(C) The nutrition information in written form required by paragraph (b)(2)(ii) of this section, except for packaged food insofar as it bears nutrition labeling information required by and in accordance with paragraph (b)(2)(ii) of this section and the packaged food, including its label, can be examined by a consumer before purchasing the food.

(c) *Determination of nutrient content.*

(1) A covered establishment must have a reasonable basis for its nutrient declarations. Nutrient values may be determined by using nutrient databases (with or without computer software programs), cookbooks, laboratory analyses, or other reasonable means, including the use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act and §101.9, FDA nutrient values for raw fruits and vegetables in Appendix C of this part, or FDA nutrient values for cooked fish in Appendix D of this part.

(2) Nutrient declarations for standard menu items must be accurate and consistent with the specific basis used to determine nutrient values. A covered establishment must take reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(3) A covered establishment must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient values. This information must include the following:

(i) For nutrient databases:

(A) The name and version (including the date of the version) of the database, and, as applicable, the name of the applicable software company and any Web site address for the database. The name and version of a database would include the name and version of the computer software, if applicable;

(B) The recipe or formula used as a basis for the nutrient declarations;

(C)(1) Information on:

(i) The amount of each nutrient that the specified amount of each ingredient identified in the recipe contributes to the menu item; and

(ii) How the database was used including calculations or operations (*e.g.*, worksheets or computer printouts) to determine the nutrient values for the standard menu items;

(2) If the information in paragraph (c)(3)(i)(C)(1) of this section is not available, certification attesting that the database will provide accurate results when used appropriately and that the database was used in accordance with its instructions;

(D) A detailed listing (*e.g.*, printout) of the nutrient values determined for each standard menu item.

(E) Any other information pertinent to the final nutrient values of the standard menu item (*e.g.*, information about what might cause slight variations in the nutrient profile such as moisture variations);

(F) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(G) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount

of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(ii) For published cookbooks that contain nutritional information for recipes in the cookbook:

(A) The name, author, and publisher of the cookbook used;

(B) If available, information provided by the cookbook or from the author or publisher about how the nutrition information for the recipes was obtained;

(C) A copy of the recipe used to prepare the standard menu item and a copy of the nutrition information for that standard menu item as provided by the cookbook; and

(D) A statement signed and dated by a responsible individual employed at the covered establishment certifying that that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the standard menu item but no changes may be made to the proportion of ingredients used.)

(iii) For laboratory analyses:

(A) A copy of the recipe for the standard menu item used for the nutrient analysis;

(B) The name and address of the laboratory performing the analysis;

(C) Copies of analytical worksheets, including the analytical method, used to determine and verify nutrition information;

(D) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(E) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types

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and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(iv) For nutrition information provided by other reasonable means:

(A) A detailed description of the means used to determine the nutrition information;

(B) A recipe or formula used as a basis for the nutrient determination;

(C) Any data derived in determining the nutrient values for the standard menu item, *e.g.*, nutrition information about the ingredients used with the source of the nutrient information;

(D) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(E) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(d) *Voluntary registration to be subject to the menu labeling requirements—(1) Applicability.* A restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items may voluntarily register to be subject to the requirements established in this section. Restaurants and similar retail food establishments that voluntarily register will no longer be subject to non-identical State or local nutrition labeling requirements.

(2) *Who may register?* The authorized official of a restaurant or similar retail food establishment as defined in paragraph (a) of this section, which is not otherwise subject to paragraph (b) of this section, may register with FDA.

(3) *What information is required?* Authorized officials for restaurants and similar retail food establishments

must provide FDA with the following information on Form FDA 3757:

(i) The contact information (including name, address, phone number, and email address) for the authorized official;

(ii) The contact information (including name, address, phone number, and email address) of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official on-site, such as the owner or manager, for each specific restaurant or similar retail food establishment;

(iii) All trade names the restaurant or similar retail food establishment uses;

(iv) Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and

(v) Certification that the information submitted is true and accurate, that the person submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act and this section.

(4) *How to register.* Authorized officials of restaurants and similar retail food establishments who elect to be subject to requirements in section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act can register by visiting <http://www.fda.gov/food/ingredientpackaginglabeling/labelingnutrition/ucm217762.htm>. FDA has created a form (Form 3757) that contains fields requesting the information in paragraph (d)(3) of this section and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

(i) Information should be submitted by email by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by email to menulawregistration@fda.hhs.gov.

(ii) If email is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301–436–2804 or

mail it to FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, Rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(5) *When to renew the registration.* To keep the establishment's registration active, the authorized official of the restaurant or similar retail food establishment must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA. Registration will automatically expire if not renewed.

(e) *Signatures.* Signatures obtained under paragraph (d) of this section that meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

(f) *Misbranding.* A standard menu item offered for sale in a covered establishment shall be deemed misbranded under sections 201(n), 403(a), 403(f) and/or 403(q) of the Federal Food, Drug, and Cosmetic Act if its label or labeling is not in conformity with paragraph (b) or (c) of this section.

[79 FR 71253, Dec. 1, 2014]

EFFECTIVE DATE NOTE: At 79 FR 71253, Dec. 1, 2014, § 101.11 was added, effective December 1, 2015.

§ 101.12 Reference amounts customarily consumed per eating occasion.

(a) The general principles and factors that the Food and Drug Administration (FDA) considered in arriving at the reference amounts customarily consumed per eating occasion (reference amounts) which are set forth in paragraph (b) of this section, are that:

(1) FDA calculated the reference amounts for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These reference amounts are based on data set forth in appropriate national food consumption surveys.

(2) FDA calculated the reference amounts for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These reference amounts are based on data set forth in appropriate national food consumption

surveys. Such reference amounts are to be used only when the food is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, FDA considered the mean, median, and mode of the consumed amount per eating occasion.

(5) When survey data were insufficient, FDA took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the reference amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The reference amount is based on the major intended use of the food (e.g., milk as a beverage and not as an addition to cereal).

(8) The reference amounts for products that are consumed as an ingredient of other foods, but that may also be consumed in the form in which they are purchased (e.g., butter), are based on use in the form purchased.

(9) FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount.

(b) The following reference amounts shall be used as the basis for determining serving sizes for specific products:

BUILD YOUR OWN PIZZA

SELECT YOUR CRUST, SAUCE, TOPPINGS

CRUST

Inspired Hand Tossed
Deep Dish (additional cost)

Crunchy Thin
Brooklyn Style

SAUCE

Robust Inspired Tomato OPTIONAL: White Hearty Marinara BBQ



TOPPINGS

MEAT: Pepperoni • Bacon • Ham • Beef • Salami
Chicken • Philly Steak • Italian or Sliced Sausage

VEGGIES: Green Peppers • Onions • Black Olives
Mushrooms • Banana Peppers • Jalapenos • Tomatoes
Roasted Red Peppers • Fresh Baby Spinach

OTHER: Extra Cheese • Cheddar • Feta
Provolone • Parmesan-Asiago • Pineapple

Cheese Pizza

Additional Toppings (each)

S \$ 7.99 cal. 910–1390
M \$ 9.99 cal. 1310–2390
L \$ 11.99 cal. 1620–3230
XL \$ 12.99 cal. 2450–3500

S \$ 1.29 cal. 10–270
M \$ 1.49 cal. 10–350
L \$ 1.69 cal. 15–500
XL \$ 1.89 cal. 15–670

All calorie information is for the entire item.

1



Large Popcorn Large Drink
950 - 2030 Cal 13.49

2



Large Popcorn 2 Large Drinks
950 - 3110 Cal 19.19



Add a little extra flavor
to your popcorn

POPCO

Large 838
Medium 5
Small 358

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-026

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Frozen Foods Maintained Frozen

Issue you would like the Conference to consider:

Clarifying that Time Temperature Control in both Section 3-202.11(E) and 3-501.11 of the 2013 FDA Food Code is only necessary for Time Temperature Control for Safety Food (TCS) foods and not all frozen foods.

Public Health Significance:

Time Temperature Control in both Section 3-202.11(E) and 3-501.11 of the 2013 FDA Food Code is only necessary for Time Temperature Control for Safety Food (TCS) foods .

Recommended Solution: The Conference recommends...:

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

Section 3-302.11

(E) TIME/TEMPERATURE CONTROL FOR SAFETY-A-FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen. Pf

and

Section 3-501.11

Stored frozen TIME/TEMPERATURE CONTROL FOR SAFETY FOODS shall be maintained frozen.

Submitter Information 1:

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-027

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Protecting Unwashed Produce From Cross Contamination

Issue you would like the Conference to consider:

The 2013 FDA Food Code does not prohibit storing raw animal foods above or contacting unwashed produce. Washing may not eliminate pathogens from produce exposed to cross contamination. The Food Code should be amended to include unwashed produce in the prohibition of storage under raw animal foods.

Public Health Significance:

Produce that will not be cooked to a specific temperature could cause an illness if exposed to cross contamination.

Recommended Solution: The Conference recommends...:

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

3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.

(A) FOOD shall be protected from cross contamination by:

(1) Except as specified in (1)(c) below, separating raw animal FOODS during storage, preparation, holding, and display from:

(a) Raw READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, ~~or other~~

(b) ~~r~~Raw ~~READY-TO-EAT~~ non-animal FOOD such as fruits and vegetables, ^P

Submitter Information:

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-028

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

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Amend Returned Food and Re-Service of Food

Issue you would like the Conference to consider:

Request an interpretation from FDA that clarifies the intent of the 2013 Food Code Section 3-306.14(A) allowing for food that is immediately served and in possession of a consumer to be returned for further cooking before being returned to the same consumer.

Public Health Significance:

Food that is returned by the consumer after immediate service for further cooking, would not pose a risk when cooked to a higher temperature and returned to the same consumer.

Any potential contamination would be eliminated by the temperature of the cooking equipment, such as a grill. Separate single use utensils may be used for a returned item and then wash, rinsed, sanitized and air dried.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting an interpretation that clarifies/explains Section 3-306.14(A) of the 2013 Food Code and allows for return of food that is immediately served to a specific consumer back to the same consumer after further cooking. The letter shall also request that FDA post their final interpretation document to the FDA Food Code Reference System.

Submitter Information:

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-029

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Labeling for Food Allergen Cross-Contact

Issue you would like the Conference to consider:

Adding an addendum to the 2013 FDA Food Code subparagraph 3-602.11(B)(5) to include a statement on a product's label, when applicable, that cross-contact with specifically named allergens is possible.

Public Health Significance:

Consumers assume that delis, bakeries, grocery stores, restaurants, and other venues that sell pre-packaged foods (i.e., foods NOT produced and packaged in manufacturing plants that fall under the provisions of the Food Allergen Labeling and Consumer Protection Act, FALCPA) are labeled as stringently for the presence of allergens as manufactured products, and also assume that these venues practice strict allergen control. Because the labels seldom indicate the potential presence of allergens due to cross-contact, reactions have occurred, including food anaphylaxis deaths.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that subparagraph 3-601.11(B)(5) of the 2013 Food Code be amended as follows (language to add is underlined):

3-601.11 Food Labels.

(B) Label information shall include:

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient.^{Pf} When applicable, all pre-packaged items will have a label stating that the food may have been in contact with allergens specifically named by the venue preparing and/or packaging the product.

Submitter Information:

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Supporting Attachments:

- "Suit in Allergy Death: Should Store Bakeries Have to Label? (redacted)"

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

Suit in Allergy Death: Should Store Bakeries Have to Label?

Posted By *Ishani Nath* On 2015/07/08 @ 9:10 am In Food Allergy

A lawsuit in the death of an Alabama boy, who suffered fatal anaphylaxis from eating a cookie, could have broad implications for supermarket bakeries and food-allergic consumers.

The family of 11-year-old Derek “Landon” Wood filed the lawsuit, in which a crucial aspect is whether a grocery store’s bakery should be required to label all of its products, since many of them are made, either entirely or mostly, off the bakery premises.

██████████, which sold the cookie, takes issue with that interpretation of the U.S. food allergen labeling law, known as FALCPA ([Food Allergen Labeling and Consumer Protection Act](#)^[2]). It had filed a motion to get the case dismissed.

But on June 11, 2015, a U.S. district judge denied that motion, finding that the family’s case has sufficient merit, and allowing the case to proceed.

One thing that no one disputes is that Landon’s death was a tragedy and a traumatic experience. The boy, who had multiple food allergies and asthma, and his mother Beth Cline were visiting family in Clarksville, Tennessee on June 3, 2014 when, along with his aunt and cousin, they stopped at a ██████████ store.

In the bakery section, Landon asked his mother to buy him an unlabeled, ready-to-eat “Chocolate Chew” cookie. In the lawsuit, Cline says she spoke to the bakery employee and was assured that the cookie did not contain tree nuts – one of Landon’s allergens. (In its legal response, ██████████ denies a bakery employee would have told Cline this.) Cline says it is based on this information that she bought her son the cookie, and a sugar cookie for his cousin.

After returning to the aunt’s house, the suit says that Landon had three bites of the cookie, and began saying that his mouth was burning. His mother gave him Benadryl, but the symptoms progressed, with Landon finding it harder to breathe, and his face turning red. His mother administered his epinephrine auto-injector as her sister called an ambulance.

The boy’s condition improved briefly during the ambulance ride, but in hospital, even with further medication, his breathing worsened, and he suffered extreme swelling and plummeting blood pressure. Landon was airlifted to Vanderbilt Children’s Hospital in Nashville, but his condition could not be stabilized; he died at 10:19 that evening.

The family's lawsuit against the grocery chain calls for "compensation for [REDACTED]'s negligence and to raise awareness of potential fatal food allergies in American children."

[REDACTED], for its part, denies the negligence claims. The grocery chain has yet to either agree or deny that a conversation took place between Cline and one its bakery employees. But [REDACTED] does say that the Chocolate Chew cookies were known by staff to contain tree nuts as an ingredient, and it denies that a bakery employee would have told Cline that these cookies were free of nuts.

As the case moves forward, a key element is the legal interpretation of [FALCPA](#) ^[2], which requires manufacturers to list the Top 8 allergens on the labels of packaged foods, but **exempts foods that are placed in a wrapper or container or prepared on a made-to-order basis** – like a deli sandwich. Further, FALCPA does not cover foods "served in restaurants or other establishments in which food is served for immediate human consumption".

In Landon's death, however, the family argues that these exemptions should not apply, since the [REDACTED] supermarket that sold the cookie makes most of its finished baked goods at a regional facility, and products are then shipped to in-store bakeries. ([REDACTED] has not yet answered how Landon's specific cookie was prepared.)

In its response, [REDACTED] contends that the Chocolate Chew Cookie does not require ingredient labeling because it is "prepared and displayed in a bakery setting and then placed in a wrapper or similar package in response to a consumer's order."

U.S. District Court Judge Aleta Trauger noted that, in attempting to have the family's case dismissed, [REDACTED] had argued that the cookies that were sold fell within this exception in FALCPA as well as within a similar "immediate consumption" clause in the federal Food, Drug and Cosmetic Act. The judge summarized that the supermarket chain also suggested that the cookie could be considered "made-to-order", making it exempt from labeling requirements.

"[REDACTED] appears to contend that, because products sold from behind the display case are not packaged and can be sold individually, the products are indistinguishable from cookies sold at a mall cookie counter or a muffin sold at a coffee cart," Trauger wrote.

But in denying the [REDACTED] motion, she found that, because the cookie did not appear to be served for immediate consumption, nor prepared fresh such as from a food truck, **"the plaintiffs (the family) have sufficiently alleged that the [REDACTED] bakery was subject to the labeling requirements"**.

"From my perspective, [REDACTED] the retail store is not operating a bakery," Eddie Schmidt, the attorney representing Landon's family, told Allergic Living. "It's simply a

section of the grocery store.” ██████████ would not comment directly to Allergic Living on the continuing lawsuit.

“Part of this lawsuit seeks a declaratory judgment from a federal court that ██████████ cannot use this FDA-interpreted exception to bakeries for not labeling its bakery products,” Schmidt said. “If that is accomplished, that will require ██████████, as well as all other grocery stores who are selling bakery products, to identify the food allergens within its products.”

Donna Rosenbaum, a consultant with Food Safety Partners, has given the plaintiffs some advice in this suit. She views the in-store bakery labeling issue as an example of how FALCPA has “eroded and evolved over time”.

“I would love to see movement from within the industry, and not just from the consumer base; I would love to see people come together on this,” she said. “Stores don’t want to get sued and consumers certainly don’t want to get sick from store products, so it should be a win-win.”

She acknowledges, however, that any significant changes will take time. For now, she says the allergic community should look at grocery store bakery products with an added layer of suspicion, and she encourages parents to raise these concerns with grocery store managers, to let them know it’s an important issue.

Article printed from Allergic Living: <http://allergicliving.com>

URL to article: <http://allergicliving.com/2015/07/08/suit-in-allergy-death-should-store-bakeries-have-to-label/>

URLs in this post:

[1] Image: <http://allergicliving.com/wp-content/uploads/2015/03/d8b41ce6-9ac5-4d69-aa47-d30db88d49af.jpg>

[2] Food Allergen Labeling and Consumer Protection Act:
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm>

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-030

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

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Issue History:

This is a brand new Issue.

Title:

Documenting Food Allergy Labeling Violations

Issue you would like the Conference to consider:

Adding an addendum to the 2013 FDA Food Code Section 8-403.10(B) to include a provision to document on an inspection report form any violation of food allergen labeling on foods pre-packaged and sold by the establishment as required by 3-602.11(B)(5).

Public Health Significance:

Mislabeled pre-packaged foods can cause life-threatening anaphylactic allergic reactions.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended to include a new subparagraph #7 in paragraph 8-403.10(B) (language to be added is underlined):

8-403.10 Documenting Information and Observations.

The REGULATORY AUTHORITY shall document on an inspection report form:

(B) Specific factual observations of violative conditions or other deviations from this Code that require correction by the PERMIT HOLDER including:

(7) Failure of pre-packaged items produced by the establishment to include listed allergens and potential cross-contact with allergens, when applicable.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-031

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

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Harmonizing a Food Code Labeling Requirement w/ a CFR Labeling Requirement

Issue you would like the Conference to consider:

Subparagraph 3-602.11(B)(4) of the 2013 FDA Food Code requires that food packaged in a food establishment be labeled with the name and address of the manufacturer, packer, or distributor.

However, 21 Code of Federal Regulation (CFR) 101.100(b)(1) exempts a food repackaged in a retail establishment from being labeled with the name of the manufacturer, packer or distributor.

It would seem logical that the same exemption can be reasonably applied to any food packaged or repackaged in a food establishment. Customers have the opportunity to ask the operator about any aspect of the food and decide if their questions are sufficiently answered.

Public Health Significance:

Eliminating Food Code requirements that conflict with Federal food regulations and also provide limited benefit allows resources to be focused on higher risk items.

Recommended Solution: The Conference recommends...:

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

Subparagraph 3-602.11

(B) Label information shall include:

- (1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;
- (2) If made from two or more ingredients, a list of ingredients

and sub-ingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the net quantity of contents;

~~(4) The name and place of business of the manufacturer, packer, or distributor; and~~

~~(5)~~ (4) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient. Pf

~~(6)~~ (5) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(g)(3) - (5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

~~(7)~~ (6) For any salmonid FISH containing canthaxanthin or astaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin. retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-032

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

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Issue History:

This is a brand new Issue.

Title:

Proposed Revision to Food Code Section 3-401.14, Non-Continuous cooking

Issue you would like the Conference to consider:

Subparagraph 3-401.14 of the 2013 FDA Food Code, together with supporting paragraphs 3-501.14 (A), 3-501.16 (A) (2), 3-401.11 (A-C), 3-501.19 & 3-302.11 (A), deals with very basic food safety principles; cooking, cooling and holding. This section is very prescriptive, lists all necessary steps for safe food preparation and does not require review of any new science to ensure it is being conducted properly.

Developing a non-continuous cooking procedure and providing a copy to the regulatory authority prior to implementation gives notice to the regulatory authority that the food establishment intends to conduct non-continuous cooking operations for raw animal foods and makes it possible for the regulatory authority to verify, if they so desire, that the appropriate non-continuous cooking procedures are being followed and that the requirements of §3-401.14 together with supporting paragraphs 3-501.14 (A), 3-501.16 (A), 3-401.11 (A-C), 3-501.19 & 3-302.11 (A) are being met.

Consequently, we request consideration of changing Section 3-401.14 (F) (1) of the FDA Food Code from requiring a food establishment to obtain pre-approval of a non-continuous cooking process to providing the regulatory authority notice of intent to conduct a non-continuous cooking process along with the procedures the food establishment will use to comply with section 3-401.14 of the FDA Food Code.

Public Health Significance:

This process would not result in any additional public health or food safety risk to consumers. Some of the benefits would include:

1. Developing a non-continuous cooking process and providing a copy to the regulatory authority prior to implementation gives notice to the regulatory authority that the food establishment intends to conduct non-continuous cooking operations for raw animal foods and makes it possible to verify that the appropriate non-

continuous cooking procedures are being followed and that the requirements of §3-401.14 are being met.

2. Subparagraph 3-401.14 deals with very basic food safety principles-heating, cooling and cooking. This section is very prescriptive, lists all necessary steps for safe food preparation and does not require review of any new science or evaluations to ensure it is being conducted properly.
3. This process would allow regulatory agencies to focus on reviews of processes they had concerns on and avoid detailed administrative reviews for complete processes.
4. Encouraging industry to submit their plans for their non-continuous cooking procedures to regulatory agencies for their review without a fear of potential delay that could take weeks or months.
5. Would allow for identification of establishments that needed additional training before implementing a non-continuous cooking process.
6. Reducing the need for overburdened regulatory agencies from needing to conduct a detailed review of each non-continuous cooking process and issuing approvals.
7. Places greater responsibility on industry to ensure their non-continuous cooking plans and procedures are sound and executed properly.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that Subparagraph 3-401.14 (F) (1) of the 2013 Food Code be modified to read (language to be added is underlined; language to be deleted is in strikethrough format):

(F) Prepared and stored according to written procedures that:

1. Have ~~obtained prior Approval from~~ been provided to the REGULATORY AUTHORITY prior to implementation describing the process they will use to comply with section 3-401.14;

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-033

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

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Issue History:

This is a brand new Issue.

Title:

Thawing 3-501.13

Issue you would like the Conference to consider:

With the change in the FDA Food Code to priority, priority foundation and core violations, I believe that the thawing of potentially hazardous food (time/temperature control for safety food (TCS)) should be a priority foundation violation rather than core. It should be a priority foundation violation since improper thawing methods can directly lead to the priority violation of Section 3-501.16.

The definition of a priority foundation violation (per preface page xi, 2013 FDA Food Code) is a provision that "supports, facilitate or enables one or more priority violations."

Public Health Significance:

Improper thawing methods can result in TCS foods being out of temperature control which can lead to bacterial growth and toxin production. Thawing should be viewed in the same manner as improper cooling methods (Section 3-501.15) which is a priority foundation violation. Especially, since many foods being thawed are previously cooked and cooled TCS foods.

The FDA Food Code and most enforcement policies give the regulatory authority the ability to take more immediate action and more progressive enforcement for a priority foundation violation than a core violation.

Recommended Solution: The Conference recommends...:

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

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, potentially hazardous food (time/temperature control for safety food) shall be thawed:

- (A) Under refrigeration that maintains the food temperature at 5°C (41°F) or less^{Pf}; or
- (B) Completely submerged under running water:
- (1) At a water temperature of 21°C (70°F) or below^{Pf},
- (2) With sufficient water velocity to agitate and float off loose particles in an overflow^{Pf}, and
- (3) For a period of time that does not allow thawed portions of ready-to-eat food to rise above 5°C (41°F)^{Pf}, or
- (4) For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), for more than 4 hours including:
- (a) The time the food is exposed to the running water and the time needed for preparation for cooking^{Pf}, or
- (b) The time it takes under refrigeration to lower the food temperature to 5°C (41°F)^{Pf};
- (C) As part of a cooking process if the food that is frozen is:(1) Cooked as specified under ¶ 3-401.11(A) or (B) or § 3-401.12^{Pf}, or
- (2) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process^{Pf}; or
- (D) *Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.*

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-034

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

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Issue History:

This is a brand new Issue.

Title:

Interpretation of Food Code Section 3-501.17 (A) & (B)

Issue you would like the Conference to consider:

When a Ready-to-Eat (RTE); Time/Temperature Control for Safety (TCS) food is prepared and held for more than 24 hours, the 2013 FDA Food Code requires that the product be properly Date Marked. It can be held for those 24-hours plus up to six additional days for a total of seven (7) days from the time it was prepared or from the time the original package was opened (in the case of commercially prepared food). By the end of 7-days, the food must either be used or discarded.

The language, "...date or day by which food shall be consumed, sold or discarded when held for a maximum of 7-days," found in Sections 3-501.17 (A) & (B) of the 2013 FDA Food Code is being variously interpreted by regulatory authorities. Consider this example: A facility that is a 24 hour operation prepares a RTE/TCS food at 11:00 pm on 1/1/16. It should not have to discard that food until 11:00 pm on 1/7/16. The product specifically has 24 hours from the precise time it was prepared (or opened) and then six (6) more days before it has to be fully used or discarded. The current language in the 2013 FDA Food Code is being interpreted by some regulators to mean that the food has to be discarded on 1/7/16 without regard to its actual "preparation time." This leads to confusion among operators and the unnecessary premature discard of food that has not yet reached the limit of its full 7-day shelf life.

On this basis, facilities are being given violations on health inspections and food is being wasted. For clarity, the terms "date or day" should be defined in the context of a 24-hour period of time and the calculation of 7-days should include the time-of-day as well as the date or day that the food is prepared or opened.

Public Health Significance:

With the designation of a specific time being placed on the Date Marking Label, it would allow both regulators and the food service facility to have a specific time line in which the RTE/TCS food would have to be properly discarded as required under Section 3-501.17 (A)

& (B) of the 2013 FDA Food Code and therefore less opportunity for miss-information pertaining to time line, date, and possible violation of this section.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting an interpretation that clarifies/explains the terms "date or day" in Section 3-501.17 (A) & (B) of the 2013 Food Code to better define a day as a 24 hour period of time with respect to the protocols for Date Marking. The Conference further requests that that the final interpretation document be posted to the FDA Food Code Reference System.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-035

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

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Issue History:

This is a brand new Issue.

Title:

Missing reference in 2013 FDA Food Code Section 3-501.19(A)(1)(a)

Issue you would like the Conference to consider:

Section 3-501.19(A)(1)(a) of the 2013 FDA Food Code should reference 3-501.19(B)(1)-(4), not just (1)-(3). This would be consistent with its reference to the equivalent requirement in (C)(5).

3-501.19(B)(4) requires that, when using time without temperature control as the public health control, foods that are not marked or have exceeded the time are discarded. Adding (B)(4) to the reference in 3-501.19(A)(1)(a) will require that discarding such food be addressed in the required written procedures.

Public Health Significance:

Requiring disposal to be included in the time as a public health control procedures will help prevent unsafe food from being served or sold.

Recommended Solution: The Conference recommends...:

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

3-501.19 Time as a Public Health Control.

(A) Except as specified under ¶ (D) of this section, if time without temperature control is used as the public health control for a working supply of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD before cooking, or for READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is displayed or held for sale or service:

(1) Written procedures shall be prepared in advance, maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that specify: ^{Pf}

(a) Methods of compliance with Subparagraphs (B)(1)-(~~3~~4) or (C)(1)-(5) of this section; ^{Pf}

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-036

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

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Clarifying Date Marking Disposition

Issue you would like the Conference to consider:

Subparagraph 3-501.18(A)(3) of the 2013 FDA Food Code refers to a food that is "appropriately marked with a date or day that exceeds" date marking timeframes. The word "appropriately" is confusing.

Public Health Significance:

Clarifying the Food Code can help with compliance.

Recommended Solution: The Conference recommends...:

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

3-501.18 Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.

(A) A FOOD specified in ¶ 3-501.17(A) or (B) shall be discarded if it:

(3) Is ~~appropriately~~ marked with a date or day that exceeds a temperature and time combination as specified in ¶ 3-501.17(A).^P

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-037

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

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code - Additional Requirements for Consumer Advisories

Issue you would like the Conference to consider:

Amending Section 3-603.11 of the 2013 FDA Food Code to include training and verbal communication of risk.

Public Health Significance:

An *E. coli* O157:H7 outbreak occurred in May 2014, in which 12 became ill and 7 were hospitalized after eating hamburgers in restaurants in 4 different states (CDC, 2014). Initially, the Michigan Department of Health reported that undercooked ground beef eaten at several different restaurants was a suspected source (WILX News, 2014). A recall of 1.8 million pounds of ground beef products suspected of contamination by *E. coli* O157:H7 was subsequently issued (CDC, 2014; Erb, 2014). Interviews with the sickened individuals revealed that eight of the twelve had ordered their hamburgers cooked rare or medium rare (Andrews, 2015). Four of the five illnesses reported in Ohio were traced to a restaurant chain. Epidemiological investigation revealed that all of the cases were tied to one strain of *E. coli* O157:H7, but could not reveal whether the risk of consuming undercooked hamburgers had been communicated with consumers (Andrews, 2015; CDC, 2014). The outbreak highlights several issues. First, it reveals the riskiness of undercooked hamburgers and the restaurant culture of ordering undercooked hamburgers. It also shows that using terms such as "medium rare" are not effective in describing how well-cooked a hamburger will be.

Measuring the temperature of a hamburger with a thermometer is the only reliable method to determine that it has reached a safe temperature; color is not a reliable indicator of doneness. Hamburgers can brown at temperatures well below the recommended endpoint temperature (Hague *et al.*, 1994, Lyon *et al.*, 2000). Premature browning is related to the oxidative state of the meat (Hunt *et al.*, 1999). The form of myoglobin at the time of cooking directly correlated to the visual and instrumental analysis results; hamburger patties that contained deoxymyoglobin (DMb) had more pink color when cooked than those that

contained oxymyoglobin (OMb) and metmyoglobin (MMb) (Hunt *et al*, 1999). Numerous other factors can contribute to the color of ground beef. Cooking pre-frozen hamburger patties results in more premature browning than allowing patties to thaw before cooking (Hunt *et al*, 1999). pH played a direct role in the thermostability of the different myoglobin forms; as pH increased, OMb and MMb became more stable (Hunt *et al*, 1999). Hamburger containing less fat takes longer to cook than hamburgers with a higher fat content (Troutt *et al.*, 1992). Meat from older carcasses showed a higher rate of premature browning than meat taken from younger carcasses (Marksberry, 1990).

Chefs and other culinary specialists cite methods of determining doneness other than temperature, such as color and touch (Levine and Chapman, 2014). A local food writer and chef writes about cooking hamburgers, "With practice, you can check doneness by touch: a little give for medium and just barely firm for well-done. Until you get good enough at that, though, the best bet is to peek. Make a small slit in a thicker part of the burger. The interior will be light pink for medium or just browned all the way through, but still juicy, for well-done." (Washington Post, 2007).

Recommended Solution: The Conference recommends...:

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

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

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

Those who are communicating to consumers must be trained in the hazards and risks associated with consuming raw or undercooked animal foods not otherwise processed to eliminate hazards and how to convey risk messages verbally to consumers.

(B) DISCLOSURE shall include:

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

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

(3) State there is a risk for foodborne illness associated with what they are ordering

(4) provide a safe temperature guideline so the consumer can request that temperature if desired, with a statement of how to significantly reduce risk (i.e., ordering cooked to above a certain endpoint temperature).

(5) State that color is not an indicator of doneness.

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

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

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

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

(4) The verbal statement must include that ordering /purchasing raw undercooked product increases risk of foodborne illness. All references to determining safety and doneness of a product should be made to temperature, not color or other indicators that are not reliable.

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Supporting Attachments:

- "Of course I know what I'm talking about: Assessment of Risk Communication a"

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**Of course I know what I'm talking about: Assessment of Risk Communication
about Undercooked Hamburgers by Restaurant Servers**

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KEY WORDS: hamburger safety, measuring doneness in hamburgers, risk communication

ABSTRACT

According to the U.S. Food and Drug Administration 2013 Model Food Code, it is the duty of a food establishment to disclose and remind consumers of risk when ordering undercooked food such as ground beef. The purpose of this study was to explore actual risk communication activities of food establishment servers. Secret shoppers visited restaurants (n=265) in seven geographic locations across the U.S., ordered medium rare burgers, and collected and coded risk information from chain and independent restaurant menus and from server responses. The majority of servers reported an unreliable method of doneness (77%) or other incorrect information (66%) related to burger doneness and safety. These results indicate major gaps in server knowledge and risk communication, and the current risk communication language in the Model Food Code does not sufficiently fill these gaps. Furthermore, should servers even be acting as risk communicators? There are numerous challenges associated with this practice including high turnover rates, limited education, and the high stress environment based on pleasing a customer. If it is determined that servers should be risk communicators, food establishment staff should be adequately equipped with consumer advisory messages that are accurate, audience-appropriate, and delivered in a professional manner so as to help their customers make more informed food safety decisions.

Introduction

Ground beef is a vehicle for human pathogens and its consumption has been identified as a risk factor for foodborne illness (7). Various pathogenic bacteria may be found in the gut of cattle (and on hides) and can contaminate meat during slaughtering and processing (5, 10). One of the pathogens commonly associated with ground beef is *Escherichia coli* O157:H7. Other serotypes of *E. coli* have also resulted in foodborne illness associated with ground beef (1). If ground beef is contaminated, two risk-reduction steps have been shown to be achieve a 5-log reduction: cooking to 155°F for 15 seconds or 160°F for <1 second, and avoiding cross-contamination (the transfer of pathogens from one surface to another post-processing). Sensory qualities such as color or texture, and/or cook time, are not reliable indicators of pathogen risk reduction on a hamburger, but are often cited by culinary professionals as indicators of doneness (8).

The U.S. FDA 2013 Model Food Code stipulates that when a food of animal origin (such as beef, eggs, fish, lamb, milk, poultry, or shellfish) is served raw, undercooked, or has been insufficiently processed to eliminate pathogens, the restaurant shall disclose and remind consumers of risk (6). Disclosure is defined as including a description of the animal-derived food (such as, “hamburger can be cooked to order”) and stating that the food is served undercooked, which is typically identified by an asterisk.

The reminder is to asterisk the food with a footnote stating that “consuming raw or undercooked meat, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness.” The consumer advisory may also include the distinction that this risk is especially increased if an individual has a particular medical condition, and that additional safety information is available upon request (6). However, there is little research to illustrate whether disclosure and reminder of risk is actually occurring, and what the role of restaurant servers is in the process.

The goal of this project was to investigate the process of risk disclosure and reminder in restaurants, on both the menu and by the server. It was hypothesized that there would be numerous gaps and inconsistencies in how risk is communicated in restaurants.

MATERIALS AND METHODS

Recruitment. Forty-four secret shoppers were recruited and trained to collect data in seven locations: Raleigh, NC; Blacksburg, VA; College Station, TX; Manhattan, KS; Lincoln, NE; Davis, CA; and Philadelphia, PA. Geographic locations were selected for convenience based on where project collaborators were located nationally, and to represent multiple regions of the United States. Restaurants were selected by using an online restaurant directory for each geographic location. Locations were classified according to the U.S. Census Bureau standards, which include urbanized areas (UA), which are defined as a densely developed territory (at least 1,000 people per square mile) of 50,000 people or more, or urbanized clusters (UC), which are defined as a densely developed territory between 2,500 and 50,000 people (12).

Secret shopper training was standardized and consisted of an in-person meeting between trainer and trainee at the sampling location. The secret shoppers were presented a brief background of the rationale for the project, followed by a walk-through of the script, which included an explanation of Likert scale coding, designed to rank degree of agreement or disagreement with certain statements. Likert scales were used to rank the level of correctness or incorrectness of server responses about undercooked hamburgers.

Data collection was primarily conducted during lunchtime on a weekday, and for convenience, the restaurant sample was limited to a radius of approximately 10 miles from the secret shopper's work location. Exceptions included Virginia and Kansas, where secret shoppers visited other cities in the state to reach the restaurant quota. A sample list was generated by randomly selecting from online regulatory catalogs of permitted food premises. A chain restaurant was defined as a franchised restaurant that included 10 or

more locations; less than 10 locations was classified as an independent restaurant. Each secret shopper was assigned a random number, restaurants generated from the sample list were assigned a number, and restaurants were randomly assigned to the secret shoppers.

Data Collection. Two secret shoppers visited each restaurant. First, secret shoppers captured pictures of the consumer advisory messages on the restaurant menu(s). Secret shoppers then ordered lunch to eat at the restaurant site, specifically not a hamburger. During the meal, secret shoppers ordered two hamburgers to go: one was ordered cooked medium rare, and the other, well done. The secret shopper ordering the medium rare hamburger ordered first. When ordering the medium rare burger, if the server did not proactively provide any risk information, the secret shopper ordering the well-done burger interjected to ask:

- Is that safe to eat?
- How do you determine doneness (whether it is safely cooked or not)?

Secret shoppers occasionally went off script based on server responses and how the conversation progressed. Server responses to the questions were documented by the secret shoppers, in most cases as text on a cell phone.

Coding. Data were segmented by server response to secret shopper questions for each restaurant, and a codebook was developed to analyze these responses. Five categories were used to examine the different aspects of server communication. Specifically, server responses were coded for (1) availability of medium rare ordering; (2) method of determining doneness; (3) whether safety information was mentioned; (4) whether incorrect information was mentioned; and (5) appearance of server confidence.

The question of availability of medium rare burgers was addressed by coding for whether servers allowed medium rare to be ordered.

- **Yes** was coded when servers allowed burgers to be ordered
- **No** was coded when servers cited restaurant policy that did not allow medium rare to be ordered.

One of the primary goals of this research was to capture the method of doneness cited by the server; more specifically, how many restaurant servers communicate an unreliable indicator of doneness to consumers. After review of the data, six codes emerged to describe types of “doneness” as described by servers. Some data units were double-coded or even triple-coded in cases when servers mentioned more than one method of determining doneness.

- **Temperature** was coded when a thermometer use was referenced, or when a specific temperature was mentioned. Temperature was sometimes double-coded with color.
- **Color** was coded when mentioned by the server. Color was often double-coded with touch, and sometimes double-coded with temperature.
- **Touch** was coded when a textural quality was mentioned, or when words such as “warm” or “cold” were used. Touch was often double-coded with color.
- **Time** was coded when any unit of time was mentioned or implied.
- **Cooks know** was coded when cook experience was used as the criteria for judging degree of doneness.
- **I don’t know** was coded when the server stated that he or she did not know or was not sure.

The third category addressed the question: Is safety information provided by the server? Because servers frequently referred to factors that were more directly related to quality, but believed them to be safety related, such statements were also coded as safety information.

- **Yes** was coded when the risk for foodborne illness was stated; when the consumer was told directly whether it was safe or not to consume medium rare burgers; when the health department or Food Code was mentioned; or when a quality factor was mentioned as an answer to a safety question, implying that the two are related.
- **No** was coded when the above information was not provided. Some servers provided a method of doneness, but made no statements about safety. These instances were also coded under this category.

The fourth category further addressed the question of risk information by coding for whether incorrect information was provided.

- **Yes** was coded when any incorrect information was stated. Incorrect information included any method to determine doneness other than temperature; statements about quality that implied a correlation with safety; and/or a direct statement of safety if the temperature was stated to be below 160°F.
- **No** was coded when all information provided was correct.

The fifth category was the appearance of confidence of the server: positive or negative.

- **Positive** was coded with the use of “to be” verbs, indicative mood, no hedging, and overall apparent confidence of the server as noted by direct observation by the secret shopper.
- **Negative** was coded with the use of conditional language or hedging, and overall appearance of little confidence as observed by the secret shopper.

Code reliability was confirmed by determining simple reliability and Cohen’s kappa using a second coder for the initial 40 restaurants visited. Both values for each code are listed in Table 1. Because Cohen’s kappa values were all within the range of acceptability, refinement of codes was not necessary.

Likert scales were also developed to score the risk messages found on the menus and to provide a comprehensive score for server responses. This was done because there were varying degrees of correct or incorrect information provided, as well as depth of information, and the need to characterize such variations quantitatively. There were a total of four scales used: a menu scale; an initial server response scale (assigned to each server response that dictated whether it was subsequently scored as correct or incorrect information; a correct server response scale (used when the response contained correct information); and an incorrect server response scale (used when the response contained incorrect information). Each site visited was assigned a score from three of the four scales. Scores ranged from a low of 1 to a high of 7. For the menu and initial server scales, incorrect information received scores between 1 and 3, and correct information received scores between 4 and 7. The correct and incorrect scales were used to further quantify the type of information that was shared by the server. Secret shoppers and an additional coder scored the data based on these scales.

The three most recent inspection reports were collected from those restaurants for which they were available. Inspection frequencies varied, but inspection typically occurred once per year. The information from inspection reports about posted consumer advisory messaging [in compliance (I), out of compliance (O), or N/A] were collected from each report.

Data Analysis. Data were analyzed using SAS 9.4 software (SAS Institute, Cary, NC). Analysis consisted of running a GLIMMIX procedure to determine a p value for each comparison and compare differences in code frequencies and Likert scores between states, restaurant type, and restaurant location. A Spearman correlation was performed on secret shopper Likert scores for menu and server response scores to test the consistency of training and ensure validity.

RESULTS

Coding. A total of 265 restaurants were visited (132 chain, 133 independent); 87.6% of them were in urbanized areas, while 12.4% were in urban clusters. Based on the coding explained above, six subcodes were used to describe servers' reporting of method used to determine doneness: temperature, color, touch, time, cooks know, or server stated that they did not know. In some instances, servers did not mention a method of doneness; some servers listed more than one method of doneness in a conversation. A total of 296 responses were obtained, exclusive of 66 instances in which the server did not mention a method of doneness and inclusive of server responses in which more than one subcode was cited. Response rate to this question was 74.0% ($n = 199$) and Figure 1 illustrates the overall percentage of each method of doneness mentioned by a server. The majority of server respondents cited a single subcode, but 23.6% ($n = 47$), 4.0% ($n = 8$), and 0.5% ($n = 1$) provided double coding, triple coding, or quadruple coding. The most frequent instances for which multiple methods of doneness were mentioned were for temperature and color, color and touch, or all three.

Overall, 74.1% of restaurants ($n = 196$) allowed medium rare burgers to be ordered. There was not a significant difference between states or population area, but significantly more independently owned restaurants allowed secret shoppers to order medium rare burgers than did chain restaurants ($p = 0.0007$).

In 50.7% of the conversations ($n = 134$), servers mentioned safety information (both correct and incorrect information). There was a difference between states, with California having the highest rate of safety information sharing, and significantly differing from Kansas, Nebraska, and Pennsylvania ($p = 0.0095, 0.0316, 0.0014$,

respectively). There was not a difference between type of restaurant ($p = 0.6183$) or population area ($p = 0.1952$) relative to servers discussing safety.

For those instances in which servers shared information, that information was incorrect in 66.7% of the interactions ($n = 177$). There were significant state-to-state differences; Pennsylvania had the highest rate of incorrect information shared ($p = 0.0051$). There was no difference when comparing information sharing by type of restaurant or population area. Approximately 70% of servers appeared confident ($n = 189$). There was not a significant difference in appearance of confidence by state ($p = 0.5776$), restaurant type (0.6321), or population area ($p = 0.9737$).

Likert Scoring. A Spearman's correlation was run on secret shopper and control Likert scores to ensure that they were a consistent standard, and that the secret shopper training was valid. The scores that were generated confirmed validity (menu = 0.741, initial server = 0.612, correct server = 0.354, incorrect server = 0.388).

The Likert scale data are summarized in Tables 3, 4, and 5. Virginia had the highest menu scores, while California scored the lowest. Similar results were observed for the initial server scores, although Pennsylvania and Texas also scored low. Chain restaurant menu and initial server scores were significantly higher than independent restaurant scores ($p < 0.001$). Urbanized clusters scored significantly higher than urbanized areas for menu scores ($p < 0.001$) but not for initial server scores.

Thirty-five percent of server interactions ($n = 93$) qualified to be scored on the correct server response Likert scale, while 67% of server interactions qualified to be scored on the incorrect server response Likert scale. There was wide variability in these scores when comparing states. There was not a significant difference for restaurant type

for either types of server response (correct $p = 0.6705$, incorrect $p = 0.7950$). However, urbanized areas scored higher than urbanized clusters for the correct server response scoring ($p = 0.0080$), but not for incorrect server response ($p = 0.0752$).

Inspection Reports. Not all of the inspection reports were available to access for each restaurant (0% missing for Nebraska; 46% missing for Pennsylvania). Based on those available, the majority of restaurants were reported to be in compliance with consumer advisory messaging in inspection reports (Table 6). North Carolina had the highest rate of noncompliance. For all of the other states, there was at least one round of inspections in which noncompliances related to written consumer advisories were absent.

Server Responses. Posing questions to servers yielded a wide array of responses related to safety of the product, determining doneness, and servers' personal opinions. Particularly notable responses included stating that undercooked burgers were safe even for pregnant women, just the outside of burgers are where the bad bacteria lives, and the cook just knows if the burger is done by feeling it. These types of responses highlight the major gaps and inconsistencies in the information that servers provide to consumers.

DISCUSSION

Beef hamburgers are a favorite of Americans, and despite their association with some high profile foodborne illness outbreaks and the scientific consensus that temperature is the only reliable indicator of doneness, consumers continue to eat burgers that are not thoroughly cooked as a result of personal and cultural preferences. Consumer messaging can take many forms, both written and oral. The purpose of this study was to determine whether restaurant servers discuss risks of consuming undercooked hamburgers with consumers, and if so, what information they share. Identifying current practices helps determine inconsistencies in the risk information that is being communicated, and to make recommendations as to what information would most effectively communicate risk so that consumers can make an informed decision. A secret shopper study design was chosen, in which data collectors posed as restaurant patrons and collected information from servers while actually ordering medium rare hamburgers. While more expensive than a national survey of servers in which they self-report their behaviors, this design allowed for direct communication with the servers and the opportunity to present the data in both qualitative and quantitative manners. A previous secret shopper study conducted in 13 supermarkets in Ontario revealed that store employees appeared confident in the advice they offered, but it was incorrect; poor food handling practices were also observed (9). Points of particular interest were the methods used to determine hamburger doneness; whether ordering undercooked hamburgers was allowed; and whether the information shared by servers was correct. Information on written menu messages and inspection reports were provided as a framework for comparison.

While inspection reports for the restaurants visited showed a high rate of compliance with Food Code-recommended consumer advisory messaging, the Likert scores for menu messaging and server response were not always consistent, and servers frequently provided contradictory information. For example, servers used a wide array of unreliable factors when discussing burger doneness, particularly color. In some cases, this was simply because the server did not know the temperature ranges used to cook hamburgers. This lack of knowledge suggests poor communication between the kitchen staff and serving staff, as well as the possibility that thermometers are not being used by kitchen staff. This is consistent with the literature (2). When servers did mention temperature, it was often in conjunction with another qualitative factor, such as color or time.

Similarly, the majority of restaurants were in compliance relative to consumer advisory messaging on inspection reports. Nonetheless, servers frequently contradicted the risk information found on the menu by citing qualitative indicators of doneness (as described above); assuring consumers that undercooked hamburgers were safe to consume; or by listing temperatures that are not sufficient to kill pathogens. For the servers that did share correct information, the average Likert scores show that prompting by the secret shopper was still required to get any risk information, which was part of the secret shopper ordering protocol if servers did not volunteer risk information. The inconsistency between inspection reports and server risk messaging illustrates a major drawback of the former, in that formal inspections can miss the impact of personal communication in risk management. Stressing the importance of consumer advisory in the process of inspections would be one step towards a more positive risk communication

culture in restaurants. Adding this component not only fills the gap in investigating how a restaurant communicates risk, but also serves to emphasize its importance to those administering and receiving the inspection.

The Likert scoring revealed some differences between states and restaurant type with respect to the quality of risk information that was shared by servers. For example, California scored the lowest for menu and initial server score. North Carolina, which adopted the 2009 FDA Food Code shortly before the secret shopper study began, had high scores. Chain restaurant servers consistently scored higher than independent restaurant servers. This is to be expected, as chain restaurants typically have standardized food safety programs that include employee training and appropriate messaging.

The data presented here demonstrate a gap in server knowledge about food safety risks and the communication of that risk to consumers. But should servers be risk communicators? Placing them in this role presents challenges: (i) high turnover and low pay; (ii) limited education; (iii) high stress and fast-paced environment; and (iv) pressure to “please” the consumer and provide a pleasurable dining experience. If we were to rely on servers for food safety communication, the data presented here suggests the need for a more formal food safety curriculum specifically aimed towards servers, with the ultimate goal of improving risk messaging to consumers. Risk communication literature demonstrates that consumers need to understand the context of a risk in order to identify and remember it (4). Familiarity also plays a strong role in consumer perception of a risk, as does trust (11). Behavior and risk communication are more likely to be impacted when targeting both knowledge and individual intention. Food servers may be in the unique position of providing accurate food safety information to consumers. Identifying

additional roadblocks and determining server receptivity to training interventions focused on risk communication is the next step moving forward from this study.

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FIGURE LEGENDS

Figure 1. Overall percentages of method of doneness mentioned by server (n = 296).

Table 1. Simple reliability and Cohen's kappa for secret shopper codes.

Code	Simple reliability	Cohen's kappa
Medium rare allowed	100%	1
Method of doneness	72%	0.65
Safety information provided	89%	0.75
Incorrect information	85%	0.68
Appearance of server confidence	93%	0.82

Table 2. Likert scores for menu, initial server, correct server, and incorrect server by state. An asterisk designates when there was a significant difference between state scores. The highest and lowest score for each category is in bold.

State	Menu* (n = 276)	Std. dev.	Initial Score* (n = 269)	Std. dev.	Correct score* (n = 105)	Std. dev.	Incorrect score* (n = 191)	Std. dev.
California	3.19	0.83	2.89	1.25	4.25	-	4.84	1.95
Kansas	3.84	0.85	3.44	1.39	2.60	1.22	5.24	1.71
Nebraska	3.83	0.88	3.31	1.37	3.53	1.48	4.77	1.74
North Carolina	3.99	0.59	3.24	1.46	2.95	1.16	4.81	1.54
Pennsylvania	3.86	0.88	2.86	0.99	2.14	0	4.50	2.06
Texas	3.64	0.84	2.82	1.57	4.33	1.83	4.23	1.99
Virginia	4.08	0.91	3.84	1.63	3.46	0.94	2.88	1.78
Total	3.79	0.88	3.22	1.42	3.19	1.34	4.60	1.90

Table 3. Likert scores for menu, initial server, correct server, and incorrect server by restaurant type. An asterisk designates when there was a significant difference between chain and independent scores.

Restaurant Type	Menu* (n = 276)	Std. dev.	Initial Score* (n = 269)	Std. dev.	Correct score (n = 105)	Std. dev.	Incorrect score (n = 191)	Std dev.
Chain	4.09	0.94	3.40	1.45	3.21	1.78	4.68	1.92
Independent	3.52	0.66	3.03	1.38	3.17	1.78	4.52	1.89

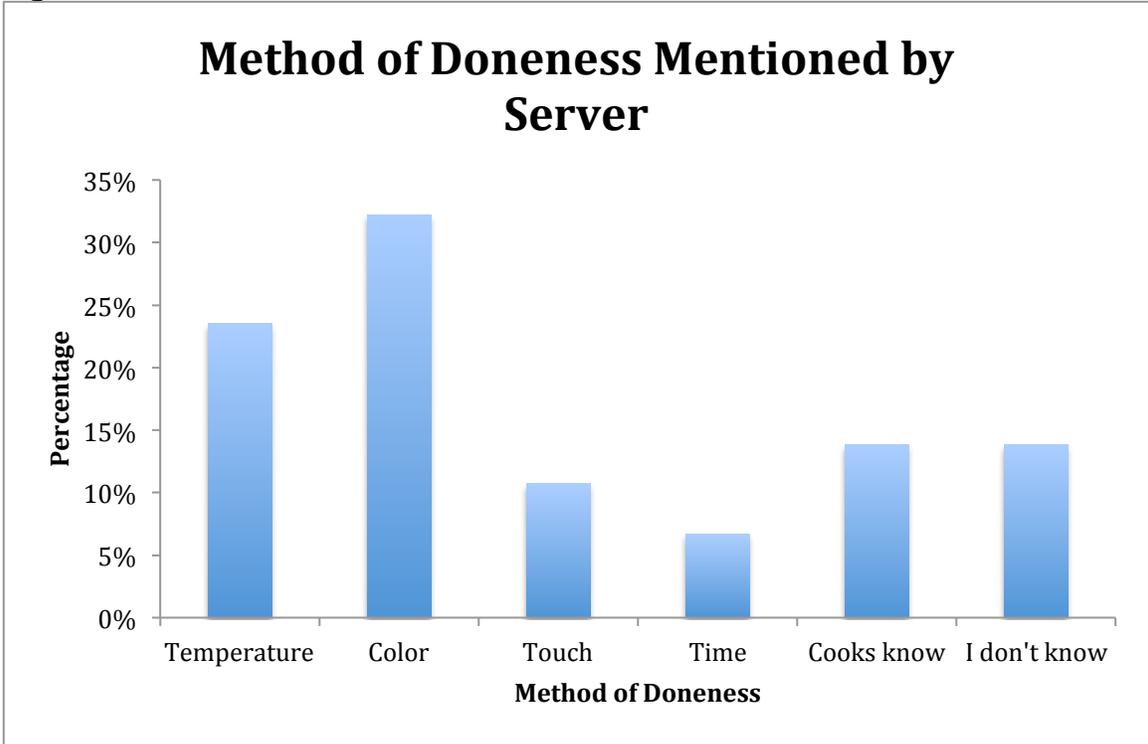
Table 4. Likert scores for menu, initial server, correct server, and incorrect server by population area. An asterisk designates when there was a significant difference between urbanized area and urbanized cluster scores.

Population Area	Menu* (n = 276)	Std. dev.	Initial Score (n = 269)	Std. dev.	Correct score (n = 105)	Std. dev.	Incorrect score* (n = 191)	Std. dev.
Urbanized Area	3.76	0.83	3.18	1.42	3.22	1.85	4.76	1.83
Urbanized Cluster	4.09	0.98	3.56	1.40	3.05	1.43	2.67	1.63

Table 5. Average rate of compliance with consumer advisory messaging in restaurants visited for past 3 inspections.

Compliance category	Percentage
In compliance	68%
Out of compliance	9%
N/A	23%

Figure 1.



**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-038

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Raw Animal Foods – Consumer Advisory

Issue you would like the Conference to consider:

Section 3-401.11(D) and 3-401.11(D)(3) in the 2013 FDA Food Code allow:

"3-401.11(D) A raw animal food such as raw egg, raw fish, raw-marinated fish, raw Molluscan shellfish, or steak tartar; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in ¶ (C) of this section, may be served or offered for sale upon consumer request or selection in a ready-to-eat form if:"

"3-401.11(D)(3) the CONSUMER is informed as specified under 3-603.11 that to insure its safety, the FOOD should be cooked as specified under (A) or (B) of this section;"

However, Section 3-603.11 does not require that the food establishment provide language informing the consumer how to request or select the animal food cooked as specified under 3-401.11(A)(B)

Since section 3-603.11 does not require the food establishment to provide language for how consumers can request or select animal food cooked as specified under 3-401.11(A)(B) people who want to order their animal food cooked safely may accidentally receive it partially cooked.

Food establishments that utilize the consumer advisory should have to have an ordering system in place that informs the consumer what to say to request or select their animal cooked as specified under 3-401.11(A)(B). Ordering animal food raw or partially cooked should be a willful act on the part of the consumer. Serving an animal food raw or partially cooked should be an intentional act on the part of the food establishment.

If, for example, a food establishment uses the terms rare, medium-rare, medium, medium-well and well done for placing an order they need to be able to convey to the consumer and the regulatory authority, in writing and upon request, which of those terms will result in the food being cooked pursuant to 3-401.11(A)(B).

By adding a new section to 3-603.11 it will:

1. Still enable consumers to request or select animal foods raw or partially cooked.
2. Allow consumers to order animal foods that are subject to the consumer advisory to be cooked safely.
3. Allow each food establishment that utilizes the consumer advisory to use their own ordering language to comply with this requirement.
4. Give regulators a way to hold the permit holder more accountable to the temperature requirements of section 3-401.11(A)(B) for those menu items that have a consumer advisory.

Public Health Significance:

The 1993 E. coli O157:H7 outbreak linked to a popular fast food restaurant chain fundamentally changed how beef is slaughtered, processed, distributed, and cooked in the United States. The outbreak, which sickened over 500 people and caused the death of four children was the catalyst for:

- E. coli O157:H7 and Hemolytic Uremic Syndrome (HUS) being added to the federal list of reportable diseases by the Center for Disease Control (CDC) in 1995,
- The Food and Drug Administration (FDA) raising their recommended internal temperature of cooked hamburgers to 155 degrees Fahrenheit in 1993,
- The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) declaring E. coli O157:H7 to be an adulterant in raw ground beef in 1994. (In 2011 six additional strains of E. coli were declared to be adulterants.)
- The USDA initiating a monitoring program for E. coli O15:H7 in raw ground beef,
- FSIS initiating a program to encourage better testing and controls by industry and,
- FSIS began requiring safe food handling labels on all raw meat and poultry.

Those measures, along with systematic changes in critical control points in processing by the beef industry, were intended to minimize E. coli contaminated beef from entering the food supply. However, the approximately 1.8 million pound recall of ground beef tied to E. coli O157:H7 in 2014; separate 5.3 million pound and 1.36 million pound recalls in 2008; a 21.7 million pound recall in 2007; and a 25 million pound recall in 1997 highlight the continued risk of contaminated beef reaching the consumer. The risk associated with E. coli is of particular concern as there is still no effective way to prevent the onset of HUS in those patients that contract a Shiga toxin-producing E. coli infection.

There are many other pathogens associated with raw and partially cooked animal foods. Poultry, Pork, Egg and Seafood Producers as well as the producers of other amenable and non-amenable meats all have challenges similar to the Beef Producers and yet unique to their own industries. Hepatitis A, Listeria monocytogenes, Clostridium botulinum, Clostridium perfringens, Campylobacter jejuni, Staphylococcus spp., Salmonella spp., Shigella spp., Vibrio spp., and Norovirus are among those diseases that are transmissible from raw animal foods. The risk of these illnesses being transmitted is increased when the animal foods associated with these pathogens are served raw or partially cooked.

At a food establishment, a consumer should be able to order animal foods- cooked safely- to minimize the risk of getting sick from these foodborne pathogens. Given the current

language of the FDA Food Code, if there is a consumer advisory present on the menu, there is often no effective means for the consumer to order food cooked safely.

The annex of the 2013 FDA Food Code states "the requirements specified under 3-401.11(D) acknowledge the rights of an informed consumer to order and consume foods as preferred by that consumer based on the consumer's health status and understanding of the risks associated with eating raw or partially-cooked animal foods."

However, I do not believe that 3-401.11 and 3-603.11, as written, adequately protect the rights of the consumers who want their animal foods cooked pursuant to 3-401.11(A)(B). Those consumers often have no effective means to order animal food cooked safely in those food establishments that choose to provide a consumer advisory.

It also has caused the unintended consequence that the regulatory community is not able to hold a food establishment accountable for accidentally undercooking animal food when there is a consumer advisory present on the menu.

Recommended Solution: The Conference recommends...:

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

Section 3-603.11

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

(D) the FOOD ESTABLISHMENT has, in writing and available to the CONSUMER and REGULATORY AUTHORITY, ordering information that will give the CONSUMER an effective means of requesting or selecting the animal FOOD cooked pursuant to 3-401.11(A)(B)^{Pf}

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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
2016 Issue Form**

Issue: 2016 I-039

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Addition of new Food Code section: Grinding Logs

Issue you would like the Conference to consider:

This proposal requests the addition of a requirement for retail food establishments to comply with regulations issued by the Food Safety and Inspection Service (FSIS) that require certain retail food establishments that grind raw beef products to maintain records of the source for the materials they use, date and time the beef was ground, and date and time when grinding equipment was cleaned and sanitized. At the retail level, state and local governments provide for regulatory oversight and enforcement. The purpose of this proposal is to provide in the 2013 FDA Food Code a requirement for retail food establishments to comply with 9 CFR (Code of Federal Regulations) 320.

Public Health Significance:

The Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some retail food establishments may grind intact beef to produce ground beef "in house". While this practice is lawful, it may present an increased risk of foodborne illness to consumers because grinding intact beef "in house" may spread pathogenic contamination from the exterior of an intact product throughout the resulting ground beef, or, may serve as a source of cross-contamination of grinding equipment. Further, consumers may mistakenly believe that ground beef produced "in house" in this way is fresher or safer, and thus may undercook such products, which is insufficient to kill pathogens.

FSIS in promulgating the rule on "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" has recognized that when illnesses occur, it is necessary to have complete records for purposes of tracing the contaminated product to its source. The Association of Food and Drug Officials (AFDO) requested FSIS to submit the rule to the Conference for Food Protection for adoption into the Food Code to address issues of oversight and enforcement.

It would thus serve public health for the Conference to act on AFDO's recommendation.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended with the addition of the following language to the appropriate section or paragraph of Part 3-2, Sources, Specifications, and Original Containers and Records (language to be added is underlined):

Grinding Log.

As required under 9 CFR 230, a grinding log shall be maintained for any beef products that are ground on the premises of a food establishment, and such log shall be open and available for inspection upon request of a duly authorized inspector.

Submitter Information:

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Supporting Attachments:

- "Official Comments from the Association of Food and Drug Officials"
- "Final Rule: Records to be Kept by Official Establishments and Retail Stores"

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



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Official Comments from the Association of Food and Drug Officials

Date:	9/19/2014
Subject:	Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products
Docket ID:	FSIS-2009-0011
RIN:	0583-AD46
CFR Citation:	9 CFR Part 320

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The Association of Food & Drug Officials [AFDO] is a national organization that represents state, local, and federal government food, drug, and medical device safety regulatory officials. Within the food protection arena, AFDO is well known for promoting uniformity and cooperation among the regulatory community and has participated in numerous collaborative projects to advance these objectives. AFDO's vision for an integrated food safety system nearly two decades ago remains a foundational goal today for improving government's oversight of our global and domestic food supply. Additionally, AFDO continues to develop a host of model codes and guidance documents that state and local regulatory agencies can utilize for promulgating their own specific regulations and for improving their field staff's inspection skills. Because of AFDO's strong allegiance to state and local food safety programs, we routinely intervene in matters we feel are important to government regulators and which can have an important impact on public health.

The USDA's Food Safety and Inspection Service has proposed amending 9 CFR Part 320 by including a rule designed to improve the traceability of ground beef by requiring all producers of these products to keep extensive records. Under the proposed new requirements, ground beef producers would have to record the source, supplier and names of all materials used in producing ground beef. FSIS officials have indicated that ground beef sold at retail is often produced by combining cuts from multiple beef sources, which becomes problematic during foodborne illness investigations when the agency attempts to identify the source of the illness outbreak.

As the proposed rule would apply to both official processing establishments and retail facilities, its application is most significant at the retail area where FSIS does not maintain an oversight presence. Government oversight at retail facilities is conducted by state and local government agencies that license or permit, conduct inspection and investigation, and collect and test food products for safety. All of these agencies are, therefore, impacted by this proposed rule. The proposed rule, if finalized, will require such facilities to maintain clear records identifying the source, supplier, and names of all materials used in the preparation of raw ground beef products.

AFDO is pleased to offer the following comments on the proposed new requirements:

September 19, 2014

Page 2

It appears USDA/FSIS is seeking to broaden its regulation of retail-exempt facilities, which have traditionally come under the purview of state and local regulatory authorities. If adopted, this rule could very well set a precedent for USDA/FSIS to expand its regulatory activities with regard to retail and grocery facilities that are not currently subject to ongoing federal inspection. AFDO would not be supportive if this were to be true but would welcome a more collaborative system of addressing FMIA requirements in retail-exempt establishments through Memorandums of Understanding [MOU's] or Cooperative Agreements with state or local food safety regulatory agencies.

FSIS should indicate how they plan to enforce the requirements of the proposed rule should they be approved. Will FSIS have their Compliance staff conduct inspections at retail, and, if so what types of enforcement actions would they take for non-compliant retail establishments? Here, again, AFDO believes FSIS should consider collaborating with state and local agencies on enforcement activities since these agencies currently license and permit them to operate.

It would seem appropriate for FSIS to submit the proposed rule to the Conference for Food Protection [CFP] for adoption into the FDA Food Code and eventually into state rules.

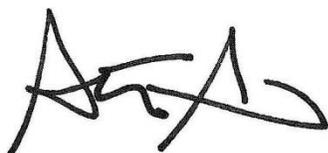
The proposed rule would provide access to records by FSIS personnel because of the importance of these records during foodborne illness investigations. FSIS investigators, however, are seldom the first responders to illness outbreaks. Local and state health officials are the first to respond and generally conduct the majority of the illness investigation in the early stages. While AFDO supports the proposed requirement for providing FSIS investigators access to records, we would strongly recommend the wording be amended in such a way to provide record access by state and local officials as well. If this proposed rule is truly intended to impact foodborne illness by helping to improve effective trace-back and trace-forward activities at retail establishments, this amended language is necessary, in our view.

Under 9 CFR 320.2, a person or business that conducts business at multiple locations are allowed to maintain required records at the business's office location. Since these records are critical in foodborne illness and recall investigations, we believe the proposed rule should require the records to be maintained at the business where ground beef is produced. In a number of circumstances, major retail grocery chains operate in multiple states with their main offices located in one location. It is not unreasonable to expect the records to be maintained at the location of production which could help speed any investigation that might occur.

AFDO is very supportive of the proposed rule as we believe it will assist regulators in the oftentimes difficult task of identifying contaminated product. Furthermore, our experience with voluntary recordkeeping indicates it is ineffective and not uniformly accepted. This proposed rule can have an impact on creating improved investigation and identification capabilities for regulatory officials.

AFDO appreciates the opportunity to comment on this important proposed rule.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Stephen Stich', with a stylized, cursive flourish at the end.

Stephen Stich
AFDO President

Rules and Regulations

Federal Register

Vol. 80, No. 244

Monday, December 21, 2015

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 320

[Docket No. FSIS-2009-0011]

RIN 0583-AD46

Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its recordkeeping regulations to require that all official establishments and retail stores that grind raw beef products for sale in commerce maintain the following records: The establishment numbers of establishments supplying material used to prepare each lot of raw ground beef product; all supplier lot numbers and production dates; the names of the supplied materials, including beef components and any materials carried over from one production lot to the next; the date and time each lot of raw ground beef product is produced; and the date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. These requirements also apply to raw beef products that are ground at an individual customer's request when new source materials are used.

DATES: Effective June 20, 2016.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; Telephone: (202) 205-0495; Fax (202) 720-2025.

SUPPLEMENTARY INFORMATION:

Executive Summary

This rule requires official establishments and retail stores that grind raw beef for sale in commerce to maintain specific information about their grinding activities. This rule is necessary to improve FSIS's ability to accurately trace the source of foodborne illness outbreaks involving ground beef and to identify the source materials that need to be recalled. The recordkeeping requirements in this final rule will greatly assist FSIS in doing so.

FSIS has often been impeded in its efforts to trace ground beef products back to a supplier because of the lack of documentation identifying all source materials used in their preparation. On July 22, 2014, FSIS published a proposed rule (79 FR 42464) to require official establishments and retail stores to maintain records concerning their suppliers and source materials received. Having reviewed and considered all comments received in response to the proposed rule, FSIS is finalizing the rule and making several changes in response to comments. Most of the proposed requirements are retained in this final rule. This final rule requires establishments and retail facilities that grind raw beef to keep the following records: The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef; all supplier lot numbers and production dates; the names of the supplied materials, including beef components and any materials carried over from one production lot to the next; the date and time each lot of raw ground beef is produced; and the date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. These requirements also apply when official establishments and retail stores grind new source materials at an individual customer's request.

In response to comments, FSIS is not adopting two proposed requirements. First, under this final rule, establishments and retail stores that grind raw beef products will not have to maintain records concerning the weight of each source component used in a lot of ground beef. After considering comments, FSIS concluded that weighing each component in a lot of ground beef was time-consuming and offered little food safety benefit because contamination in a lot of ground beef is

not dependent on the weight of any contaminated component. FSIS is also not requiring that establishments and stores that grind raw beef products maintain records of the names, points of contact, and phone numbers of each official establishment supplying source material because FSIS already has this information in its Public Health Information System (PHIS). Any marginal benefit presented by these two proposed requirements would be outweighed by the time burden associated with recording the information. In response to comments, this rule also differs from the proposed rule in terms of the place where the records must be maintained and the retention period. Under the proposed rule, based on existing recordkeeping requirements (9 CFR 320.1), establishments and retail stores would have been allowed to keep the required records at a business headquarters location if the grinding activity is conducted at multiple locations. In response to comments, however, this rule requires the grinding records to be kept at the location where the beef is ground. This change in the final rule will save investigators valuable time and will reduce the risk that records will be lost or misplaced. Finally, in response to comments, for purposes of this rule, FSIS is including the definition of a lot as set out in the regulatory text at the end of this document (9 CFR 320.1(b)(4)(iii)).

Under the proposed rule, based on existing regulations (9 CFR 320.3(a)), the required grinding records would have been required to be maintained for up to three years. However, in response to comments, FSIS concluded that because the records required by this rule are needed primarily to investigate foodborne illness outbreaks, their utility diminishes over time. FSIS consulted with its investigators and public health experts and determined that the records would rarely be needed after one year. Considering this fact and comments concerning the burden of keeping records on-site, particularly at retail stores, FSIS shortened the retention period in the final rule to one year after the date of the recorded grinding activity.

The final rule will result in storage and labor costs to official establishments and retail stores that grind raw beef for sale in commerce. Benefits will accrue

in terms of averted foodborne illnesses, less costly outbreaks and recalls, and increased consumer confidence when

purchasing ground beef. These costs and benefits are listed in Table 1.

TABLE 1—EXECUTIVE SUMMARY TABLE

<p>Costs:</p> <ul style="list-style-type: none"> Labor Storage Unquantified Costs <p>Benefits:</p> <ul style="list-style-type: none"> Unquantified Benefits 	<ul style="list-style-type: none"> ▪ \$56.6 million annually (\$45.8 million to \$67.4 million). ▪ \$2.7 million annually. ▪ Non-labor costs associated with recordkeeping for customer-requested grinds. ▪ Potential for slight costs to consumers in the form of ground beef price increases. <ul style="list-style-type: none"> ▪ Benefits to consumers in the form of averted foodborne illnesses as a result of contaminated ground beef. ▪ Benefits to retailers and official establishments grinding raw beef in the form of less costly food safety events, such as outbreaks and recalls. ▪ Benefits to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.
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Background

Under the authority of the Federal Meat Inspection Act (FMIA) and its implementing regulations (9 CFR 329.1 and 329.6), FSIS investigates reports of consumer foodborne illness associated with FSIS-regulated products. FSIS investigators and other public health officials use records kept at all levels of the food distribution chain, including the retail level, to identify the sources of outbreaks.

FSIS has often been impeded in these efforts when an outbreak involves ground beef because of a lack of documentation identifying all source materials used in its preparation (79 FR 42464). In some situations, official establishments and retail stores have not kept adequate records that would allow effective traceback and traceforward activities. Without such records, FSIS cannot conduct timely and effective consumer foodborne illness investigations and other public health activities throughout the stream of commerce.

As FSIS also explained in the proposed rule, official establishments and retail stores that grind raw beef products for sale in commerce must keep records that will fully and correctly disclose all transactions involved in their business that are subject to the FMIA (see 21 U.S.C. 642) (79 FR 42465). Businesses must also provide access to, and permit inspection of, these records by FSIS personnel.

The proposed rule also explained that under 9 CFR 320.1(a), every person, firm, or corporation required by 21 U.S.C. 642 to keep records must keep records that will fully and correctly disclose all transactions involved in the aspects of their business that are subject to the FMIA. Records specifically required to be kept under 9 CFR 320.1(b) include, but are not limited to, bills of sale, invoices, bills of lading,

and receiving and shipping papers. With respect to each transaction, the records must provide the name or description of the livestock or article, the number of outside containers, the name and address of the buyer or seller of the livestock or animal, and the date and method of shipment.

The recordkeeping requirements contained in the FMIA and 9 CFR part 320 are intended to permit FSIS to trace product, including raw ground beef product associated with consumer foodborne illness, from the consumer, or the place where the consumer purchased the product, back through its distribution chain to the establishment that was the source of the product. Having this information available will make it easier to determine where the contamination occurred. Investigators should also be able to conduct effective traceforward investigations so as to identify other potentially contaminated product that has been shipped from the point of origin of its contamination to other official establishments, retail stores, warehouses, distributors, restaurants, or other firms. FSIS must be able to carry out these investigations using records that should be kept routinely by official establishments and retail stores.

In the proposed rule, FSIS explained past efforts it has made to ensure that official establishments and retail stores that produce raw ground beef maintain necessary records. For example, the proposal explained that in 2002, FSIS published a **Federal Register** notice that listed the data that FSIS intended to collect when any samples of raw ground beef produced at an official establishment tested positive for *E. coli* O157:H7 (67 FR 62325, Oct. 7, 2002). FSIS also listed the information it intended to gather from retail stores at the time it collected a sample of raw ground beef for *E. coli* O157:H7 testing,

In the proposed rule in the present rulemaking, FSIS explained that shortly after issuing the 2002 **Federal Register** notice, the Agency began collecting the information listed in the **Federal Register** notice from official establishments and retail stores (79 FR 42465).¹ However, as the proposal explained, some retail stores and official establishments still did not maintain records sufficient for traceback, and some retail stores did not document or maintain supplier information at times other than when FSIS collected samples of ground raw beef product from the stores for *E. coli* O157:H7 testing.² As a result, FSIS was, and remains, disadvantaged in its foodborne disease investigations.

In 2009, FSIS provided guidance to a retail industry association, which was made available on the FSIS Web site, stating that retail stores should keep appropriate records to aid in investigations involving FSIS-regulated products associated with foodborne illnesses and other food safety incidents.

To further address the issue, on December 9–10, 2009, the Food and Drug Administration (FDA) and FSIS held a public meeting to discuss the essential elements of product tracing systems, gaps in then-current product tracing systems, and mechanisms to enhance product tracing systems for food.³ This meeting was followed on

¹ FSIS Notice 47–02, November 20, 2002, “FSIS Actions Concerning Suppliers that may be Associated with *Escherichia coli* (*E. coli*) O157:H7 Positive Raw Ground Beef Product.”

² On June 4, 2012, FSIS implemented routine verification testing for six Shiga toxin-producing *E. coli* (STEC), in addition to *E. coli* O157:H7, in raw beef manufacturing trimmings. See *Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products* (77 FR 31975, May 31, 2012).

³ Comments from this hearing are available at: <http://www.regulations.gov/#!searchResults:rpp=10;po=0;s=FDA-2009-N-0523;dct=PS>. A transcript of this meeting is

March 10, 2010, by an FSIS public meeting that discussed its procedures for identifying suppliers of source material used to produce raw beef product that FSIS found positive for *E. coli* O157:H7. FSIS sought input from meeting participants on ways to improve its procedures for identifying product that may be positive for *E. coli* O157:H7.

Despite these actions, as explained in the proposed rule, some official establishments and retail stores still did not keep and maintain the records necessary for effective investigation by FSIS. With this history in mind, FSIS conducted a retrospective review of 28 foodborne disease investigations from October 2007 through September 2011 in which beef products were ground or re-ground at retail stores.⁴ When records were available and complete, enabling FSIS to identify specific production in an official establishment, the Agency was able to request a recall of product from the supplying establishment in six of eleven investigations. In contrast, when records were not available or incomplete, FSIS was able to request a product recall only two of seventeen times. These results confirmed FSIS's experience in specific cases where the presence of records at the retail level was often instrumental in identifying the source of an outbreak, as well as the implicated products that should be recalled. The proposed rule includes a fuller description of this review,

including specific examples (79 FR 42464).

Since the review in the proposed rule, FSIS has completed nine ground beef outbreak investigations. Of these nine investigations, grinding records were available and complete in four of them and incomplete or not available in five. When records were available and complete, FSIS was able to request a recall of product from the supplying establishment in one of four investigations. For the remaining three, two led to store level recalls. For these two, FSIS did not request recalls at supplier establishments because in one investigation, the trim for retail product had over ten suppliers, and in the other, FSIS was not able to narrow down the list of suppliers because the retailer did not clean up in between grinding different products. FSIS did not request a recall for the third case in which records were available and complete because there were multiple products and multiple federal establishments involved, and FSIS was not able to identify the product associated with the illnesses or the supplying establishment. In the five investigations where records were not available or incomplete, FSIS was unable to request a recall from a supplying establishment.

The investigations reviewed in the proposed rule, and those reviewed since the proposed rule, confirm the Agency's findings that the records kept by official establishments and retail stores vary in type and quality and are often incomplete or inaccurate. Overall, FSIS has concluded that voluntary recordkeeping by retail stores that grind raw beef has been insufficient, as evidenced by continuing outbreaks linked to pathogens in raw ground beef that FSIS cannot trace back to the source. The lack of specific information about supplier lot numbers, product codes, production dates, and the cleaning and sanitizing of grinding

equipment has prevented or delayed FSIS in identifying the source of outbreaks, as well as other product that might be adulterated. The cleaning and sanitizing of equipment used to grind raw beef is important because it prevents the transfer of *E. coli* O157:H7 and other bacteria from one lot of product to another.

Proposed Rule

On July 22, 2014 (79 FR 42464), FSIS proposed to amend the Federal meat inspection regulations to require that all official establishments and retail stores that grind raw beef for sale keep records disclosing the following: The names, points of contact, phone numbers, and establishment numbers of suppliers of source materials used in the preparation of each lot of raw ground beef; the names of each source material, including any components carried over from one production lot to the next; the supplier lot numbers and production dates; the weight of each beef component used in each lot (in pounds); the date and time each lot was produced; and the date and time when grinding equipment and other related food-contact surfaces were cleaned and sanitized. FSIS also proposed that official establishments and retail stores would have to comply with these requirements with respect to raw beef products ground at an individual customer's request when new source materials are used.

FSIS posted the sample grinding log record below (Table 2) on its Web site in late 2011 and included it with the 2009 guidance and the proposed rule. FSIS proposed requiring the items in the sample record marked with asterisks. The proposed rule specifically stated that the information under the other column headings would not be required, but that some official establishments and retail stores might choose to keep and maintain this information.

available at: <http://www.regulations.gov/#!searchResults;rpp=10;po=0;s=FDA-2009-N-0523;dc=O>.

⁴ Ihry, T., White, P., Green, A., and Duryea, P. Review of the Adequacy of Ground Beef Production Records at Retail Markets for Traceback Activities During Foodborne Disease Investigations. Poster presented at: Annual Conference of the Council of State and Territorial Epidemiologists; 2012, June 4–6; Omaha, NE. A copy of this document is available at: <http://www.fsis.usda.gov/wps/wcm/connect/87caa3f9-0c76-45c7-be4e-84d73151ed9e/RD-2009-0011-072114.pdf?MOD=AJPERES>.

Table 2: Grinding log record that FSIS posted (2009)

<p>NEW WAVE STORE</p> <p>123 Main Street</p> <p>Anytown, USA, Zip Code</p> <p>FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST</p> <p>Employee Name _____ Today's Date _____</p>										
Date and Time of Grind*	Lot/Batch # (lot = same source material)	Exact Name/ Type of Product Produced	Package Size of Product Produced	Amount (in lbs) of Source Material Used in Each Lot, including Carryover*	Production Code of Product Produced	Manufacturer Name of Source Material Used for Product Produced*	Supplier Lot #s, Product Code and/or Pack Date of Source Material Used*	Estab. Info. from Label of Source Material Used (Est. #, ph #, contact info)*	Date and Time Grinder and Related FCSs Cleaned and Sanitized*	Comments
<p>_____ Signature of Store Management Reviewer</p> <p style="text-align: right;">_____ Date</p>										

*Information that would have been required by the proposed rule.

Final Rule

As stated above, the final rule is mostly consistent with the proposed rule. It requires official establishments and retail stores that grind raw beef products to maintain the following records: The establishment numbers of the establishments supplying the material used to prepare each lot of raw ground beef; all supplier lot numbers and production dates; the names of the supplied materials, including beef components and any materials carried over from one production to the next; the date and time each lot is produced; and the date and time when grinding equipment and other related food-

contact surfaces are cleaned and sanitized. These requirements also apply to raw ground beef products that are prepared at an individual customer's request when new source materials are used. If new source materials are not used, there is no reason to record the customer-requested grind separately.

The final rule will not require records concerning the names, points of contact, and phone numbers of each official establishment supplying source material or the weight of each source component. In consideration of comments that it received, FSIS has concluded that the records concerning the names, points of contact, and phone numbers of each

official establishment supplying source material were unnecessary given that FSIS already possesses this information through the establishment profiles in PHIS. In addition, FSIS concluded, in response to the comments submitted, that weighing each component in a lot of ground beef was time-consuming and offered little food safety benefit. Contamination occurs in a lot of ground beef regardless of the weight of the contaminated component.

In conformance with these changes, FSIS has updated its sample grinding log as pictured in Table 3 below to reflect the requirements of this final rule.

Table 3: Sample Grinding log with final rule requirements.

<p>NEW WAVE STORE</p> <p>123 Main Street</p> <p>Anytown, USA, Zip Code</p> <p>FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST</p> <p>Employee Name _____ Today's Date _____</p>					
Date and Time of Grind	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot #s, Product Code and/or Pack Date of Source Material Used	Est. Number(s) of Est. providing source material	Date and Time Grinder and Related FCSs Cleaned and Sanitized	Comments
<p>_____</p> <p>Signature of Store Management Reviewer Date</p>					

The final rule also differs from the proposed rule with respect to the place of maintenance and the retention period of the required records. Based on 9 CFR 320.2, the proposed rule would have required records to be kept at the place

where the business, in this case the grinding activity, is conducted, unless the business is conducted at multiple locations, in which case the proposal would have allowed the records to be maintained at a business's headquarters office. In response to comments, FSIS has concluded that keeping the required information at the location where the beef is ground will save investigators time and reduce the risk that records are misplaced when they are moved. This rule, therefore, establishes a new 9 CFR 320.2(b), which requires that all the information required by this final rule be kept at the location where the beef is ground.

Based on 9 CFR 320.3(a), the proposed rule would have required that the proposed grinding records be retained for a period of two years after December 31 of the year in which the transaction giving rise to the record (grinding) occurred. In response to comments discussed below, FSIS concluded that because the vast majority of ground beef is consumed within several months of its production, a one-year retention period is adequate to trace the source of any foodborne disease outbreak involving raw ground beef. Accordingly, this final rule creates a 9 CFR 320.3(c) which requires that official establishments and retail stores covered by this rule retain the required records for one year.

The final rule also makes technical changes to 9 CFR 320.2 and 320.3 to improve readability.

Summary of Comments and Responses

FSIS received 40 comments on the proposed rule from individuals, retailers, beef producers and processors, beef industry and retail trade groups, consumer advocacy groups, an organization representing food and drug officials, a State department of agricultural and rural development, a food technology company, and two members of Congress. Most of the commenters supported the proposed rule. Industry groups supported recording information for effective investigation in the event of a foodborne illness outbreak but stated that the costs of compliance were higher than estimated, and that several pieces of information were unnecessary or overly burdensome. A summary of the relevant issues raised by the commenters and the Agency's responses follows.

1. Covered Entities

Comment: Consumer and retail trade groups stated that the rule should apply to supermarkets, grocery stores, meat markets, warehouse clubs, cooperatives,

supercenters, convenience stores, wholesalers, and restaurants.

Response: This final rule applies to all official establishments and retail stores that grind raw beef products for sale to consumers in normal retail quantities. The rule covers supermarkets and other grocery stores, meat markets, warehouse clubs, cooperatives, supercenters, convenience stores, and wholesalers, if they grind raw beef product.

FSIS is not applying this final rule to restaurants. Only a small percentage of all raw beef grinding occurs at restaurants and only on a very small scale. It is thus likely that any outbreak traced to a restaurant that grinds its own raw beef will be traceable to a specific supplier.

2. Content of Records

Comment: Retail organizations, a food technology company, and a beef brand recommended reducing costs by removing from the proposed rule the requirement to weigh each source component. These commenters stated that the proposed requirement was time-consuming, disruptive to workflow, unfeasible with current equipment, and offered no public health benefit.

Response: FSIS agrees that the requirement to weigh each source component is not necessary. If a foodborne illness outbreak occurs, the weight of a source component in a lot of ground beef is not significant in tracing the material back to the suppliers. Also, any amount of adulterated source material in a lot of ground beef would adulterate the product. Accordingly, FSIS has removed this provision from the final rule and has adjusted the paperwork burden estimates and costs accordingly.

Comment: An independent grocers' trade group suggested removing the requirement to record supplier lot numbers and production dates.

Response: Supplier lot numbers and production dates are necessary to identify product at a supplier's location that may be associated with an outbreak. By including supplier lot numbers and production dates, investigators can more easily and quickly determine the source of a foodborne illness outbreak and limit the amount of product recalled.

Comment: Industry groups generally opposed recordkeeping for customer-requested grinds. They stated that it was impractical to clean grinding equipment between customer requests, meat case items usually lack supplier information, and public health benefits from logging these grinds would be limited. One meat industry trade group suggested only requiring the proposed recordkeeping provisions for customer-requested

grinds over thirty pounds. A retail trade group recommended that its members perform customer-requested grinds at the end of the day or during a clear production cycle break.

Response: Customer-requested grinds present the same food safety risk as other raw ground beef. Retailers should keep customer-requested grinds separate and must record the information required in this rule when new source materials are used for customer-requested grinds. It is also in the store's interest to perform a clean up before and after customer-requested grinds. If the source is not clear, or if there is no clean up, traceback to the supplier will be impossible. The retailer would have produced the product associated with the outbreak, and in such circumstances, FSIS will have to request that the retailer recall product. Also, if the source is not clear, FSIS will likely have to request that the retailer recall more product than would be necessary if the retailer had recorded the necessary information.

FSIS agrees that customer-requested grinds present unique challenges but estimates that the benefits of being able to rapidly identify a customer-grind associated with an outbreak outweigh the recordkeeping and clean-up costs.

Comment: Two food-safety non-profits, a grocery store chain, and a consumer group stated that the name of the retail product should be recorded to assist in identifying product subject to recall. One individual and a food-safety non-profit stated that retail products should include specific day or production lot codes to assist in tracing products back to specific grinding lots.

Response: FSIS does not believe that including retail product names on records listing source materials used to produce those products is practical. Products from different source materials may have the same name, e.g., 80/20 Ground Chuck. In addition, products from the same source materials may be marketed differently. For example, packages of "Bob's Ground Beef" and "Jan's Ground Beef" may originate from the same lot of source materials, despite bearing different retail names.

FSIS is also not requiring official establishments and retail stores to label retail products with timestamps or production lot codes to identify them with the specific lot or lots of ground beef from which they were produced. Retail ground beef products can usually be traced back to their specific grinding lots through stores' inventory data, the product's date and time of sale, and information stored on customers' shopper cards. Once a retail product is traced back to the grinding lot or lots,

the records required by this final rule will enable FSIS investigators to identify the source materials, suppliers, and production lots from which the product was produced.

Comment: Industry groups opposed recording the names, points of contact, and phone numbers of suppliers because FSIS already has this information through PHIS.

Response: FSIS agrees that the names, points of contact, and phone numbers of official establishments supplying source materials are already located in the establishment profiles within PHIS. Therefore, the establishment numbers of suppliers provide sufficient information to FSIS, and FSIS has removed those pieces of information from the recordkeeping requirements, leaving the requirement that official establishments and retail stores keep the establishment number of their suppliers of source materials. FSIS has updated its paperwork burden and costs estimates to reflect this change.

3. Use of Sample Grinding Log

Comment: A consumer group recommended that FSIS provide a sample grinding log containing all of the required information. A grocery store chain and retail trade group stated that grinders should be able to create their own logs, so long as all required information is included. A retail trade group questioned whether grinders would be required to use the sample log shown above.

Response: While FSIS has provided a sample grinding log that is depicted above, FSIS is not specifying in the final rule how official establishments and retail stores must record the required information. Entities may record the required information as they see fit, so long as the records of the required information are maintained in accordance with 9 CFR 320.2 and 320.3.

4. Imports

Comment: One individual stated that the proposed rule should apply to imported beef.

Response: FSIS' regulations do not apply directly to establishments in foreign countries, and retail stores in foreign countries are not eligible to export product to the United States. To be eligible to export raw beef product to the United States, countries must maintain an equivalent inspection system for beef. Therefore, in the event of *Salmonella* or shiga-toxin producing *E. coli* (STEC) outbreaks, countries that ship beef to the United States will need to have traceback and traceforward systems for beef products that allow the country to identify the source of

contamination. Countries that export beef to the United States may choose to establish recordkeeping requirements consistent with this rule. However, they may also have other means to track the necessary information.

5. Other Species

Comment: Individual commenters and food safety groups believed that the rule should apply to ground product produced from swine, poultry, lamb, and turkey.

Response: FSIS issued the proposed rule to address deficiencies in recordkeeping that hampered investigations into foodborne illness investigations involving raw ground beef. Between 2007 and 2013, FSIS investigated 130 outbreaks of human illness. Of those, 31 (24 percent) were linked to beef ground at a retail venue. FSIS did not propose that new records be maintained for ground products other than beef because the Agency is most often impeded in its efforts to trace back and identify sources of human illness when beef ground in retail stores is the vehicle for those illnesses. FSIS considers the comments requesting similar requirements for other ground product to be outside the scope of this rule.

6. Consumer Education

Comment: A meat processor, a meat products company, and two individuals stated that more outreach was needed to educate consumers on how to properly handle and cook meats.

Response: FSIS promotes consumer awareness of food safety issues and encourages proper food preparation practices. For example, FSIS posts consumer food safety information on its Web page.⁵ The posted information includes the kind of bacteria that can be found in ground beef, specific information as to why the *E. coli* O157:H7 bacterium is of special concern in ground beef, and the best way to handle raw ground beef when shopping and when at home. This Web page also contains the *Food Safe Families Campaign* guidelines to keep food safe, which tells consumers to cook ground beef to a safe minimum internal temperature of 160 °F (71.1 °C) as measured with a food thermometer. FSIS also provides food safety education in other forms (e.g., FSIS has continued to work with the Ad Council to launch food safety public service announcements, and FSIS staff provide

⁵ FSIS food safety guidance for meat preparation, available at: <http://www.fsis.usda.gov/wps/portal/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation>.

in-person food safety education through the mobile Food Safety Discovery Zone).

Nonetheless, recordkeeping by retail establishments will more quickly and efficiently address the concerns (i.e., traceback and identifying sources of human illness when beef ground in retail stores is the vehicle for those illnesses) raised in this final rule.

7. Supplier Process Control Actions

Comment: One individual urged official establishments to improve contamination control at slaughter. A meat products company that did not support the rule believed that suppliers cannot control *E. coli*, but that the answer is not more recordkeeping because that does not address the core problem, which is the interdependent relationship between animals and *E. coli*.

Response: FSIS is continuing to address process control actions that should be taken by beef suppliers to control *E. coli*. For example, FSIS made available updated guidance on testing and high event periods⁶ in 2013 and implemented new traceback activities in 2014.⁷ However, while better process control may reduce the incidence of *E. coli* O157:H7-adulterated ground beef, it will not address the issue of official establishments and retail stores not keeping adequate records that allow effective traceback and traceforward activities. Without the records required by this final rule, FSIS cannot conduct timely and effective consumer foodborne illness investigations and other public health activities through the stream of commerce.

8. Implementation

Comment: An independent grocers' trade group recommended a two-year delayed effective date for small businesses to comply with the rule. Alternatively, the commenter stated that small businesses should be exempt from the rule's requirements altogether. Similarly, a retail trade group believed that small retailers would need more time for outreach and training and that implementation would take longer than anticipated by the proposed rule

⁶ Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers, available at: <http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance-Guide-Est-Sampling-STEC.pdf?MOD=AJPERES>.

⁷ FSIS Directive 10,010.3, Traceback Methodology for *Escherichia coli* (*E. coli*) O157:H7 in Raw Ground Beef Products and Bench Trim, available at: <http://www.fsis.usda.gov/wps/wcm/connect/ae5e81d0-c636-4de1-93f3-7a30d142ae69/10010.3.pdf?MOD=AJPERES>.

because of the need to create or modify records forms.

Response: FSIS has provided sample grinding logs in this rule and the proposed rule. Small businesses may use these logs, or any other recordkeeping system they wish, to record the required information. FSIS believes that the recordkeeping requirements are straightforward and do not require extensive training or guidance materials. FSIS has also not adopted the proposed requirements that grinders record and maintain records of the weight of each source material used in a grinding lot, and the names, points of contact, and phone numbers of each official establishment supplying source material.

In addition, as is discussed above, FSIS has advised official establishments and retailers to maintain these types of records since 2002. Nonetheless, in response to comments, this final rule provides that retailers and official establishments will have 180 days from the date of publication of this final rule to comply with its requirements. This effective date should provide industry sufficient time to comply with the requirements because FSIS has simplified the requirements originally proposed, and FSIS will ensure that establishments and retailers are aware of the new requirements through the outreach activities discussed below and through partnering with the States and other organizations, such as retail organizations.

9. Training

Comment: One consumer group recommended face-to-face contact by FSIS with entities that grind raw beef to explain the rule's requirements. A beef producers' trade group encouraged FSIS to conduct outreach through webinars and by attending industry meetings. One individual stated that operators should be trained to understand the risks of *E. coli* in grinding. Another individual suggested more training on keeping logs, proper attire, and hand-washing. A State agriculture department believed it would incur costs associated with responding to questions from grinders and training State personnel to field such questions appropriately.

Response: As noted above, the recordkeeping requirements in the final rule are straightforward and do not require extensive training or guidance materials. FSIS will update its Sanitation Guidance for Beef Grinders,⁸ which includes sample grinding logs and instructions, and will hold

webinars to explain the requirements of this final rule and answer questions from official establishments, retailers, and other organizations. FSIS will also provide guidance to small businesses through its Small Plant Help Desk and *Small Plant News* newsletter, and at industry conferences, exhibitions and workshops.

10. Retention and Maintenance of Records

Comment: A food-safety non-profit organization suggested that records required under this rule be retained for at least ninety days. A grocery store chain believed six-to-twelve months would be adequate. A retail trade group believed six months was appropriate. The latter two commenters mentioned that frozen beef should be consumed within three to four months.

Response: While ground beef is safe indefinitely if kept frozen, it will lose quality over time. FSIS recommends consuming fresh ground beef within two days and frozen ground beef within four months.⁹ These recommendations suggest that records documenting the grinding of raw beef need only be kept for a short period of time. However, the Agency is aware that consumers do not always follow such recommendations, sometimes keeping ground beef in their freezers for up to a year, for example. FSIS is therefore requiring in the final rule that official establishments and retailers maintain the prescribed records for one year (9 CFR 320.3).

Comment: A trade group representing food safety officials stated that records should always be maintained at the location where the beef was ground.

Response: This final rule amends 9 CFR 320.2 to require that official establishments and retail stores maintain the required records at the place where the raw beef is ground. This approach, along with the shorter record retention period being required in 9 CFR 320.3, balances the burden on retailers of storing records for the necessary period of time with the needs of investigators to have such records available at the grinding location.

11. Enforcement

Comment: Three individuals stated that FSIS should assess additional fines or penalties to enforce the final rule's requirements. A consumer group recommended FSIS perform verification checks at retailers to monitor compliance. A trade group representing

food safety officials asked how FSIS would enforce the rule and urged FSIS to work more cooperatively with State and local food safety agencies. The commenter also recommended that local officials have access to the new records, as they are often involved at the earliest stages of an outbreak.

Response: The FMIA provides FSIS with authority to require specified persons, firms, and corporations to keep records that will fully and correctly disclose all transactions involved in their businesses subject to the FMIA and to provide access to facilities, inventory, and records (21 U.S.C. 642). If official establishments do not maintain the required records, FSIS will issue noncompliance records. FSIS may also take any regulatory control actions as defined in 9 CFR 500.1(a), including the tagging of product, equipment, or areas.

FSIS personnel conduct in-commerce surveillance related to wholesomeness, adulteration, misbranding, sanitation, and recordkeeping.¹⁰ When this rule becomes final, FSIS compliance investigators will verify that retail grinders meet the recordkeeping requirements. If compliance investigators find they do not, they may issue a Notice of Warning to the retail store.

If FSIS personnel find noncompliance at an official establishment, the Agency could issue non-compliance reports, letters of warning, or request the Department of Justice to initiate a civil proceeding in Federal court to enjoin the defendant from further violations of the applicable laws and regulations. If FSIS personnel find noncompliance at a retail facility, the Agency may issue notices of warning or request the Department of Justice to initiate a civil proceeding to enjoin the defendant from further violations of the applicable laws and regulations.

States with their own meat and poultry inspection (MPI) programs will need to be aware of the requirements of this rule and are required to enforce requirements "at least equal to" the Federal inspection program. Therefore, they will need to require that establishments under State inspection maintain records consistent with what FSIS is requiring.

FSIS will also explore ways to partner with States, with or without MPI programs, so that State employees can provide information about the recordkeeping requirements to grocery stores, help them to keep logs in the most efficient and effective way

⁸ Available at: http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf.

⁹ FSIS Ground Beef and Food Safety, available at: http://www.fsis.usda.gov/wps/portal/portal/fsis/topics/food-safety-education/get-answers/food-safety-factsheets/meat-preparation/ground-beef-and-food-safety/CT_Index.

¹⁰ FSIS Directive 8080.1, Rev. 4, *Methodology for Conducting In-Commerce Surveillance Activities*, April 24, 2014.

possible, and provide other information that will enhance the efficiency and effectiveness of store efforts. FSIS intends to provide information to State officials about the grinding logs requirement during regular monthly Webinars that FSIS conducts for State MPI Directors and State HACCP Contacts and Coordinators.

FSIS also routinely cooperates with State and local authorities to conduct effective foodborne illness investigations, including by sharing epidemiological data, records, and investigative resources. FSIS intends to provide information to State and local authorities during the course of these illness investigations about the role that grinding logs can play in facilitating these investigations.

12. Grinding Frequency and Time Burden

Comment: To reduce costs, a grocers' trade group stated that FSIS should require records only for all source materials used in grinds during a single production day, requiring a new log for production that would begin only after the end-of-day full cleaning of the grinding equipment. Several commenters also stated that many retail stores grind several times per day and may use several different suppliers, significantly increasing recordkeeping costs.

Response: In the proposed rule, FSIS considered requiring documentation of information on a weekly basis, but rejected this approach because it would be difficult to differentiate between lots ground from different suppliers throughout the week (79 FR 42469). The same holds true for daily logs. In either situation, investigators would be unable to effectively conduct traceback and traceforward activities in the event of an outbreak because of limited detail. FSIS is not dictating how often the required information must be physically recorded. Under the final rule, the required information must be recorded whenever any of the information required for the lot of product being ground changes. For example, if an entity uses the same source material for multiple grinds throughout the day, it would only need to record the source material information (9 CFR 320.1(b)(4)(i)(A)–(C)) once but would need to record the date and time of each grind (9 CFR 320.1(b)(4)(i)(D)). However, if a store or establishment were to start using a different supplier or lot number during the day, it would need to document that change (9 CFR 320.1(b)(4)(i)(B)). This approach minimizes the recordkeeping burden

but preserves the information needed by investigators.

Comment: A grocery store chain disagreed with FSIS's estimates of grinds per day and average number of suppliers at retail, suggesting that beef is ground every day, several times per day as needed, and with several different cases of raw material. A retail trade group estimated more average grinds at retail per day than FSIS's estimate, stating that its average member grinds four times per day. A State agriculture department and a beef producers' trade group urged further study of the economic impact of the rule on small businesses, including feedback from industry. A retail trade group estimated that the time needed for the proposed recordkeeping is much higher per respondent per year than estimated by FSIS, suggesting that a conservative estimate would be 214 hours per year.

Response: FSIS has taken into account comments on the amount of time required for recordkeeping and made adjustments to its cost estimate. For the final estimates, FSIS adjusted the average number of recordkeeping tasks per day at official establishments and retail stores from one to a range of four-to-five-and-a-half, plus an additional task if an entity conducts a grind composed of only trim. FSIS also adjusted the assumed time required to complete a record at official establishments and retail stores to account for multiple source materials, from 30-to-90 seconds to one minute for grinds not including trim, two minutes for grinds including trim and other ground beef components, and six-to-ten minutes for trim-only grinds. Trim-only grinds are usually composed of trim from different suppliers and production lots. Therefore, more time is needed to document the required information as compared to other grinding activities. In updating these estimates, FSIS has taken into account, in addition to the comments, the changes in the final rule concerning required records. Specifically, FSIS is using the low end of time estimates from the comments because, for the final rule, FSIS has significantly reduced the information required to be kept compared to the proposed rule.

13. Waste

Comment: Two individuals and an independent grocers' trade group stated that retailers would simply throw out bench trim to avoid the recordkeeping requirements.

Response: In its proposed rule, FSIS considered a 2008 study that found that recording grinding information is already prevalent among official

establishments and retail stores that grind raw beef. The 2008 study found that 74 percent of chain retail stores and 12 percent of independent retail stores kept grinding logs. Of the stores that kept grinding logs, the study reported that 78 percent of those logs were incomplete (79 FR 42471). Although insufficient voluntary recording is one impetus for this rule, FSIS is not aware of any instance when official establishments and retail stores that were keeping necessary records discarded source material in lieu of recording necessary records. Therefore, FSIS concludes that the costs of recordkeeping will rarely be greater than the costs of discarding bench trim, and that the amount of product discarded as a result of the rule should be negligible.

14. Effect on Small Businesses

Comment: An independent grocers' trade group stated that the proposed rule would have a significant economic impact on a substantial number of small entities, and, therefore, FSIS must conduct an initial regulatory flexibility analysis.

Response: While the rule will affect a substantial number of small businesses, the cost of complying with the proposed regulations will be relatively small on a per firm basis. FSIS has provided guidance and a sample grinding log, which FSIS will update as appropriate. Similar guidance is available from other providers, including industry associations.¹¹ Entities can use these materials to minimize the costs of their recordkeeping programs. In addition, as is discussed above, FSIS will hold webinars to provide small businesses additional information on the rule and will publish information through its Small Plant Help Desk and *Small Plant News* newsletter. The fact that a number of small firms already maintain adequate grinding records suggests that the cost of the practice is not prohibitive to doing business.

15. Definition of a Lot of Ground Beef

Comment: A beef industry trade group commented that some ground beef producers have different definitions for "lots" or "batches" of ground beef.

¹¹ Food Marketing Institute, Comprehensive Guide Meat Ground at Retail Recordkeeping and Sanitation, available at: <http://www.fmi.org/docs/default-source/food-safety-best-practice-guides/meat-ground-at-retail-comprehensive-guide.pdf?sfvrsn=6>. Conference for Food Protection, Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments, available at: <http://www.foodprotect.org/media/guide/CFP%20Beef%20Grinding%20Log%20Template%20Guidance%20Document%20-%208-2014.pdf>.

Response: FSIS did not propose a definition for a “lot” of ground beef in the proposed rule. In response to this comment, and for the sake of consistency in implementing this final rule, FSIS has added a new 9 CFR 320.1(b)(4)(iii), which defines a lot.

Implementation

All retailers and official establishments will have 180 days from the date of publication of this final rule to comply with its requirements.

As is discussed above, this rule does not prescribe the method by which official establishments and retail stores must keep the required information but does require that the information be kept at the location where the beef is ground. The records must be retained for one year after the transaction giving rise to the record (grinding) occurred. FSIS will update its Sanitation Guidance for Beef Grinders,¹² which currently includes sample grinding logs and instructions, and hold webinars to explain the requirements of the final rule and answer questions from official establishments, retailers, and other organizations. FSIS will also provide information to small businesses through its Small Plant Help Desk and *Small Plant News* newsletter. FSIS will provide guidance to State MPI programs on the requirements of this rule and seek to partner with States to ensure that the requirements of this rule are communicated to official establishments inspected by State MPI programs and to retail stores that grind raw beef. FSIS will also work with States and universities around the nation to conduct outreach workshops targeted to retailers and official establishments to explain the requirements of the rule. Records of the required information must be made available to authorized USDA officials upon request (9 CFR 300.6(a)(2)). These officials may examine and copy such records (9 CFR 320.4). At official establishments, FSIS inspection personnel will verify compliance. As is discussed above, if FSIS personnel find noncompliance at an official establishment, the Agency could issue non-compliance reports, letters of warning, or request the Department of Justice to initiate a civil proceeding in Federal court to enjoin the defendant from further violations of the applicable laws and regulations. At retail stores, FSIS compliance investigators will verify that retail grinders meet the recordkeeping requirements. If compliance investigators find they do not, the

Agency may issue notices of warning or request the Department of Justice to initiate a civil proceeding to enjoin the defendant from further violations of the applicable laws and regulations.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “non-significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

In updating the preliminary regulatory impact analysis of the proposed rule, FSIS has made several changes in response to public comments and newly available information. Specifically, FSIS has made the following changes in the final regulatory impact analysis:

- Increased the number of retail firms in the baseline using new U.S. Census Bureau data;
- Added assumptions about the percentage of retail firms that grind raw beef;
- Incorporated new distributions relating to source materials used to reflect the complexity of grinding operations;
- Adjusted the time estimates for recordkeeping activities, the frequency of recordkeeping tasks, and the number of active grinding days per week based on comments received;
- Added estimates of labor to incorporate recordkeeping for grinds, including pieces of trim and customer-requested grinds;
- Updated the wage rate and benefits factor for firm employees that record or maintain required records based on the newest available information;
- Added discussion about unquantified costs associated with maintaining records for customer-requested grinds; and
- Expanded the benefits discussion to include benefits not previously addressed, such as the mitigation of costly spillover effects from foodborne illness outbreaks, and the incentive traceability provides to produce safe product.

Need for the Rule

During investigations of foodborne illness outbreaks attributed to ground beef, grinding records are an important part of the traceback and traceforward processes. Without accurate records, it is difficult to identify where ground beef components originated. If investigators cannot identify a source, it is likely that adulterated product will remain in commerce and more consumers will eat the product and become ill. Delays in identifying the source of contamination can also negatively affect sales of ground beef due to loss in consumer confidence. Despite efforts by FSIS, industry associations, and other regulators to provide retailers and official processing establishments with guidance and examples of best practices, the current level of recordkeeping is still less than what is needed for timely and accurate traceability investigations.

Traceability systems are a potential way to lessen the costs of foodborne illness outbreaks and other food safety events. In the case of private regulation, each firm will ultimately decide what level of traceability to implement on the basis of costs and potential benefits, such as smaller losses of reputation and reduced liability costs during foodborne illness outbreaks.¹³ Some firms may decide not to invest at all. Insufficient traceability, however, is not optimal for the industry as a whole.¹⁴ In some cases industry associations and third parties can influence firms to adopt traceability measures, but in the case of grinding records, these efforts have not achieved an acceptable level.¹⁵

Forms of private regulation, such as those currently in place for raw beef grinding entities, are vulnerable to firms that do not invest their fair share to the detriment of others, commonly referred to as the “free rider” problem.¹⁶ In the event of a foodborne illness outbreak

¹³ Hobbs, Jill E., (2004) “Information Asymmetry and the Role of Traceability Systems,” *Agribusiness*, Vol. 20 (4), 397–415, available at: <http://onlinelibrary.wiley.com/doi/10.1002/agr.20020/pdf>.

¹⁴ McEvoy, David M. and Souza-Monteiro, Diogo M., (2008) “Can an Industry Voluntary Agreement on Food Traceability Minimize the Cost of Food Safety Incidents?” *12th Congress of the European Association of Agricultural Economists*, Gent, Belgium, July 26–29, available at: <http://ageconsearch.umn.edu/bitstream/43860/2/397.pdf>.

¹⁵ Gould, Hannah L. et al. (2011) “Recordkeeping Practices of Beef Grinding Activities at Retail Establishments,” *Journal of Food Protection*, Vol. 74 (6), 1022–1024, available at: <http://www.ncbi.nlm.nih.gov/pubmed/21669085>.

¹⁶ Havinga, Tetty, (2006) “Private Regulation of Food Safety by Supermarkets,” *Law and Policy*, Vol. 28 (4), 515–533, available at: <http://www.ru.nl/publish/pages/552245/havingasupermarketslapo2006.pdf>.

¹² Available at: http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf.

attributed to ground beef, if traceback is conducted at an entity that maintains adequate records, there is a strong chance that the source of contamination will be identified. When this happens, losses in reputation, consumer confidence, and sales are generally limited to the firm supplying the adulterated product. Other firms, such as the retailers (both those that invest in traceability and those that do not), are to some degree insulated from negative spillover effects. In this case, free-rider firms—those that do not invest in traceability—benefit from the investments of others.

If, however, traceback occurs at a firm that does not invest in recordkeeping, the chances of investigators successfully tracing adulterated product to its source are low. An illness outbreak attributed to ground beef in which the source is unidentified will negatively affect ground beef producers and retailers indiscriminately. In this case, firms that have invested in traceability will bear costs that could have been avoided were it not for the free-rider firm. Mandatory recordkeeping requirements will help to eliminate insufficient traceability systems and therefore mitigate the free rider problem.

Inadequate traceability systems can also contribute to moral hazard, which, in the case of ground beef, is a lack of incentives to produce a safe product.¹⁷ Producers of ground beef components endeavor to produce safe product because the consequences of producing unsafe product are great. However, if adulterated ground beef is often unable to be traced back to its source, producers face less risk when the components they produce are unsafe.

Mandatory recordkeeping requirements can help to reduce moral hazard by increasing the chances that adulterated product is traced back to its source, thereby strengthening the incentives for fabricators of ground beef components to supply the safest product that they can produce.

Industry Baseline

FSIS has identified four groups of businesses that will be subject to the final rule.

1. Official, federally-inspected establishments that grind beef: FSIS used information from PHIS to determine the number of federally inspected establishments subject to FSIS sampling of ground beef product for *E. coli* O157:H7 and *Salmonella* in the past calendar year (2014). To ensure that only those establishments that receive ground beef components from a supplier are included in the total, FSIS excluded those establishments that also slaughtered beef in the past calendar year.¹⁸ Using the Hazard Analysis and Critical Control Point (HACCP) size categories available in PHIS, FSIS determined that there are 12 large establishments and 1,132 small (including HACCP size small and HACCP size very small) establishments that fall into this category.

2. Supermarkets and other grocery stores that grind beef: FSIS used data from the U.S. Census Bureau to determine the number of grocery stores in the U.S. Specifically, FSIS used the 2012 Statistics of U.S. Business (SUSB) data set¹⁹ to determine the number of stores under the North American Industry Classification System (NAICS) code 445110—Supermarkets and Other

Grocery (except Convenience) Stores. FSIS found that there are 21,543 stores owned by large firms (≥500 employed), and 44,504 stores owned by small firms (<500 employed). FSIS is aware that not all supermarkets and grocery stores grind beef in store. However, for the purposes of the cost estimate, FSIS assumed that 100 percent of supermarkets and grocery stores grind beef. While this results in a minor overestimate, FSIS lacks the data needed to support a different assumption.

3. Meat markets that grind beef: FSIS used the 2012 SUSB Census data to determine the number of stores under the NAICS code 445210—Meat Markets. FSIS found that there are 123 stores owned by large firms, and 5,105 stores owned by small firms. The NAICS code for meat markets includes six subcategories, three of which do not grind beef, including Baked Ham Stores, Frozen Meat Stores, and Poultry Dealers. To account for these stores, FSIS assumed that 50 percent of large stores and 50 percent of small stores in this category grind beef.

4. Warehouse clubs and supercenters that grind beef: FSIS used the 2012 SUSB Census data to determine the number of stores under the NAICS code 452910—Warehouse Clubs and Supercenters. FSIS determined that there are 5,124 such stores owned by large firms, and 40 stores owned by small firms. FSIS is aware that not all warehouse clubs and supercenters grind beef in store. To account for this, FSIS assumed that 20 percent of large stores and 100 percent of small stores grind beef.²⁰

TABLE 4—ENTITIES THAT GRIND RAW BEEF

Entity type Establishment type	Total entities		Percent grinding		Entities grinding	
	Large	Small	Large	Small	Large	Small
Official Establishments	12	1,132	100	100	12	1,132
Supermarkets and Other Grocery Stores	21,543	44,504	100	100	21,543	44,504
Meat Markets	123	5,105	50	50	62	2,553
Warehouse Clubs and Supercenters	5,124	40	20	100	1,025	40
Total	26,802	50,781	22,641	48,229

Values in Table may not sum to totals because of rounding.

¹⁷ Starbird, S. A., Amanor-Boadu, V., and Roberts, T. (2008) "Traceability, Moral Hazard, and Food Safety," *12th Congress of the European Association of Agricultural Economists*, available at: http://ageconsearch.umn.edu/bitstream/43840/2/EAAE_0398.pdf.

¹⁸ If an official establishment slaughters beef, then it is likely the only source of components for its own ground beef production, and therefore it would

not need to keep records pertaining to suppliers. While it is possible that some official establishments both slaughter beef and receive components from other official establishments for grinding, the number of such establishments is likely very small.

¹⁹ U.S. Census Bureau, (2012), *Statistics of U.S. Businesses*, accessed January 28, 2015, available at: <http://www.census.gov/econ/susb/>.

²⁰ FSIS was able to determine that the majority of large stores in this category do not grind beef in store because two large firms which account for approximately 80 percent of supercenters have ceased this practice. These firms purchase beef pre-ground and pre-packaged from federally inspected establishments or have it shipped from one of their other branded chains.

To estimate the number of entities that are already maintaining adequate records, FSIS used a Centers for Disease Control and Prevention (CDC) study of ground beef recordkeeping practices at retail stores and applied the distributions in the study to the entities that grind raw beef. The study found that 74 percent of chain retail stores and 12 percent of independent retail stores kept grinding logs. Of the stores that kept grinding logs, the study reported 78

percent of those logs as incomplete.²¹ For the purposes of this estimate, FSIS used the chain stores surveyed in the study as a proxy for large retailers and official establishments, and the independent stores as a proxy for small retailers and official establishments. Therefore, the recordkeeping distribution of large entities based on the survey results is approximately 16 percent complete (74 percent*(1-78 percent)), 58 percent incomplete (74

percent*78 percent), and 26 percent no records. For small entities, the distribution is approximately 3 percent complete (12 percent*(1-78 percent)), 9 percent incomplete (12 percent*78 percent), and 88 percent no records. FSIS applied these distributions to the set of all grinding entities in Table 4, above. The current recordkeeping practices of beef grinding entities are displayed in Table 5.

TABLE 5—BASELINE RECORDKEEPING PRACTICES AT ENTITIES THAT GRIND RAW BEEF

Entity size	Recordkeeping	Distribution (percent)	Entities
Large	Complete	16	3,686
	Incomplete	58	13,069
	No Records	26	5,887
	Total		22,641
Small	Complete	3	1,273
	Incomplete	9	4,514
	No Records	88	42,441
	Total		48,229

Values in table may not sum to Totals because of rounding.

Alternative Regulatory Approaches

FSIS considered a number of alternatives designed to achieve the regulatory objective outlined in the Need for the Rule section. The final rule was chosen as the least burdensome, technically acceptable regulatory approach to ensure that adequate grinding records are maintained for the purposes of outbreak investigation and product trace back. While some alternatives would result in lesser costs to industry, and some alternatives would result in more complete information for outbreak investigators, in FSIS’s judgment the final rule is the alternative that maximizes net benefits. Cost estimates were developed for the final rule but not for the rejected alternatives because the costs for these alternatives are discernibly higher or lower because of the amount of time spent on recordkeeping.

Alternatives Considered

(1) Encouraging rather than requiring grinding records: FSIS provided industry voluntary guidelines (see Table 2) in 2009. As stated previously, the Agency has concluded that a policy of voluntary guidelines for recordkeeping has not ensured that all official establishments and retail stores maintain complete records that will ensure quick identification of contaminated product.

(2) Regulated Daily Recordkeeping Program: FSIS considered requiring that retail stores and official establishments maintain grinding records such that each producer recorded grinding activities once per day, and information on all suppliers that were used during that day but not on when during the day those suppliers were used. Daily recording may have been sufficient if entities typically cleaned their equipment once a day, rarely changed suppliers, and conducted few grinds per day, but FSIS has found that the majority of retailers grind product and clean their equipment multiple times per day. A single daily recordkeeping task is, therefore, insufficient to provide the necessary information for traceback and could inhibit FSIS’s ability to identify suppliers during ongoing outbreaks. In addition, the time savings of daily recordkeeping over per-grind recordkeeping is likely low since most of the same information will need to be kept. Therefore, FSIS rejected this alternative.

(3) The Final Rule: The chosen alternative requires that retail stores and official establishments maintain grinding records such that each producer must record the required information whenever any of the required information for the lot of product being ground changes. To minimize the burden placed on these entities, FSIS has removed certain

pieces of information from the requirements that were included in the proposed rule, ensuring that only the necessary information for traceability is maintained. Requiring records that pertain to each individual grind guarantees that investigators will be able to identify the components included in an adulterated package of ground beef, creating a narrower list of potential sources of adulterated product and increasing the chances that the source of contamination is identified. FSIS has determined that this alternative is the least burdensome option that achieves the regulatory objective.

(4) More Detailed Recordkeeping Program: FSIS also considered expanding the proposed recordkeeping requirements to include all fields suggested in the 2009 FSIS guidance (all fields in the Table 2 sample log). This approach would provide FSIS with more detailed records to use during an investigation, which may improve traceability slightly. However, the small improvement in the trace back process provided by the additional level of detail would place an unnecessarily large burden on those entities that grind product and must keep records. Any such small improvement would not outweigh the costs incurred for keeping the more detailed records. For this reason, FSIS decided to require that only the most critical information be recorded. Other information, including

²¹ See footnote 3.

that which appears on the sample log, is voluntary.

The costs and benefits of the final rule and each regulatory alternative are displayed in Table 6.

TABLE 6—REGULATORY ALTERNATIVES CONSIDERED

Alternative	Costs	Benefits
(1) Encouraging Voluntary Recordkeeping.	No additional costs	No additional benefits.
(2) Regulated Daily Record-keeping.	Slightly less costly alternative to industry due to small time savings over per-grind recordkeeping.	Improvement over voluntary recordkeeping because records are required and must be created every day of grinding, but the records will in most cases not be detailed enough to facilitate traceability. Therefore, any benefits that can realistically be expected will be minimal, and the objective of facilitating traceability will not be met.
(3) The Final Rule	\$59.3 million (\$48.5 million to \$70.2 million) annual costs to the industry, plus additional costs associated with recording the source of trim and customer-requested grind components. Potential slight costs to consumers.	Achievement of regulatory objective resulting in benefits to consumers in the form of averted foodborne illness, to retailers and official establishments grinding components from suppliers in the form of less costly outbreaks and recalls, and to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.
(4) More Detailed Record-keeping.	Most costly alternative to industry	Achievement of regulatory objective resulting in the benefits described above. Potential for small increase in traceback speed and therefore small increase in avoided illnesses.

Expected Costs of the Final Rule

Costs to Industry

Retailers and official establishments that grind raw beef will incur costs to comply with the final rule. These include the labor cost of employees who record and maintain the records, storage costs, and those costs associated with trim and customer-requested grinds. FSIS has attempted to estimate the cost of labor and storage using information obtained from industry associations, the U.S. Census Bureau, the U.S. Bureau of Labor Statistics, a commercial real estate services firm report, and public comments.

In order to keep adequate records when grinding trim, entities will need to keep track of the source of each cut of beef from which the trim was separated. If not all of the trim is ground in a single batch, then entities will need to record each lot in which the trim is used. Similarly, if retail stores grind beef at the request of customers, they will need to record the required information for that small grind if new source materials are used. How entities choose to deal with the requirements will differ, and the costs associated with these requirements will vary greatly because of differences in firm size, component ordering practices, and grinding practices. FSIS used labor-time estimates from a grocery store chain’s public comments to estimate additional costs related to grinding trim. FSIS left additional costs related to customer requested grinds unquantified because

of the many variations in how retail stores will deal with the requirements and the relatively small number of customer grinds that take place.

Entities may incur other costs for training and investment should they choose to implement complex recordkeeping systems. Electronic recordkeeping options exist, which are likely more expensive than paper records but provide additional benefits such as improved accuracy, lower labor requirements, useful reporting and recall management tools, and supply-side management functions. Firms will decide individually whether these systems are suitable to their needs, and the proportion of those choosing more complex systems is uncertain. For the purposes of the cost estimate, FSIS has only estimated costs and benefits of the basic, paper-based system of recordkeeping. FSIS assumes that if firms choose to invest more in their recordkeeping systems, they will do so because the benefits achieved outweigh the costs.

Model records are available in the preamble of this final rule, on the FSIS Web site,²² and on the Web sites of industry associations. Best practices and guidance for beef grinders are also available from a number of sources.²³

²² FSIS, (2012) Sanitation Guidance for Beef Grinders, available at: http://www.fsis.usda.gov/wps/wcm/connect/b002d979-1e1e-487e-ac0b-f91ebd301121/Sanitation_Guidance_Beef_Grinders.pdf?MOD=AJPERES.

²³ Food Marketing Institute, (2013) “Comprehensive Guide Meat Ground at Retail

Therefore, FSIS does not anticipate that entities will incur significant costs for the development of records and standard operating procedures. FSIS also believes that training for recordkeeping can be done informally, on the job, and will therefore result in minimal costs. Also, as noted above, FSIS will conduct webinars and provide guidance to help inform industry of the new requirements, which will help minimize training costs.

To estimate the labor costs associated with recordkeeping, FSIS divided the entities keeping no records and incomplete records into categories based on three basic types of grinding activities:

1. No trim—grinds in which no trim is used, only chubs of ground beef;
2. With trim—grinds in which trim is added to chubs of ground beef; and
3. Trim-only—grinds consisting only of trim.

Using distributions from the CDC recordkeeping study, FSIS was able to estimate the number of official establishments and retail stores that do not use trim in their grinds (no trim), that use trim in their grinds (with trim), and that use no trim in some grinds and

Recordkeeping and Sanitation,” accessed February 12, 2015, available at: <http://www.fmi.org/docs/default-source/food-safety-best-practice-guides/meat-ground-at-retail-comprehensive-guide.pdf?sfvrsn=6>. Beef Industry Food Safety Council, (2005) “Best Practices For Retailer Operations Producing Raw Ground Beef,” accessed February 12, 2015, available at: <https://www.bifsc.org/CMDocs/BIFSCO/Best%20Practices/bestpracticesforretail4-05.pdf>.

only trim in others (trim-only). While there are likely other combinations of practices, and not all entities will fall

into the three defined categories, these categories are sufficient for the purposes

of the cost estimate. The categorization of entities is displayed in Table 7.

TABLE 7—ENTITIES CATEGORIZED BY TYPES OF GRINDING PERFORMED

Size	Recordkeeping	Entities	Trim or no trim	Trim practices	Entities
Large ...	Incomplete	13,069	Using Trim (91%)	Trim-Only (90%)	10,703
			No Trim (9%)	With Trim (10%)	1,189
	No Records	5,887	Using Trim (91%)	Trim-Only (90%)	4,821
			No Trim (9%)	With Trim (10%)	536
Small	Incomplete	4,514	Using Trim (61%)	Trim-Only (52%)	1,432
			No Trim (39%)	With Trim (48%)	1,322
	No Records	42,441	Using Trim (61%)	Trim-Only (52%)	13,462
			No Trim (39%)	With Trim (48%)	12,427
				16,552	

Values in table may not sum to Totals because of rounding.

FSIS assigned time estimates for each of the three types of grinds based on public comments. For no trim grinds, FSIS assumed that recordkeeping would take approximately 1 minute per grind.²⁴ For with trim grinds, FSIS assumed that the number of components would approximately double, and therefore recordkeeping would take about 2 minutes. For trim-only grinds, FSIS assumed that recordkeeping would vary depending on the number of sources and take approximately 6 to 10 minutes per grind.²⁵ If an entity is keeping complete records, FSIS assumed that it would not incur any additional costs; if an entity is keeping no records, it would incur costs associated with the full labor time estimate, and if an establishment is keeping incomplete records, FSIS assumed it would incur costs associated with half of the labor time estimate.

FSIS also relied on public comments to estimate the number of grinding activities completed per day. FSIS consequently estimated that the average entity grinds 4 to 5.5 times per day,²⁶ with the exception of those that do trim-only grinding. For those entities, FSIS estimated that they would complete no

trim grinds 4 to 5.5 times per day and then perform an additional trim-only grind (for a total of 5 to 6.5 per day). Further, FSIS estimated that approximately 90 percent of retailers perform customer-requested grinds, and that those grinds make up 1 percent of the total grinds.²⁷ FSIS estimated that the recordkeeping for customer-requested grinds would take about 1 minute. Customer-requested grinds were not applied to official establishments. Finally, FSIS estimated that the average retailer grinds 6 days per week.²⁸

To illustrate the time estimate, FSIS has provided the following example of a retail store that does trim-only grinds, performs customer-requested grinds, and has incomplete records:

- Low Estimate: [4 grinds per day × 1 min per grind (no trim) + 1 grind per day × 6 min per grind (trim-only) + {5 grinds (no trim + trim-only) * 1/99²⁹} grinds per day × 1 min per grind (customer request)] × 6 days per week × 50 percent (incomplete records) = 30.2 minutes per week.

- High Estimate: [5.5 grinds per day × 1 min per grind (no trim) + 1 grind per day × 10 min per grind (trim-only) + {6.5 grinds (no trim + trim-only) * 1/99} × 1 min per grind (customer request)] ×

6 days per week × 50 percent (incomplete records) = 46.7 minutes per week.

If the store in the example above started with no records, the 50-percent factor would be removed, increasing the time burden to 60.3 to 93.4 minutes per week. If instead the store were an official establishment, the customer grinds would be removed, resulting in a burden of 30 to 46.5 minutes per week.

Time estimates were calculated for each entity in Table 7 and then multiplied by 52 weeks for an annual estimate. To calculate the cost of this added labor, FSIS estimated that the recordkeeping would be performed by an employee paid at the Bureau of Labor Statistics “Butchers and Meat Cutters” (occupation code 51–3021) mean hourly wage rate of \$14.40.³⁰ To account for benefits paid to these employees, such as paid leave and retirement contributions, FSIS applied a benefits factor of 1.412³¹ to the wage rate, resulting in a total compensation rate of \$20.33 per hour. FSIS then multiplied the labor time estimates by the total compensation rate estimate to get the total annual cost of labor, displayed in Table 8.

²⁴ “60 seconds to fill each grind log entry”—Docket ID# FSIS–2009–0011–0035, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0035>.

²⁵ “8 minutes per day to log beef trim,” ± 2 minutes to account for varying number of components—Docket ID# FSIS–2009–0011–0035, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0035>.

²⁶ Low estimate: “Grinds raw beef 4x per day”—Docket ID# FSIS–2009–0011–0034, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0034>. High estimate: Midpoint of “3–8 batches a day”—Docket ID# FSIS–2009–0011–0040, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0040>.

www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0040.

²⁷ “90 percent of the retailers that grind beef in store perform grinds at a consumer’s request . . . the figure is 1 percent or less”—Docket ID# FSIS–2009–0011–0047, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0047>.

²⁸ “6x per week”—Docket ID# FSIS–2009–0011–0034, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0034>.

²⁹ (1/99) is the factor used to calculate the number of customer-requested grinds as 1 percent of the total grinds.

³⁰ Bureau of Labor Statistics, May 2013 National Occupational Employment and Wage Estimates, accessed February 2, 2015, available at: http://www.bls.gov/oes/current/oes_nat.htm.

³¹ Bureau of Labor Statistics, Employer Costs for Employee Compensation, September 2014, accessed February 2, 2015, available at: <http://www.bls.gov/news.release/ecec.t06.htm>. Wages and salaries as a percentage of total compensation are estimated at 70.8% for all service-providing industries, with total benefits accounting for the other 29.2%. To estimate total compensation, FSIS applied a benefits factor of (29.2%/70.8% + 1) = 1.412 to the hourly wage rate.

TABLE 8—ANNUAL LABOR COSTS

Entity size	Low estimate (\$mil)	High estimate (\$mil)	Midpoint estimate (\$mil)
Large	12.24	18.70	15.47
Small	33.54	48.74	41.14
Total	45.78	67.44	56.61

Values in table may not sum to Totals because of rounding.

To account for record storage costs, FSIS again used distributions of recordkeeping practices from the aforementioned CDC study.³² According to the study, 36 percent of retailers that maintain records keep them for greater than 1 year, 39 percent keep records for 6 months to 1 year, and 25 percent keep records for less than 6 months. FSIS assumed that grinding records for a full year could be kept in 3 square feet of storage space, and that the cost of that storage would be approximately \$15.50 annually.³³ FSIS then assumed that those retail stores that already kept records, but for less than 6 months, would incur \$46.50 in costs for a full

year of storage (3 sq. ft. × \$15.50), and those entities that already kept records for 6 months to 1 year would pay half the annual cost, or \$23.25. Those entities keeping records for greater than 1 year would have no additional costs because they are already maintaining records at the minimum level.

The distribution from the CDC study was applied to the number of retail stores keeping complete or incomplete records, and then multiplied by the assumed annual cost of storage. The retail stores that do not keep records will incur the \$46.50 in costs for a full year of storage.

For official establishments, FSIS assumed that those already maintaining

records would be keeping those records for at least 2 years, as required by 9 CFR 320.3(a). For these establishments there would be cost savings associated with one year of reduced storage time equivalent to \$46.50. For official establishments not maintaining records, there would be an additional cost of \$46.50. FSIS applied the cost savings to those official establishments keeping records and the additional costs to those official establishments keeping no records, and added those costs and savings to the recordkeeping costs estimated for retail stores. The results are displayed in Table 9.

TABLE 9—ANNUAL RECORD STORAGE COSTS

Entity size	Affected entities	Storage costs (\$mil)
Large	16,613	0.62
Small	46,194	2.08
Total	62,807	2.70

Values in table may not sum to Totals because of rounding.

The total cost to industry was calculated as a sum of the previously estimated costs. The results of the

annual industry cost estimate are displayed in Table 10.

TABLE 10—TOTAL ANNUAL INDUSTRY COSTS

Entity size	Low estimate (\$mil)	High estimate (\$mil)	Midpoint estimate (\$mil)	Unqualified costs
Large	12.86	19.32	16.09	Additional costs associated with the grinding of trim and customer requested grinds.
Small	35.63	50.83	43.23	
Total	48.48	70.15	59.32	

Values in table may not sum to Totals because of rounding.

Cost to Consumers

This rule will not result in any direct costs to consumers. It is possible that retailers and official establishments that grind raw beef will pass on a portion of the increased cost of grinding to

consumers. In most cases these costs should be small. In the case of customer-requested grinds, consumers may end up paying a small fee, as is presently customary at some retail stores. While this practice may

discourage some consumers, the facts that customer-requested grinds are so infrequent, and fees are already applied at some locations, suggest that fees will not cause major disruptions to ground beef sales. Therefore FSIS expects that

³² See footnote 3.
³³ Cassidy Turley, National Retail Review Winter 2014, accessed February 3, 2015, available at: <http://dtz.cassidyurley.com/DesktopModules/>

[CassidyTurley/Download/Download.aspx?contentId=3926&fileName=Cassidy_Turley_National_Retail_Review_Winter_2014.pdf](#). FSIS used the national average quoted rate for Community/

Neighborhood/Strip Shopping Centers (see page 11) to approximate the cost of storing records at a retail store.

any indirect costs to consumers will be minimal.

Cost to Agency

FSIS does not anticipate that the Agency or other regulators will incur additional costs as a result of this rule. FSIS has provided guidance to retailers that grind raw beef and will continue outreach efforts to ensure that retailers are aware of the rule and are able to comply. FSIS will also hold webinars and provide guidance on the new recordkeeping requirements.

FSIS will conduct a retrospective analysis to quantify what effects, if any, the final rule has on Agency resources. To do so, FSIS will examine the following:

- Number, length, and outcome of recall effectiveness checks.
- Regulatory noncompliance citations at official establishments for the proposed revisions to 9 CFR 320.1(b)(4).

We determined to not examine the overtime hours for enforcement, district office, and recall staff on a per-outbreak basis, as suggested in the proposed rule. The overtime hours cannot directly link to outbreaks.

Expected Benefits of the Final Rule

Public Health Benefits

Mandatory grinding logs with a minimum level of necessary information will improve FSIS investigators' ability to trace implicated product to its source, recommend timely and accurate recalls, remove adulterated product from commerce, and prevent illnesses at later stages of outbreaks.³⁴

Mandatory grinding logs will increase the likelihood that adulterated product is able to be traced back to its source. When FSIS identifies official establishments producing adulterated product, it takes steps to assess their production processes through comprehensive food safety assessments and follow-up evaluations. In doing so, FSIS is able to identify poor practices and deficiencies in process control and to require changes to resolve these issues. In some cases these assessments lead to findings that are valuable to industry as a whole, and the lessons learned can be documented and disseminated in the form of guidance. Improvements to production practices and process control, whether at implicated official establishments or

other establishments that have benefited from lessons learned, will result in reductions in foodborne illness outbreaks.

Firms that supply ground beef components will have incentives to apply the guidance developed as a result of previous outbreak investigations and to improve the safety of their product in general. As traceability systems improve as a result of better recordkeeping, liability for food safety events will be shifted from retailers to suppliers. This shift will reduce the prevalence of moral hazard—explained previously in the Need for the Rule section—thereby incentivizing supplier firms to produce safer product through the potential for adverse consequences of supplying unsafe product, such as reputation loss and litigation.³⁵ Therefore, by improving traceability through better recordkeeping, this rule has the potential to promote a safer supply of ground beef for consumers.

Benefits to Retailers and Official Establishments That Grind Raw Beef

Retailers and official establishments that grind raw beef products purchased from a supplier will benefit from mandatory recordkeeping because investigators have a better chance of tracing the adulterated product back to the supplier. Investigations that end at the retail level often result in recalls that are very costly for retailers because they bear the burden of product loss and compensating customers for returned product. These recalls can also negatively affect the brand of the store or chain, resulting in a loss in consumer confidence and a loss in sales. In some cases outbreak investigations that end at the retail level could result in exposure to legal liability.³⁶ Accurate records increase the likelihood that contaminated product is traced to its source, lessening the impact of recalls on retailers and official establishments that purchase ground beef components from suppliers.

For retailers that are already maintaining accurate records, there will be benefits from the reduction in free rider firms, as explained previously in the Need for the Rule section. Fewer free rider firms will decrease the chances that outbreak investigations go unresolved, which can greatly reduce

the cost to retailers. When a source is not identified, an outbreak may indiscriminately affect firms selling and producing ground beef. The fresh spinach outbreak in 2006 is a prime example of the consequences of an outbreak where the source of contamination is in doubt. Bagged spinach was associated with infections of *E. coli* O157:H7, but because no individual processor could be identified as having been the source of the outbreak, FDA and CDC issued a public alert advising consumers not to eat bagged spinach and eventually advised consumers not to eat all fresh spinach. Six companies issued voluntary recalls in September 2006. Sales of spinach plummeted from \$14.3 million in September to \$3.7 million in October and did not recover fully until January 2008.³⁷ An outbreak caused by a single firm, which was identified weeks after public warnings and recalls took place, ended up causing serious losses to the entire industry. Mandatory recordkeeping increases the chances that an investigator identifies the source of contamination, thereby increasing the chances that an outbreak will have minimal impact on uninvolved firms.

Benefits to Official Establishments That Supply Ground Beef Components

Official establishments supplying retail stores and processing establishments with ground beef components will also benefit from the increased ability of FSIS investigators to identify sources of contamination. When individual establishments are found to be suppliers of adulterated product, other uninvolved establishments are insulated from large spillover effects such as those illustrated in the spinach recall described above. Identifying the source establishment will likely be even more significant for official establishments because ground beef components make up a greater portion of their sales than ground beef would at a retail store. Mandatory recordkeeping could help to preserve consumer confidence and ground beef sales in the event of a foodborne illness outbreak, benefiting all firms that are uninvolved in the outbreak, while penalizing the establishment that supplied the adulterated product.

Another potential benefit for official establishments is a reduction in the scope of ground beef recalls. All else being equal, more accurate grinding records should result in the

³⁴ For a visual representation of the potential for averted illnesses due to quicker investigations and an earlier recall, please refer to Figure 1 of the FDA *Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* final rule, available at: <https://federalregister.gov/a/04-26929/#p-674>.

³⁵ See footnote 9.

³⁶ See *Financial Exposures* section of: Grocery Manufacturers Association (GMA), Covington & Burling, and Ernst & Young "Capturing Recall Costs," 2011, accessed January 15, 2015, available at: http://www.gmaonline.org/file-manager/images/gmapublications/Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf.

³⁷ University of Minnesota Food Industry Center, (2009) "Natural Selection: 2006 *E. coli* Recall of Fresh Spinach," accessed January 20, 2015, available at: <http://ageconsearch.umn.edu/bitstream/54784/2/Natural%20Selection.pdf>.

identification of specific lots of implicated product and therefore a narrower recall.³⁸ Smaller recalls will result in lower costs from product loss and reimbursement and recall execution costs such as advertising and public relations management. In some cases, smaller recalls as a result of better recordkeeping could even minimize sales losses, because a recall could be limited to a smaller geographical region

thereby reducing losses in consumer confidence. Finally, official establishments will benefit from lessons learned during recalls and follow-up assessments at entities linked to foodborne illness outbreaks. As recordkeeping practices at retail and official processing establishments improve, more outbreaks will be able to be traced to their source. This traceback will initiate further

examination of current practices and could lead to the identification of significant issues that, if corrected, would benefit official establishments generally.

Net Benefits of the Final Rule

The total costs and benefits achieved as a result of the final rule are displayed in Table 11.

TABLE 11—NET BENEFITS OF THE FINAL RULE

Costs:	
Labor	\$56.6 million annually (\$45.8 million to \$67.4 million).
Storage	\$2.7 million annually.
Unquantified Costs	Non-labor costs associated with recordkeeping for the grinding of trim and customer requested grinds. Potential slight costs to consumers in the form of ground beef price increases.
Benefits:	
Unquantified Benefits	Benefits to consumers in the form of averted foodborne illnesses as a result of contaminated ground beef. Benefits to retailers and official establishments grinding raw beef in the form of less costly food safety events, such as outbreaks and recalls. Benefits to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.

Regulatory Flexibility Analysis

The FSIS Administrator certifies that, for the purpose of the Regulatory Flexibility Act (5. U.S.C. 601–602), the final rule will not have a significant economic impact on a substantial number of small entities in the United

States. While the rule does affect a large number of small businesses, the average per entity annual cost is relatively low, at approximately \$905 (746 to 1,064). This estimate does not include unquantified costs associated with customer-requested grinds. These costs

will vary by retail store, but the total cost of compliance across the industry will be low because of the relatively small number of customer requested grinds. Table 12 provides a summary of the small entities affected by the final rule and the average annual cost.

TABLE 12—TOTAL COSTS AND AVERAGE COST PER ENTITY FOR SMALL BUSINESSES

Entity type	Entities	Total annual cost (\$mil)	Average annual cost (\$)
Retailer	46,649	42.22	905.16
Official	1,132	1.00	885.63
Total	47,781	43.23	904.70

Values in table may not sum to Totals because of rounding.

There is a multitude of guidance already available that small businesses can use, and FSIS has provided a sample grinding log in this final rule that can be used. These resources will help to keep the cost of implementing a new recordkeeping program low. In general, as the size of the business and the amount of ground product sold gets smaller, so too will the number of suppliers and components used, and the number of grinds performed. The smaller scale of production should contribute to lower average costs for smaller businesses. Moreover, the fact that some small firms are already

maintaining adequate records shows that the cost of the practice is not prohibitive to doing business.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the new information collection requirements included in this final rule have been submitted for approval to the Office of Management and Budget (OMB).

Title: Records to be Kept by Official Establishments and Retail Stores that Grind Raw Beef Products.

Type of Collection: New.

Abstract: Under this final rule, all official establishments and retail stores that grind raw beef products for sale in commerce, including products ground at a customer’s request, will have to maintain certain records.

The required records will have to include the following information:

- (A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product,
- (B) All supplier lot numbers and production dates,
- (C) The names of the supplied materials, including beef components

³⁸Resende-Filho, Moises A. and Buhr, Brian L. “Economics of Traceability for Mitigation of Food Recall Costs,” prepared for presentation at the International Association of Agricultural

Economists (IAAE) Triennial Conference, Foz do Iguaçu, Brazil, 18–24 August, 2012, available at: http://ageconsearch.umn.edu/bitstream/126193/2/IAAE_2012_Paper.pdf. This paper presents

simulation results of a model that indicated that that presence of a traceability system decreased volumes of recalls by over 90 percent (see Table 3).

and any materials carried over from one production lot to the next,

(D) The date and time each lot of raw ground beef product is produced, and

(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

In response to comments, FSIS removed requirements for entities covered by this rule to provide names, points of contact, and phone numbers for official establishments. Also in response to comments, the Agency eliminated the requirement that the weight of each source component used in a lot of ground beef be kept. However, in response to other public comments, FSIS increased the time estimates for recordkeeping activities, the frequency of recordkeeping tasks, and the number of active grinding days per week. FSIS also increased the number of retail stores that will be affected by the rule. These changes resulted in a significant increase in the number of burden hours initially estimated in the proposed rule.

Estimate of Burden: FSIS estimates that it would take a maximum of 50.33 hours per respondent annually.

Respondents: Official establishments and retail stores that grind raw beef products.

Estimated Number of Respondents: 65,911.

Estimated Maximum Annual Number of Responses per Respondent: 1,878.

Estimated Maximum Total Annual Recordkeeping Burden: 3,317,493 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Ave. SW., Room 6065 South Building, Washington, DC 20250-3700; (202) 720-5627.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that

have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication 1400 Independence Avenue SW., Washington, DC 20250-9410

Fax: (202) 690-7442

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

List of Subjects in 9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FSIS is amending 9 CFR part 320, as follows:

PART 320—RECORDS, REGISTRATION, AND REPORTS

■ 1. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, 2.53

■ 2. Amend § 320.1 by adding paragraph (b)(4) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(4)(i) In the case of raw ground beef products, official establishments and retail stores are required to keep records that fully disclose:

(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;

(B) All supplier lot numbers and production dates;

(C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;

(D) The date and time each lot of raw ground beef product is produced; and

(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

(ii) Official establishments and retail stores covered by this part that prepare ground beef products that are ground at an individual customer's request must keep records that comply with paragraph (b)(4)(i) of this section.

(iii) For the purposes of this section of the regulations, a lot is the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean up, during which the same source materials are used.

* * * * *

■ 3. Revise § 320.2 to read as follows:

§ 320.2 Place of maintenance of records.

(a) Except as provided in paragraph (b) of this section, any person engaged in any business described in § 320.1 and required by this part to keep records must maintain such records at the place where such business is conducted, except that if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records must be kept in a safe place at the prescribed location in accordance with good commercial practices.

(b) Records required to kept under § 320.1(b)(4) must be kept at the location where the raw beef was ground.

■ 4. Revise § 320.3 to read as follows:

§ 320.3 Record retention period.

(a) Except as provided in paragraphs (b) and (c) of this section, every record required to be maintained under this part must be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates has occurred and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records under this part.

(b) Records of canning as required in subpart G of part 318 of this chapter, must be retained as required in § 318.307(e); except that records required by § 318.302(b) and (c) must be retained as required by those sections.

(c) Records required to be maintained under § 320.1(b)(4) must be retained for one year.

Done in Washington, DC, on: December 14, 2015.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2015-31795 Filed 12-18-15; 8:45 am]

BILLING CODE 3410-DM-P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 348 and 390

RIN 3064-AE20

Removal of Transferred OTS Regulations Regarding Management Official Interlocks and Amendments to FDIC's Rules and Regulations

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation ("FDIC") is adopting a final rule to rescind and remove from the Code of Federal Regulations the transferred OTS regulation entitled "Management Official Interlocks." This subpart was included in the regulations that were transferred to the FDIC from the Office of Thrift Supervision ("OTS") on July 21, 2011, in connection with the implementation of applicable provisions of title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act"). The requirements for State savings associations in the transferred OTS regulation are substantively similar to those in the FDIC's regulation, which is also entitled "Management Official Interlocks" and is applicable for all insured depository institutions ("IDIs") for which the FDIC has been designated the appropriate Federal banking agency.

DATES: The final rule is effective on January 20, 2016.

FOR FURTHER INFORMATION CONTACT: Jennifer Maree, Counsel, Legal Division, (202) 898-6543; Mark Mellon, Counsel, Legal Division, (202) 898-3884; Karen Currie, Senior Examination Specialist, (202) 898-3981.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Dodd-Frank Act

The Dodd-Frank Act¹ provided for a substantial reorganization of the regulation of State and Federal savings associations and their holding companies. Beginning July 21, 2011, the

transfer date established by section 311 of the Dodd-Frank Act, codified at 12 U.S.C. 5411, the powers, duties, and functions formerly performed by the OTS were divided among the FDIC, as to State savings associations, the Office of the Comptroller of the Currency ("OCC"), as to Federal savings associations, and the Board of Governors of the Federal Reserve System ("FRB"), as to savings and loan holding companies. Section 316(b) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(b), provides the manner of treatment for all orders, resolutions, determinations, regulations, and advisory materials that had been issued, made, prescribed, or allowed to become effective by the OTS. The section provides that if such materials were in effect on the day before the transfer date, they continue to be in effect and are enforceable by or against the appropriate successor agency until they are modified, terminated, set aside, or superseded in accordance with applicable law by such successor agency, by any court of competent jurisdiction, or by operation of law.

Section 316(c) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(c), further directed the FDIC and the OCC to consult with one another and to publish a list of the continued OTS regulations that would be enforced by the FDIC and the OCC, respectively. On June 14, 2011, the FDIC's Board of Directors approved a "List of OTS Regulations to be Enforced by the OCC and the FDIC Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act." This list was published by the FDIC and the OCC as a Joint Notice in the **Federal Register** on July 6, 2011.²

Although section 312(b)(2)(B)(i)(II) of the Dodd-Frank Act, codified at 12 U.S.C. 5412(b)(2)(B)(i)(II), granted the OCC rulemaking authority relating to both State and Federal savings associations, nothing in the Dodd-Frank Act affected the FDIC's existing authority to issue regulations under the Federal Deposit Insurance Act ("FDI Act") and other laws as the "appropriate Federal banking agency" or under similar statutory terminology. Section 312(c) of the Dodd-Frank Act amended the definition of "appropriate Federal banking agency" contained in section 3(q) of the FDI Act, 12 U.S.C. 1813(q), to add State savings associations to the list of entities for which the FDIC is designated as the "appropriate Federal banking agency." As a result, when the FDIC acts as the designated "appropriate Federal banking agency" (or under similar terminology) for State

¹ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111-203, 124 Stat. 1376 (2010).

² 76 FR 39247 (July 6, 2011).

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-040

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

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

FOOD guard criteria comprise a CORE item, not a PRIORITY ITEM.

Issue you would like the Conference to consider:

Section 3-306.11 of the 2013 FDA Food Code describes FOOD guards as a PRIORITY ITEM ("P"). "Preface x" of the code defines a PRIORITY ITEM as ". . . a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness. . ."

We looked for data to support the categorization of FOOD GUARDS as PRIORITY ITEMS. A review of scholarly articles and discussions with epidemiologists at various agencies, including Dr. Aron Hall at the CDC did not turn up any evidence of food borne disease transmission being associated with the lack of FOOD GUARDS, or their being out of position in some way. Frankly, we were surprised as retail grocery stores merchandise produce without FOOD GUARDS, and we had assumed that if there was data it would likely be associated with these large and numerous open food display areas. Instead, Dr. Hall responding in writing to our inquiry, stated that he was not aware of any data indicating a relationship between FOOD GUARDS and disease transmission. Section 3-306.11 "FOOD DISPLAY" is designated as a PRIORITY ("P") item, and requires food on display to be protected by various means, one of which is by the use of FOOD GUARDS, which are also known as "sneeze guards". The American National Standards Institute (ANSI) sanitation standard for FOOD GUARD's extremely granular and its specified measurements for the food guard based upon the anthropometrics of "the average person" whereby the guard or shield, must intercept the straight line from the "average" persons mouth to the food on display. If a regulatory authority determines that a ANSI sanitation listed FOOD GUARD is slightly out of place given its installation on the counter and the location of the food on display, the operator is cited for a critical violation. The entire premise of using these precise measurements for the "average" persons anthropometrics lacks substance. Designing a functional, compliant food guard is often an impossible feat as consumers can range in height from 4' tall in elementary school, to 6'8" tall and taller in high school, or in a corporate cafeteria or any other commercial food service operation. Because compliant FOOD GUARDS are often (if not always) an obstruction to reach-in

access for many above or below average persons, patrons have to contort themselves to reach their desired items, and in so doing can touch with hands or articles of clothing - other foods. Touching ready to eat foods with hands is a known contributing factor to food borne disease transmission. Food Guards being in or out of position to intercept the direct line from the average persons mouth to the food on display, is not a contributing factor to food borne disease transmission. We maintain that function takes precedence over form and that when FOOD GUARDS are provided, they must enable convenient access of food for the self-service guest. Further, there is no critical need for the food guard to intercept the line from the average persons mouth to the food on display as theorized and assumed as is evidenced by the ANSI sanitation standards precise measurement criteria.

Public Health Significance:

PRIORITY ITEM ("P") designations are supposed to be reserved for critical safety criteria for hazards known to contribute to food borne disease and injury. Assigning this designation to items that lack criticality such as FOOD GUARD'S, is wasteful and does nothing to promote food safety. The mis-categorization of this risk adds confusion and diminishes the importance of other to Priority designations due to its arbitrary, non-scientific categorization. Further, because ("P") item criteria comprise the highest risk categorization in the FDA Food Code, inspection agencies and design professionals are persuaded to waste thousands if not millions of hours every year complying with the arbitrary ANSI sanitation standards specified measurements because of the sections Priority designation. The cost of of compliance with section 3-306.11 is staggering, especially in light of the fact that it does nothing to improve public health and safety and instead wastes valuable time and money that could instead be used to mitigate risk factors known to contribute to food borne disease transmission.

There are some other reasons one might want a FOOD GUARD. For example, it could be used as a barrier or heat shield adjacent to a griddle or a broiler, or perhaps a hot food well or baines marie. But the ANSI sanitation measurements for a FOOD GUARD's are irrelevant for these examples - as the function of the FOOD GUARD here is actually to be a patron or child guard to reduce likelihood that they could be burned. Surely no reasonable person would think that the FOOD GUARD provides any microbial risk mitigation in these examples, as the thermal mass of the hot food would destroy any aerosolized organism from a cough or sneeze on contact. One could argue that such a guard protects from physical hazards. But foods on display are there for a short amount of time, and there is no data to suggest a physical or chemical hazard exists whether there is a FOOD GUARD used or not.

When the ANSI sanitation standards precise measurement requirements for FOOD GUARDS result in them becoming an obstacle to easy access to food, a documented hazard to the food is created; the inadvertent bare hand contact with ready to eat foods. The logical risk based preventative control for this hazard is to require convenient access to foods for all consumers, even those that are above or below "average", or handicapped. FOOD GUARDS that are obstacles to food access cause many patrons to simply choose not to reach for the item, diminishing the sales opportunity for the operator and the nutritional choice of the consumer. This is especially true with children and the handicapped.

Lacking scientific data that FOOD guards effectively protect food from contamination, the PRIORITY ITEM designation in section 3-306.11 of the FOOD CODE is arbitrary and inappropriate. This is not to say that FOOD guards cannot or should not be used. Rather, when FOOD GUARDS are used, form must follow function. Finally, FOOD GUARDS comprise a Core item, not a Priority item nor a Priority foundation item.

Recommended Solution: The Conference recommends...:

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

Section 3-306.11 Food Display.

~~Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the CONSUMER before consumption,~~ FOOD on display shall can be protected from contamination shielded by the use of PACKAGING; counter, service line, or salad bar FOOD guards; display cases; or other effective means^P. When FOOD guards are used, they shall be installed and maintained in a manner that allows self-serve consumers convenient access to the displayed foods.

Section 4-204.12 Equipment Openings, Closures and Deflectors

(E) When FOOD guards are provided, they shall be installed and maintained in a manner that self-service consumers are allowed convenient access to the food in order to reduce the risk of inadvertent hand or clothing contact with other foods on display.

Submitter Information 1:

Name: Thomas Johnson, Chief Manager
Organization: Johnson Risk Solutions, LLC
Address: 1408 Northland Dr #406
City/State/Zip: Mendota Heights, MN 55120
Telephone: 651-587-0418
E-mail: tomj@jdpinc.com

Submitter Information 2:

Name: Steve Carlson, President
Organization: Rippe Associates
Address: 6117 Blue Cir Dr, Suite 100
City/State/Zip: Minnetonka, MN 55343
Telephone: 952-933-0313
E-mail: scarlson@ripple.com

Supporting Attachments:

- "CDC Food Guards (2015)"

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.

Subject: RE: Food borne disease transmission/contributing factors
Date: Monday, December 7, 2015 at 10:17:02 Eastern Standard Time
From: Hall, Aron (CDC/OID/NCIRD) <esg3@cdc.gov>
To: Tom Johnson <tomj@jdpinc.com>

Dear Tom,

I am not aware of any such data.

Kind Regards,

Aron J. Hall, DVM, MSPH, DACVPM
CDC Division of Viral Diseases
ajhall@cdc.gov

From: Tom Johnson [mailto:tomj@jdpinc.com]
Sent: Friday, December 04, 2015 8:21 AM
To: Hall, Aron (CDC/OID/NCIRD) <esg3@cdc.gov>
Cc: Hall, Aron (CDC/OID/NCIRD) <esg3@cdc.gov>
Subject: Food borne disease transmission/contributing factors

Dear Aron,

I am conducting research on behalf of a client and in preparation for the 2016 Conference fo Food Protection.

Does CDC have any data relating to the transmission of a food borne disease associated with a cough or sneeze?

ANSI sanitation requirements have very specific and detailed requirements for food shields based on myriad of anthropometrics and various risk theories and opinions. Interpretation and enforcement of these criteria cost the industry tens of millions of dollars every year and also impact access to food by the public.

We seek data that may indicate that pathogenic species such as *Listeria monocytogenes*, *Salmonella*, *E.Coli*, *Staph*, *Hep A* have been transmitted because of the lack of a food shield, or that due to misuse or positioning, a cough or sneeze may have transmitted one of the target organisms of concern.

Please advise.

Thank You and Best Regards,



Thomas Johnson, Chief Manager

Johnson Risk Solutions, LLC

Insightful HACCP/Technology & Risk Mitigation Integrations

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-041

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

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Issue History:

This is a brand new Issue.

Title:

Food equipment cleanability and design

Issue you would like the Conference to consider:

Contaminated food contact surfaces of food equipment are known to be a contributing factor to food borne disease transmission. At a minimum, food contact surfaces should be designed and formed of materials conducive to their effective cleaning and sanitation across their entire service life, not just the first day they were placed into service. At a minimum, these surfaces should have recommended cleaning and sanitizing protocols that include frequency, methods and means.

American National Standards Institute (ANSI) performance certification standardized tests are only performed on brand new (virgin) equipment, the surfaces of which are free of any wear and/or food residue/biofilm accumulation at the time of certification testing. There are no current ANSI Sanitation performance certification test methods to ensure that equipment food contact surfaces can be effectively cleaned and sanitized beyond the food equipment's first use.

Matrices of soils, including inorganic and organic matter accumulates on food contact surfaces, if not cleaned and sanitized with a specific frequency using effective methods can harbor opportunistic microorganisms of many species. These include the spoilers along with pathogenic bacteria and virus. A discipline of focused and continuous effort to clean and then sanitize these surfaces is needed to ensure a reasonable standard of care, especially in those operations that serve highly susceptible persons. The artifact definition of CLEAN (*to sight and touch*) is not sufficient for food contact surfaces that are inaccessible to sight or touch.

Equipment that requires clean and sanitize in place (CIP, or CSIP) processes to clean and sanitize food contact surfaces that are not readily accessible for inspection present the greatest risk from this gap in ANSI sanitation performance certification testing. Examples include internal food contact surfaces in ice machines such as its harvest plates, sumps and the potable lines interconnecting them. Risk is amplified when a carbon filter is placed upstream from the ice machine, which is often the case. The reference link #3 below

presents a table showing growth rates for biofilms in drinking water lines where there is no residual chlorine. Since carbon filters remove chlorine, this chart has direct correlation to wetted surfaces leading into and within an icemaker. Other reference links below provide evidence of growth and propagation of biofilms even in ice waters.

Other examples of food equipment that are dependent upon CIP processes that are ill defined in the code and within ANSI sanitation standards include the interior surfaces of product lines used to deliver jumpable Time Temperature for Safety Food 9TCS0 products from a walk-in refrigerator (for example) to a dispenser (or dispensing freezer); or condiments from a bag-in-the-box to the point of application, along with soda and juice dispensers.

Section 4-205.10 of the FDA Food Code states that equipment listed to an ANSI sanitation standard is deemed to comply with chapters 4-1 and 4-2. Such a listing *does not* however relieve the operator of their duty to comply with everything else in chapter 4 beyond 4-2, such as section 4-6 and 4-7 and the remainder of the code. It is unfortunate that Section 4-602.11 (E) (4) (a) and (b) introduce an arbitration in the science based safety of the code. Here is the current text:

(4) In EQUIPMENT such as ice bins and BEVERAGE dispensing nozzles and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks and distribution lines, BEVERAGE and syrup dispensing lines or tubes, coffee bean grinders, and water vending EQUIPMENT:

(a) At a frequency specified by the manufacturer, or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

Coffee bean grinders, and cooking oil storage tanks have little in common with the other examples listed in this food codes criteria section as they do not relate to equipment designed to prepare, hold or convey liquid food products. This inconsistency creates an arbitrary circumstance that obfuscates hazards associated with food equipment with internal or external liquid food plumbing lines that otherwise lack inspection ports or access openings for all or most of the equipment's wetted food contact surfaces.

Section 4-205.10 (4) (a) (above) infers that following a manufacturers instruction for use of their equipment will ensure a reasonable standard of care. This is inaccurate. Though it is true that the manufacturer is strictly liable for their equipment design, this liability does not ensure food-safe equipment design. Few manufacturers of food equipment have conducted any kind of professional risk analysis, whether internally or a third party of the potential hazards to foods prepared or processed using their equipment across the life of their equipment.

Generally speaking, the industry pursues product certification to a large extent because it is the shortest well-traveled path to obtaining local approvals, nationwide. Their overall goal is compliance with local interpretations of adopted rules and regulations, and they rely upon the codes and standards development organizations to have their acts together to ensure reasonable minimum safety. We have let them down with this issue.

It is well known today that though a surface may appear "clean" to sight and touch it can still be contaminated with fats, oils and other invisible organic matter that both inactivates sanitizers and shields pathogens. In food equipment dependent upon clean and sanitize in

place (CSIP/CIP), surfaces can be coated with *Pseudomonas spp* (biofilms) and with them myriad other microorganisms. *Pseudomonas aeruginosa* is a gram negative, rod shaped pathogen common in almost all biofilms and is particularly dangerous to highly susceptible persons with diminished immune systems. *Pseudomonas fluorescens*, though less common and considered less virulent is known to continue to grow in waterlines and other fluid food lines at temperatures as low as 4 degrees Celsius (4°C/39.2°F).

Because the internal surfaces of small bore water lines and tubing common in liquid foodservice and beverage equipment (which includes foods such as potable water, ice, coffee, tea, juice, beer, wine, soda, etc) are inaccessible, there is no way of visually determining if biofilms are present. Without competent risk analysis as is now required in the Food Safety Modernization Act (FSMA) as described in the hazard analysis risk based preventative control (HARPC) regimes, there is no reasonable way to ensure that the manufacturers recommended cleaning and sanitizing protocols and frequency are adequate to ensure continuously sanitary food contact surfaces.

Hazard analysis critical control point (HACCP) regimes with their prerequisite programs (PRP's) and the new Hazard Analysis and Risk-based Preventive Controls (HARPC) programs with their Sanitation Standard Operation Procedures (SSOPs) provide a method by which reasonable interventions are put in place to mitigate risks to food. The fact that there are food contact surfaces that cannot be accessed for inspection, cleaning and sanitation by itself should be enough for any reasonable person concerned about public health and safety, to seek answers to the questions of risk, and to pursue improvement in poorly designed equipment with food contact surfaces that cannot be effectively inspected, cleaned and sanitized, or verified to be clean and sanitary. What is needed for equipment with inaccessible food contact surfaces is a risk based preventative control approach to ensure food safety.

Public Health Significance:

Failure to properly clean and sanitize food contact surfaces has been identified as a significant contributing factor to food borne disease transmission. Because the ANSI sanitation standards do not exist for testing food contact surfaces across their service life for continuous cleanability and sanitation suitability, the FDA Food Code needs to add new minimum safety criteria to fill the gap.

Section 4-602.11 has been used as a kind of catch-all waste basket for criteria that did not fit well in other sections of the code, or for things that are or were considered to be of lesser importance. For example, this section not only covers equipment used with liquid foods, some of which are TCS, but also coffee grinders and other equipment systems that lack similar microbiological risks. For these reasons we recommend that coffee grinders and the (hot) cooking oil systems be removed from this section entirely and replaced with examples of food service equipment with liquid food plumbing lines that depend upon a clean and sanitize in place (CSIP or CIP) capabilities to ensure clean and sanitary food contact surfaces. From a risk analysis, categorization and prioritization perspective, it is more appropriate that coffee grinders, meat saws, large cutting boards and other food equipment food contact surface too large to be cleaned out of place (COP) in a sink or dish washer should be subjected to in place cleaning (IPC) protocols, pursuant to their listings and the manufacturers instructions.

Reference links -

1. Control of Biofilm Growth in Drinking Water Distribution Systems
<http://infohouse.p2ric.org/ref/15/14291.pdf>
2. Phylogenetic and Functional Heterogeneity of Sediment Biofilms along Environmental Gradients in a Glacial Stream <http://aem.asm.org/content/67/2/799.full>
3. Water Contamination Emergencies Managing the Threats (see last page discussion) -
<http://tinyurl.com/ntah4mg>
4. Spread of *Pseudomonas fluorescens* Due to Contaminated Drinking Water in a Bone Marrow Transplant Unit: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3122780/>
5. Contaminated feeding bottles: the source of an outbreak of *Pseudomonas aeruginosa* infections in a neonatal intensive care unit: <http://www.ncbi.nlm.nih.gov/pubmed/19059675>
6. Other peer reviewed publications:
<https://www.yousendit.com/download/ZWJWR0IVNXZtNEs1eDhUQw>

Recommended Solution: The Conference recommends....:

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

Section 4-602.11

(A) through (D) remain unchanged.

(E) Except when dry cleaning methods are used as specified under § 4-603.11, surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cleaned and sanitized:

(1) At any time when contamination may have occurred;

(2) At least every 24 hours for iced tea dispensers and CONSUMER self-service UTENSILS such as tongs, scoops, or ladles;

(3) Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers ~~and~~, display containers, ice bins; and

~~(E)(4) In EQUIPMENT such as ice bins and BEVERAGE dispensing~~

~~nozzles and with enclosed with enclosed liquid food plumbing line components of EQUIPMENT such as dispensing freezers ice makers and dispensers, cooking oil storage tanks and distribution lines, BEVERAGE, syrup and condiment dispensing lines or tubes, coffee bean grinders and water vending EQUIPMENT and similar enclosed liquid food contact surfaces that depend upon CSIP processes for safety:~~

1. At a frequency of once a week or more frequently as may be necessary to preclude accumulation of soil or mold prevent accumulation of soils or the formation of biofilms, molds and other foreign contaminants.
2. Or at a frequency as recommended by the manufacturer when publicly available third party process validation test data supports their recommended cleaning and sanitizing frequency and protocols given their equipment's intended use and expected service life.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-042

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

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Issue History:

This is a brand new Issue.

Title:

Towel Drying Exception For Equipment Removed From High-Temp Dish Machines

Issue you would like the Conference to consider:

Wet stacking of equipment and utensils is a common issue and cause of concern in many food service establishments. Most facilities lack the space or time to adequately air dry utensils and equipment; therefore, stacking items while wet is frequently observed.

Single-use disposable towels, if used and stored appropriately, are sanitary. A single-use disposable towel could be used to dry equipment and then be discarded. Towel drying would also give the employee another chance to discern whether the items may need to be rewashed.

Public Health Significance:

Wet stacking prevents equipment from drying and increases the potential for bacterial growth. When food particles are not sufficiently removed in the washing process, the equipment, utensils, and food contact surfaces stacked wet support the growth of microorganisms, thus risking the public's health.

When utilizing a high-temperature sanitizing warewashing machine that reaches a temperature of at least 71°C(165°F) for a stationary rack warewashing machine or 82°C(180°F) for all other mechanical hot water sanitizing machines, the final rinse of the high temperature sanitizing warewashing machine should not exceed 90°C(194°F). If the high temperature sanitizing warewashing machine is operating according to manufacturer's specifications, and temperature limits have been met according to 4-501.112 to ensure surfaces of multiuse utensils and equipment accumulate enough heat to destroy pathogens, then single-use disposable towels used to remove remaining moisture should not pose a public health risk.

Recommended Solution: The Conference recommends...:

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

[4-901.11] Equipment and utensils, ~~Air-drying required,~~ Drying

After cleaning and sanitizing, equipment and utensils:

(A) Shall be air-dried or used after adequate draining as specified in the first paragraph of 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions), before contact with food. Stacking of wet items shall be prohibited; *OR*

(B) May not be cloth dried except that UTENSILS have been air-dried may be polished with cloths that are maintained clean and dry, *OR*

(C) May be hand-dried using individual, single-use disposable towels after removal from a high-temperature sanitizing warewashing machine operated as specified under 4-501.112

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-043

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

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Harmonizing Direct Drain Connection Allowances with Plumbing Codes

Issue you would like the Conference to consider:

Paragraph 5-402.11(C) of the 2013 FDA Food Code allows a direct drain connection from warewashing machines if certain conditions exist. Various plumbing codes require direct drain connections for warewashing machines and warewashing sinks. However, in the absence of a plumbing code, food establishments are subjected to unnecessary requirements.

The 5-402.11(C) allowance should be extended to warewashing sinks that are not used for food preparation if the installation conditions specified in 5-402.11(C) are met.

Public Health Significance:

Eliminating Food Code requirements that conflict with other regulatory requirements, when the level of public health protection is not compromised, reduces difficulties faced by food code regulatory agencies.

Recommended Solution: The Conference recommends...:

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

Paragraph 5-402.11(C)

(C) If allowed by LAW, a WAREWASHING machine or WAREWASHING sink may have a direct connection between its waste outlet and a floor drain when the machine or sink is located within 1.5 m (5 feet) of a trapped floor drain and the machine or sink outlet is connected to the inlet side of a properly vented floor drain trap.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-044

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

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Hot Water Provided at Service Sink

Issue you would like the Conference to consider:

Clarify that hot water is required to be provided at a service sink. Currently, this violation is cited under 5-501.18 using the ambiguous reference in Annex 3 of "proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated". While some public health jurisdictions may be able to require hot water at a service sink through their local plumbing codes, others cannot.

Public Health Significance:

An accumulation of greasy food residue left behind after cleaning waste receptacles, mops and mop buckets with only cold water can create a harborage area for pathogens and contribute to the breeding of pests.

Recommended Solution: The Conference recommends...:

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

Section 5-203.13(A)

(A) At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain and equipped to provide water a temperature of at least 38°C (100°F) shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-045

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

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Issue History:

This is a brand new Issue.

Title:

Consolidating Chemical Storage Provisions in the Food Code

Issue you would like the Conference to consider:

The chemical storage provisions in the 2013 FDA Food Code should be combined into one section.

In earlier versions of the code the respective paragraphs (A) were "Swing" violations, which made the division necessary. However, both storage above and immediately adjacent are classified as Priority violations.

Public Health Significance:

Simplifying the Food Code can help with compliance.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA recommending consolidating Sections 7-201.11 and 7-301.11 and paragraphs of the FDA 2013 Food Code into one section and deleting Section 7-301.11 (language to be inserted is underlined; language to be deleted is in strikethrough format):

7-201.11 Separation.

POISONOUS OR TOXIC MATERIALS shall be stored, handled and displayed, whether for use in the food establishment or for retail sale, so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLESERVICE and SINGLE-USE ARTICLES by:

~~(A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning; and~~

~~(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. This paragraph does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if~~

the materials are stored to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES. P

"POISONOUS OR TOXIC MATERIALS shall be stored, handled and displayed, whether for use in the food establishment or for retail sale, so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLESERVICE and SINGLE-USE ARTICLES by separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning and locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. *This paragraph does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES. P"*

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-046

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

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Issue History:

This is a brand new Issue.

Title:

Removing the Reference to Restricted Use Pesticides in 7-202.12(B)(2)

Issue you would like the Conference to consider:

Section 7-202.12(B)(2) of the 2013 FDA Food Code provides basic requirements to prevent pesticide contamination in food establishments. However, the requirements are limited Restricted Use Pesticides. Most pesticides being used in food establishments are not Restricted Use Pesticides, as labeled per EPA regulations.

Although pesticides labeled for use in food establishments will have use directions that require taking these precautions, having the requirements in the Food Code eliminates the need to document the label use directions in instances where the precautions are not taken.

Public Health Significance:

Extending the pesticide use requirements in Section 7-202.12(B)(2) to include General Use Pesticides will further reduce the chance of pesticide contamination of food.

Recommended Solution: The Conference recommends...:

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

7-202.12 Conditions of Use.

POISONOUS OR TOXIC MATERIALS shall be:

(A) Used according to:

(1) LAW and this Code,

(2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a FOOD ESTABLISHMENT, ^P

(3) The conditions of certification, if certification is required, for use of the pest control materials, ^P and

(4) Additional conditions that may be established by the REGULATORY AUTHORITY; and

(B) Applied so that:

(1) A HAZARD to EMPLOYEES or other PERSONS is not constituted, ^P and

(2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and ~~for a RESTRICTED-USE PESTICIDE~~, this is achieved by: ^P

(a) Removing the items, ^P

(b) Covering the items with impermeable covers, ^P or

(c) Taking other appropriate preventive actions, ^P and

(d) Cleaning and SANITIZING EQUIPMENT and UTENSILS after the application. ^P

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-047

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

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Issue History:

This is a brand new Issue.

Title:

Temporary Food Establishment Inspection Intervals

Issue you would like the Conference to consider:

The 2013 FDA Food Code Section 8-401.10(C) states that:

The regulatory authority shall periodically inspect throughout its permit period a temporary food establishment that prepares, sells, or serves unpackaged potentially hazardous food (time/temperature control for safety food) and that:

- (1) Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or
- (2) Has inexperienced food employees.

While this is a nondebitable code provision the use of the word "shall" means that the act is "imperative" and constitutes a command to the regulatory authority. However, based on risk, it may not be necessary for the regulatory authority to inspect a temporary food establishment (TFE) more than once even if the conditions stated in 8-401.10(C)(1) or (2) exist.

I propose changing the word shall to may.

Public Health Significance:

I do not believe there is a public health rationale for the use of the word "shall" in 8-401.10(C). By changing it to "may" it would still permit/allow the regulatory authority to conduct more than one inspection of the TFE during the operational period if they determine it is necessary.

Recommended Solution: The Conference recommends...:

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

Section 8-401.10

(C) The REGULATORY AUTHORITY ~~shall~~ may periodically inspect throughout its PERMIT period a TEMPORARY FOOD ESTABLISHMENT that prepares, sells, or serves unPACKAGED TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and that:

(1) Has improvised rather than permanent facilities or EQUIPMENT for accomplishing functions such as handwashing, FOOD preparation and protection, FOOD temperature control, WAREWASHING, providing DRINKING WATER, waste retention and disposal, and insect and rodent control; or

(2) Has inexperienced FOOD EMPLOYEES.

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**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-048

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

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Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2012 I-038; new or additional information has been included or attached.

Title:

Inclusion of Inspection Result Posting in Food Code

Issue you would like the Conference to consider:

Rigorous health inspections are a critical component of an effective food safety system. The 2013 FDA Food Code recognizes that the results of restaurant inspections are public documents and should be available for public review. However, complex rules regarding public access create difficulty for consumers who wish to consider inspection results.

Public Health Significance:

Consumer access to the results of these inspections plays an important role in maintaining the efficacy and credibility of the inspection system, and allows consumers to consider critical food safety information when making restaurant choices. Recent data show that nearly half of all foodborne illnesses are contracted from food prepared outside the home. Although food establishments are routinely inspected, the results of those inspections are not readily available to consumers-who thus have no way of minimizing their risk by knowing how an establishment performed on its most recent food safety assessment. This proposal was submitted previously to CFP and since that time, numerous jurisdictions have adopted requirements for restaurants to post inspection results and published articles highlighting this practice's benefits to public health (*see supporting attachments to this Issue*).

Recommended Solution: The Conference recommends...:

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

8-4 Inspection and Correction of Violations

8-403.51 Public Posting.

The REGULATORY AUTHORITY shall make available the results of the inspection report by requiring the timely posting of the most recent inspection results in the entrance, front window, or similarly prominent consumer-accessible area of the FOOD ESTABLISHMENT. Results may be posted in the form of a letter grade, numerical score, or other form as determined by the REGULATORY AUTHORITY.

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Supporting Attachments:

- "Letter Grading and Transparency Promote Restaurant Food Safety in New York"
- "Study of Retail Food Establishment Inspection Scoring and Grading Systems"
- "Impact of a Letter-Grade Program on Restaurant Sanitary Conditions (Part 1)"
- "Impact of a Letter-Grade Program on Restaurant Sanitary Conditions (Part 2)"
- "Poster: Feasibility of Restaurant Letter Grading in Utah"

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▶ DIRECT FROM CDC ENVIRONMENTAL HEALTH SERVICES BRANCH



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Letter Grading and Transparency Promote Restaurant Food Safety in New York City

New York City Department of Health and Mental Hygiene

Editor's Note: NEHA strives to provide up-to-date and relevant information on environmental health and to build partnerships in the profession. In pursuit of these goals, we feature a column from the Environmental Health Services Branch (EHSB) of the Centers for Disease Control and Prevention (CDC) in every issue of the *Journal*.

In these columns, EHSB and guest authors share insights and information about environmental health programs, trends, issues, and resources. The conclusions in this article are those of the author(s) and do not necessarily represent the views of CDC.

Wendy McKelvey is principal investigator for two CDC grants that promote environmental public health—one from the Environmental Health Specialists Network (EHS-Net) and the other from the Environmental Public Health Tracking Program. Melissa Wong had been project director for the NYC EHS-Net Program for the past five years. Bailey Matis is the current project director.

Each year in New York City (NYC), more than 6,000 people end up hospitalized for foodborne illness (New York City Department of Health and Mental Hygiene, 2014). Although the proportion of illness caused by food prepared away from the home is uncertain, the food service setting is associated with 68% of nationally reported foodborne illness outbreaks where food was prepared in one place (Gould et al., 2013). New Yorkers eat out nearly one billion times a year (New York City Department of Health and Mental Hygiene, 2011), and

two-thirds eat meals from a restaurant, deli, coffee shop, or bar at least once per week, so the potential public health impact of unsafe food handling practices in NYC restaurants is enormous (Wong et al., 2015).

Improving food handling practices across the approximately 24,000 restaurants that operate in NYC on any given day can reduce risks of foodborne illness. Not having a certified kitchen manager on site, employees working while ill, limited food handler knowledge of food safety, and food workers touching food with their bare hands have been identified as

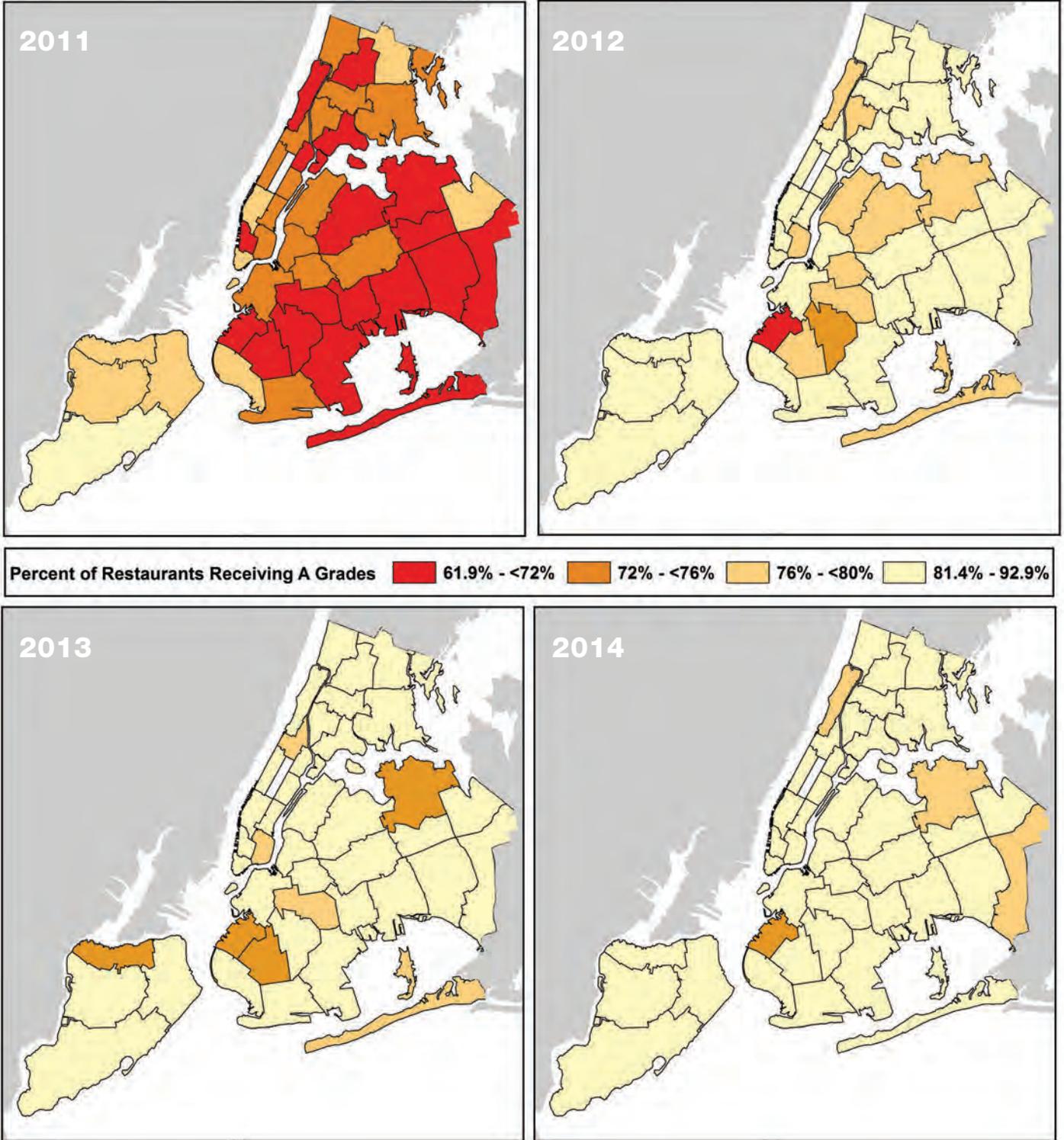
factors that increase the risk of restaurant-related foodborne illness (Gould et al., 2013; Hedberg et al., 2006). In an effort to prevent these and other unsafe food handling practices, the New York City Department of Health and Mental Hygiene launched the restaurant letter grading program in July 2010. The program requires restaurants to post a letter grade that reflects their most recent sanitary inspection results in a visible window location. It also targets the poorest performers with more frequent inspections.

The premise of the NYC letter grading program is that consumer access to inspection results will encourage restaurant operators to better comply with food safety rules. In addition to a conspicuously posted letter grade, the NYC Health Department has increased the transparency of restaurant inspection results by making them available in detail on a searchable Web site and a free smartphone app (“ABCEats,” available for download on iTunes and Google Play). Both of these data resources provide maps and street views of establishments and allow users to filter restaurants by zip code, cuisine type, and grade.

The NYC letter grading program also supports industry by using a dual inspection approach that allows restaurants to improve before being graded. If a restaurant does not earn an A grade on its initial unannounced inspection, it receives a reinspection approximately 7–30 days later, at which point the grade is issued. Restaurants that earn an A grade at initial or reinspection do not pay fines for sanitary violations cited. Those that do not earn an A grade have the

FIGURE 1

Percentage of Restaurants Achieving A Grades by New York City Neighborhood, 2011–2014



right to contest their grade and fines at an administrative tribunal.

As a part of the Centers for Disease Control and Prevention's Environmental Health Specialists Network (EHS-Net) cooperative agreement, we evaluated the impact of the NYC restaurant letter grading program on health hazard reduction (Wong et al., 2015). We tracked scores on initial inspection before and after grading began in July 2010 and measured a 35% increase in the probability of a restaurant practicing A-grade hygiene by 2013. Specifically, we observed more food safety certified managers on site, better worker hygiene, more restaurants with proper hand washing stations, and fewer restaurants with mice. We also measured public response to restaurant letter grades in two population-based telephone surveys conducted 12 and 18 months after the program began. In both surveys, more than 90% of respondents said they approved of restaurant letter grading, and 88% said they considered the grades in dining decisions.

Restaurant sanitary conditions have been steadily improving in NYC since implementation of letter grading (Figure 1). In 2011, 72% of restaurants were posting A grades, and by 2014, after four years, 85% were post-

ing A grades (New York City Department of Health and Mental Hygiene, 2015). Findings from our evaluation suggest that increasing transparency of restaurant inspection results and providing the public with these results in the form of an easily interpreted letter grade posted at the point of consumer decision making is an effective regulatory approach. 🐹

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Did You Know?

The U.S. Environmental Protection Agency's third annual SepticSmart Week is September 21–25. Check out www.epa.gov/septicSMART for planned activities and valuable educational materials.

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Study of Retail Food Establishment Inspection Scoring and Grading Systems



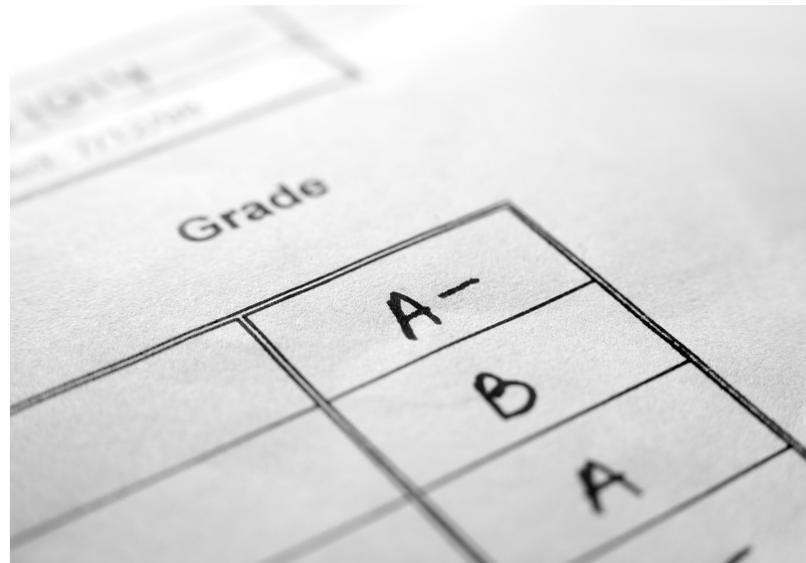
Introduction

Local health departments (LHDs) play a major role in ensuring the food people eat every day is safe. In the United States, approximately 3,000 entities regulate food safety. The vast majority of these entities are LHDs, with more than 75% of the 2,800 LHDs in the United States educating, inspecting, or licensing retail food establishments.

Through a cooperative agreement with the Food and Drug Administration (FDA), in 2012, the National Association of County and City Health Officials (NACCHO) studied the way that LHDs use scores or grades to convey the results of their retail food establishment¹ inspections.

While food establishment inspection grading and scoring (FISG) systems vary throughout the United States, generally numerical scores, letters, colors, graphics/symbols, or any combination thereof are used to systematically quantify or illustrate the inspection performance of a retail food establishment. Gaining a better understanding of the use, composition, successes, and shortcomings of FISG systems could help additional LHDs implement their own systems. This research brief presents findings from NACCHO's survey to learn more about retail FISG systems implemented by LHDs, including the following:

- National prevalence of LHDs that assign a score or grade to an inspection of licensed food establishments;
- Distribution of different types of scoring and grading systems;
- Relationship between scoring/grading systems and other food safety practices; and
- Potential areas for further research or in-depth case studies.



Methodology

Informed by the NACCHO-FDA Food Safety Advisory Group, NACCHO developed, piloted, and executed an electronic quantitative survey instrument in 2012 to a sample of 2,565 LHDs. A stratified random sample of 531 LHDs was selected from this sample. The strata included 48 states and the District of Columbia (excluding Rhode Island and Hawaii). The sample included approximately 20% of LHDs from each state.

The survey included key elements and questions intended to ascertain the following:

- Presence of any scoring or grading system;
- Type of score or grade assigned (e.g., numerical score, letter score, color, or graphic);
- Communication to the public;
- Perceived impact on food safety;
- Implementation year and changes since implementation;
- Regulations, licensing, inspections, and penalties; and
- Geographic barriers and staffing challenges.

Local health departments play a major role in ensuring the food people eat every day is safe.

Findings and Results

General Information

The survey had a response rate of 39% (208).² Non-response includes both survey non-contact³ and refusal;⁴ differentiation between these non-response types is not possible. Among the responses, 183 were from LHDs in states where statewide requirements for how inspections were scored or graded were not present. Twenty-five responses were from states with a statewide requirement for how inspections were scored or graded.

To better understand the prevalence of states with statewide inspection scoring or grading systems, NACCHO contacted the National Conference of State Legislatures (NCSL) to assist with the post-hoc identification. NCSL identified 10 states with a statewide policy regarding how inspection scores or grades were determined and communicated. Fifty LHDs that did not respond to the survey were located in one of those 10 states, so NACCHO concluded that the non-respondents also had a statewide system; however, these LHDs were not imputed into the results.

Prevalence of FISG Systems

NACCHO asked respondents to indicate their use of FISG systems. Nearly 38% (79) of respondents answered “yes” when asked if their LHD jurisdiction, either entirely or within some political subunits, provided licensed food establishments an overall food grade, score, or graphic after an inspection.

Type of FISG System in Use

The following findings were true of the 79 LHDs that responded that they used an FISG system (Figure 1):⁵

- 75% indicated use of a numerical score, 4.5 times greater than the next most frequently used type—letter grade, which 16.5% of respondents reported using;
- 10% indicated use of a color or other graphic to describe an inspection result;
- 11% indicated use of another, unspecified type of FISG system;
- 77% indicated using only one FISG type; and
- 16% indicated using two or more FISG types in combination.

75% of respondents indicated use of a *numerical score*, 4.5 times greater than the next most frequently used type—*letter grade*

Communication

NACCHO asked respondents to provide data on the methods used to communicate grading or scoring of food establishment inspections to the public. The questionnaire allowed respondents to select more than one method of communication. The following findings were true of the 79 respondents who reported using a scoring or grading system:

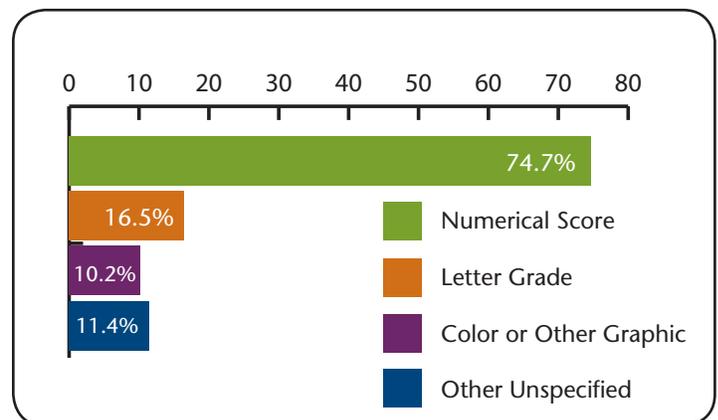
- 62% indicated that the LHD made inspection scores or grades available upon request by the public, making this method the most prevalent among those investigated;
- 41% indicated that inspection scores or grades appeared in local print or broadcast media;
- 37% indicated that inspection scores or grades were made available on the Internet; and
- 35% indicated that inspection scores or grades were posted on the premises of the food establishment.

Perceptions

NACCHO asked respondents to provide information about their perception of how FISG systems impacted food safety within the regulated establishment and the manner in which regulatory inspections were conducted. Respondents were equally divided that FISG systems impacted the manner in which inspectors conducted inspections. The following findings were true of the 79 respondents who reported use of a FISG system:

- 67% perceived that an FISG system had no impact on how operators shared information during an inspection;
- 66% either agreed (52%) or strongly agreed (14%) that an assigned score or grade was perceived as correlated with an establishment’s control of risk factors;
- 59% perceived that an FISG system had impacted how much attention operators paid to food safety; and
- 58% perceived an improved impact on food safety.

FIGURE 1. TYPE OF FISG SYSTEM IN USE



n=79; percentages do not total 100 because respondents may have selected more than one choice



Next Steps and Future Research Questions

NACCHO plans to conduct six to eight case studies with LHDs to explore key questions and hypotheses determined through the data analysis. LHDs selected for case studies will vary based on perceived impact of FISG system, maturity of FISG system, public access to grades or scores, and degree of urbanization, among other considerations.

NACCHO will develop the case studies through record review, open-ended questions, and telephone interviews with key informants (e.g., food establishment operators, board of health representatives, municipality supervisors, and LHD professionals). Through case studies, NACCHO intends to explore further the following questions:

- Does any particular approach to scoring and grading have a greater impact than others on the control of foodborne illness risk factors in retail food establishments?
- Does any particular approach to scoring and grading have a greater impact than others on consumer attitudes and behavior?
- Does the presence of an FISG system affect the behavior of health inspectors?
- Does the presence of an FISG system affect the behavior of establishment operators?
- Does the method used to communicate inspection results to the public affect the perceived impact or value of FISG systems?
- What motivates LHDs to employ FISG systems?
- Are LHDs in areas with strong local media more likely to use FISG systems or report violation results openly and routinely to the public?

[RESEARCH BRIEF]

September 2014



Notes

1. A retail food establishment generally refers to operations that (1) store, prepare, package, serve, vend food directly to the consumer; or (2) provide food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank.
2. With an assumed population of 2,565 LHDs, a response sample of 335 was needed to reach a confidence level of 95% and confidence interval of +/-5.
3. Inability to contact units selected for the survey.
4. Refusal of selected unit to participate and provide some or all of the information requested.
5. To have a requirement for scoring and grading and imputed as affirmative responses when asked if their LHD jurisdiction, either entirely or within some political subunits, provided licensed food establishments an overall food grade, score, or graphic after an inspection.

Acknowledgments

This project was made possible through the support of the Food and Drug Administration, cooperative agreement #5U50FD004334-04. NACCHO is grateful for this support. The views expressed within do not necessarily represent the official views of the sponsor.

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NACCHO

National Association of County & City Health Officials

The National Connection for Local Public Health



The mission of the National Association of County and City Health Officials (NACCHO) is to be a leader, partner, catalyst, and voice with local health departments.

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**Study of Retail Food Establishment
Inspection Scoring and Grading Systems**

Appendix A—Univariate Data Tables

Uses Food Grading and Scoring System			
	Freq.	Percent	Cum.
No	129	62.02	62.02
Yes	79	37.98	100.00
Total	208	100.00	

Uses Letter Grade			
	Freq.	Percent	Cum.
No	66	83.54	83.54
Yes	13	16.46	100.00
Total	79	100.00	

Uses Numerical Score			
	Freq.	Percent	Cum.
No	20	25.32	25.32
Yes	59	74.68	100.00
Total	79	100.00	

Uses Other Image			
	Freq.	Percent	Cum.
No	78	98.73	98.73
Yes	1	1.27	100.00
Total	79	100.00	

Uses Other Graphic			
	Freq.	Percent	Cum.
No	72	91.14	91.14
Yes	7	8.86	100.00
Total	79	100.00	

Uses Other			
	Freq.	Percent	Cum.
No	70	88.61	88.61
Yes	9	11.39	100.00
Total	79	100.00	

Number of Types Used in Combination			
	Freq.	Percent	Cum.
0	5	6.33	6.33
1	61	77.22	83.54
2	11	13.92	97.47
3	2	2.53	100.00
Total	79	100.00	

Assigned Score or Grade is Correlated with Establishment Control of Risk Factors			
	Freq.	Percent	Cum.
Strongly Agree	10	13.70	13.70
Agree	38	52.05	65.75
Neither	15	20.55	86.30
Disagree	7	9.59	95.89
Strongly Disagree	3	4.11	100.00
Total	73	100.00	

System has Impacted How Much Operators Pay Attention to Food Safety			
	Freq.	Percent	Cum.
No	32	40.51	40.51
Yes	47	59.49	100.00
Total	79	100.00	

System has Impacted How Operators Share Information during Inspections			
	Freq.	Percent	Cum.
No	53	67.09	67.09
Yes	26	32.91	100.00
Total	79	100.00	

System has Impacted Manner in which Inspectors Conduct Inspections			
	Freq.	Percent	Cum.
No	39	49.37	49.37
Yes	40	50.63	100.00
Total	79	100.00	

Perceived Impact on Food Safety			
	Freq.	Percent	Cum.
No Impact	4	5.56	5.56
Improved Impact	42	58.33	63.89
Unclear Impact	26	36.11	100.00
Total	79	100.00	

Year Implemented Food Grading and Scoring System			
	Freq.	Percent	Cum.
Before 2000	49	67.12	67.12
2000	1	1.37	68.49
2001	3	4.11	72.60
2002	1	1.37	73.97
2006	1	1.37	75.34
2007	2	2.74	78.08
2008	4	5.48	83.56
2009	2	2.74	86.30
2010	3	4.11	90.41
2011	3	4.11	94.52
2012	4	5.48	100.00
Total	73	100.00	

Inspection Report Posted on Premises			
	Freq.	Percent	Cum.
No	50	63.29	63.29
Yes	29	3.71	100.00
Total	79	100.00	

Inspection Report Available upon Request			
	Freq.	Percent	Cum.
No	11	13.92	13.92
Yes	68	86.08	100.00
Total	79	100.00	

Inspection Report Available on the Internet			
	Freq.	Percent	Cum.
No	53	67.09	67.09
Yes	26	32.91	100.00
Total	79	100.00	

Grades or Scores Posted on the Premises			
	Freq.	Percent	Cum.
No	51	64.56	64.56
Yes	28	35.44	100.00
Total	79	100.00	

Grades or Scores Available upon Request			
	Freq.	Percent	Cum.
No	30	37.97	37.97
Yes	49	62.03	100.00
Total	79	100.00	

Grades or Scores Available on the Internet			
	Freq.	Percent	Cum.
No	50	63.29	63.29
Yes	29	36.71	100.00
Total	79	100.00	

Grades, Scores, Violations Appear in Local Print or Broadcast Media			
	Freq.	Percent	Cum.
No	47	59.49	59.49
Yes	32	40.51	100.00
Total	79	100.00	

Impact of a Letter-Grade Program on Restaurant Sanitary Conditions and Diner Behavior in New York City

Melissa R. Wong, MPH, Wendy McKelvey, PhD, Kazuhiko Ito, PhD, Corinne Schiff, JD, J. Bryan Jacobson, MPH, and Daniel Kass, MSPH

Restaurant food safety is increasingly important, with almost half of the US food dollar spent on restaurant food¹ and about one third of caloric intake from foods prepared outside the home.² In New York City (NYC), residents eat out nearly 1 billion times each year.³ Although most diners do not get sick, foodborne pathogens cause millions of preventable illnesses in the United States annually.⁴ The exact proportion of restaurant-attributable foodborne illness is unknown, but national surveillance in the United States found that two thirds of reported foodborne outbreaks from 1998 through 2008 occurred in the restaurant or deli setting,⁵ and consumption of food prepared outside the home has been linked to an increased risk of sporadic foodborne diseases.⁶

Regular inspection of restaurants for food safety is a core function of local health authorities, guided by the US Food and Drug Administration (FDA) Food Code.⁷ Although all states have sanitation codes modeled after the FDA Food Code,⁸ implementation methods vary by jurisdiction. The NYC Department of Health and Mental Hygiene (hereafter, Health Department) is charged with inspecting restaurants, coffee shops, bars, nightclubs, employee or university cafeterias, bakeries, and fixed-site food stands (hereafter, restaurants). Its inspection program uses a scoring system to measure compliance with the NYC Health Code, which is updated regularly to maintain consistency with the FDA Food Code and the New York State Sanitary Code. Restaurants are entitled to an impartial review of inspection results by an administrative tribunal, which can improve an assigned score and reduce associated monetary fines.

Before letter grading, the Health Department aimed to inspect restaurants at least once per year and imposed monetary fines for violations cited at inspections. Inspection results were available on the Health Department Web site. However, financial disincentives and the

Objectives. We evaluated the impact of the New York City restaurant letter-grading program on restaurant hygiene, food safety practices, and public awareness.

Methods. We analyzed data from 43 448 restaurants inspected between 2007 and 2013 to measure changes in inspection score and violation citations since program launch in July 2010. We used binomial regression to assess probability of scoring 0 to 13 points (A-range score). Two population-based random-digit-dial telephone surveys assessed public perceptions of the program.

Results. After we controlled for repeated restaurant observations, season of inspection, and chain restaurant status, the probability of scoring 0 to 13 points on an unannounced inspection increased 35% (95% confidence interval [CI] = 31%, 40%) 3 years after compared with 3 years before grading. There were notable improvements in compliance with some specific requirements, including having a certified kitchen manager on site and being pest-free. More than 91% (95% CI = 88%, 94%) of New Yorkers approved of the program and 88% (95% CI = 85%, 92%) considered grades in dining decisions in 2012.

Conclusions. Restaurant letter grading in New York City has resulted in improved sanitary conditions on unannounced inspection, suggesting that the program is an effective regulatory tool. (*Am J Public Health.* 2015;105:e81–e87. doi:10.2105/AJPH.2014.302404)

Web site posting were insufficient to drive improvements across the industry, with most restaurants cited for multiple public health hazards. Mean inspection scores and restaurant sanitary conditions were stagnant (D. Kass, email communication, February 2009).

In an effort to improve restaurant food safety and increase transparency of inspection information, the Health Department launched its letter-grade program on July 27, 2010. The program uses public disclosure of inspection scores in the form of letter grades at point of decision-making; a more finely tuned, risk-based inspection schedule; and financial incentives to encourage high food-safety standards. It began after an 18-month planning process that included a public announcement of the intent to begin letter grading; meetings with restaurant industry representatives, food safety experts, and regulators from a jurisdiction with a restaurant sanitary grade program; promulgation of 2 regulations subject to notice and comment; and training and education for restaurateurs. The process was covered by the

media, and by July 2010, restaurateurs were aware of the program and anticipating the launch.^{9,10}

We evaluated the impact of the restaurant letter-grade program by assessing (1) hygiene and food-safety practices as characterized by inspection outcomes before and after program implementation and (2) public response to the program measured by 2 population-based telephone surveys.

METHODS

The NYC restaurant inspection program has been using a point system to score inspections since 2005.¹¹ Presence and severity of violations contribute to an inspection score. Under the grading program, an inspection score of 0 to 13 points is in the A-range; 14 to 27 points is in the B-range; and 28 or more points is in the C-range. Restaurants scoring 0 to 13 points on the first inspection of their inspection cycle (initial inspection) are issued an A grade. Restaurants not earning an A grade on initial

inspection receive a full reinspection no less than 7 days later. The grade card is issued based on the reinspection score. The initial inspection and any reinspection together are an “inspection cycle.” Upon completion of an inspection cycle, there is an interval before the next cycle. Restaurants earning an A grade on initial inspection of a cycle are inspected in 11 to 13 months. Restaurants scoring 28 or more points on either initial or reinspection of a cycle have a 3- to 5-month interval. The remaining restaurants scoring 14 to 27 points on either initial inspection or reinspection of a cycle have a 5- to 7-month interval.

Before the grading program was launched, the Health Department aimed to conduct at least 1 inspection in all restaurants annually. Restaurants scoring 28 or more points received a follow-up compliance inspection about 1 month later. A score of 28 points or higher could result in a restaurant being placed on a twice-yearly inspection schedule. Administrative violations (e.g., expired permit) were included in the scoring system before implementation of letter grading, but they are not included under the grading program.

Health Department inspectors cite violations with standardized forms on handheld computers. They also collect data on restaurant descriptors such as cuisine, service method to customer (e.g., wait service, counter service), venue description (e.g., restaurant, bar), and chain status (15 or more national outlets). Inspectors are trained in the classroom and under an experienced inspector in the field before they are allowed to work independently.

Data Analysis

We analyzed preadjudicated inspection scores and points for violations cited on initial or reinspections conducted between July 27, 2007, and July 26, 2013. We subtracted administrative violation points from pregrading inspection scores to make pregrading scores more comparable with postgrading.

We calculated measures that used “most recent initial inspection” among restaurants in business as of July 27 in each year. “Most recent initial inspection” is used in crude analyses to depict a restaurant’s usual sanitary conditions closest to the specified period end date. We consider initial inspections of a cycle the best indicator of usual sanitary conditions

because they occur at the longest interval after the previous inspection and they are unannounced to operators. Crude metrics were percentage of restaurants scoring in the A-, B-, or C-range; percentage scoring 40 points or higher (85th percentile score on initial inspection in the program’s first year); median inspection score; and average points for specific violations or violation groups. Average violation points characterize both presence and severity of violations over time.

We assessed performance on reinspection of a cycle by calculating percentage of restaurants scoring in the A-range on reinspection among those with B-range or C-range initial inspection scores. We tracked the percentage of restaurants with A, B, or C grades on a cycle that went on to earn an A grade on their next cycle.

We modeled the probability of scoring 0 to 13 points (A-range score) across all initial inspections in all 43 448 restaurants by fitting a binomial regression model that included 5 indicators of time: 13 to 36 months before grading (reference), 0 to 12 months before grading, 0 to 12 months after grading, 13 to 24 months after grading, and 25 to 36 months after grading. We fit restaurant random intercepts to account for repeated observations and variation across individual restaurants. We used indicator variables to adjust for potential confounding by season of inspection (January–March, April–June, July–September, October–December), because pest and holding temperature–related violations increase during the warmest season and the distribution of inspection date varied over time.¹² We did not think chain restaurant status was a potential confounder because the distribution before and after grading remained constant, but we included it to estimate the probability that a chain restaurant scored 0 to 13 points relative to a nonchain. We also ran the fully adjusted model for the subset of restaurants with inspections in the first and last year of the study ($n = 7059$) to evaluate whether improvement differed among the most stable restaurants.

To assess whether an excess or deficit in the frequency of inspection scores around grade cut-offs could have biased our results, we estimated the underlying (unbiased) smooth frequency distribution of scores by fitting a generalized additive model with penalized splines¹³ and used the smoothed distribution

to estimate the “bias-corrected” percentage of A-range scores in the postgrading period. The percentage of A-range scores across initial inspections in the postgrading period dropped only slightly from 30.7% to 27.4% upon correction. We therefore deemed it unnecessary to correct for potential bias resulting from an excess or deficit of scores around grade cut-offs.

We conducted analyses in SQL Management Studio 2008 R2 (Microsoft, Redmond, WA), SAS version 9.2 (SAS Institute, Cary, NC), and R version 3.0.1 (R Project, Vienna, Austria).

Public Perception Surveys

The Health Department worked with Baruch College Survey Research (BCSR) to conduct 2 English/Spanish bilingual telephone surveys in July 2011 and February 2012 to assess public perceptions of the grading program. Landline samples on a random-digit-dial design and respondents were selected randomly within the household; cell phones were randomly selected from a mobile number database for NYC county telephone numbers. Respondents were screened for NYC residency and age of 18 years or older.

In July 2011 and January 2012, 502 and 511 adults completed surveys, respectively. Based on the American Association for Public Opinion Research (AAPOR) standard definitions,¹⁴ response rates were 26% and 22%, and cooperation rates were 60% and 51%, respectively. AAPOR response rates incorporate estimates of the proportion of respondents of unknown eligibility that might have been eligible. Data were weighted to the US Census 2009 American Community Survey to ensure the samples represented the age, gender, race, Hispanic origin, and borough distribution of NYC adults. Confidence intervals (CIs) for proportions were calculated with SAS version 9.3 (SAS Institute, Cary, NC).

RESULTS

Approximately 24 000 restaurants operate in NYC on any given day. A total of 43 892 restaurants were in business at some point between July 2007 and July 2013, and 46% (20 005) of those were in operation at some point both before and after grading. During the 3 years before grading, 31 226 restaurants

operated. Of those, 41% were newly opened for business and 36% went out of business. In the 3 years since grading began, 32 700 restaurants operated. Of those, 39% were newly opened for business and 27% went out of business (Table 1). The distribution of restaurant types was nearly identical before and since grading was instituted.

Inspections

The percentages of A-range scores on recent unannounced initial inspection were similar during the 3 years before grading and have improved since grading. The proportion of restaurants with A-range scores went from 28% in July 2008 to 31% in July 2010, with an additional increase to 46% by July 2013 (Figure 1). With more restaurants achieving A-range scores after grading, the median initial inspection score went from 21 points as of July 2008 and 20 points as of July 2010 to 17 points as of July 2013.

After we controlled for chain status, season of inspection, and correlation within restaurants, the probability of attaining an A-range score on an unannounced initial inspection among all restaurants increased 26% (success ratio [SR] = 1.26; 95% CI = 1.22, 1.31) by the 2-year mark (Table 2). The SR increased at the 3-year mark to 1.35 (95% CI = 1.31, 1.40). Compared with the warmest season (July–September), the other seasons exhibited higher SRs, with the highest (SR = 1.30; 95% CI = 1.26, 1.35) in the coldest season (January–March). The SRs for the subset of restaurants in business during the whole period (data not shown in Table 2) were slightly higher—1.32 (95% CI = 1.25, 1.40) and 1.41 (95% CI = 1.33, 1.49) for the 2- and 3-year mark, respectively. Chain restaurants showed a high SR for both all restaurants (SR = 3.46; 95% CI = 3.31, 3.61) and the subset of restaurants operating during the whole period (SR = 3.79; 95% CI = 3.54, 4.07).

Certain critical food safety violations contributed fewer average points in July 2013 compared with the 2 years before grading (Table 3). In July 2012, the average points given to all restaurants declined substantially for evidence of any type of vermin (rats, mice, flies, or roaches), inadequate hand-washing facilities, and no food safety–certified supervisor on-site. Points given for improper storage or use of equipment or utensil and inadequate food worker hygiene also declined to a lesser extent. These overall point reductions were maintained in July 2013. Meanwhile, average points increased for improperly maintained food contact surfaces, and the points given for inadequate protection of food from contamination, cross contamination, and holding food at improper temperatures increased slightly (Table 3). Although average points for temperature and cross-contamination violations increased slightly, average severity of cited violations decreased (data not shown).

We observed inverse trends for C-range scores on recent initial inspection over time. The proportion of C-range scores decreased from 29% as of July 2008 and 27% as of July 2010 to 22% as of July 2013 (Figure 1). The percentage of extreme C-range (≥ 40 points)—scoring restaurants dropped from 14% in the year before grading to 13% in July 2011, dropping to 7% in July 2012, and increasing to 9% in July 2013, while the 80th percentile decreased from 36 points in July 2008 to 30 points in July 2013.

Three years after grading, more restaurants corrected unsanitary conditions observed on initial inspection of most recent inspection cycle. In July 2013, 45% of restaurants requiring reinspection earned A grades upon reinspection, up from 34% in July 2011. Likewise, there was a decrease in the proportion of poorly performing restaurants that did not improve on reinspection (28+ point scores on both initial and reinspection). The proportion of restaurants that scored poorly on both initial and reinspection dropped from 28% as of July 2009 to 22% as of July 2013.

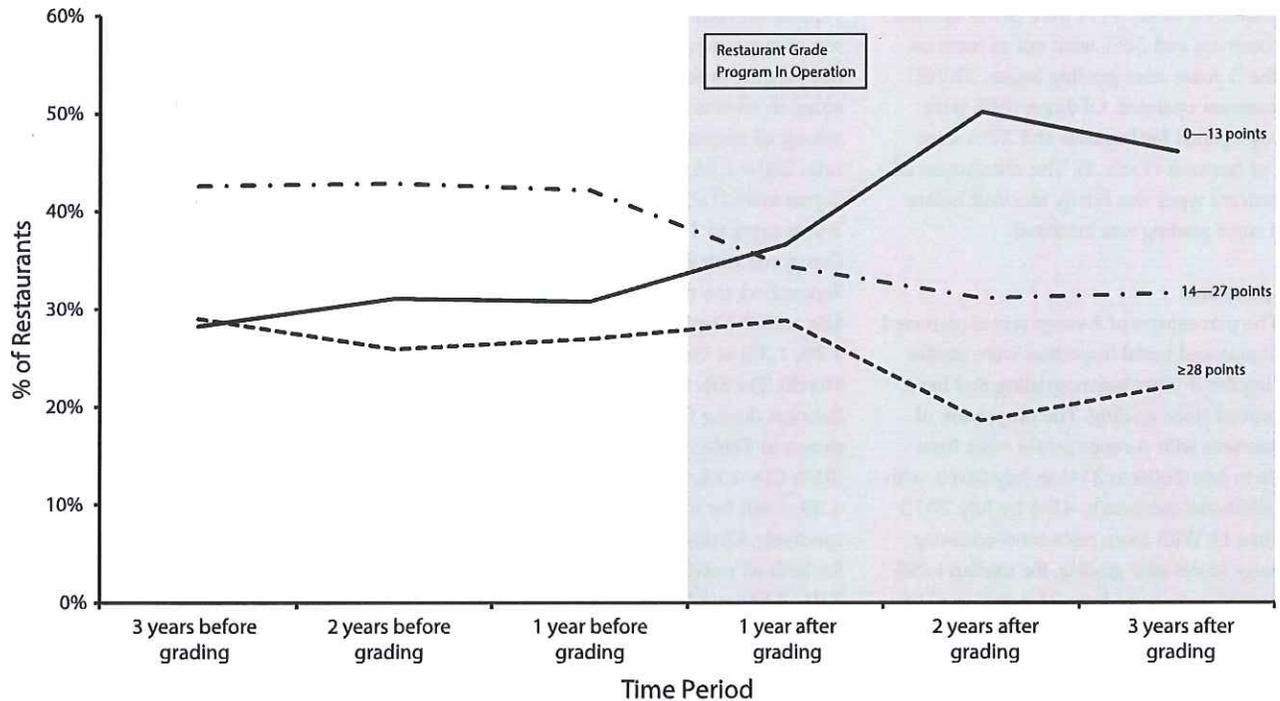
When we tracked performance from inspection cycle to inspection cycle, we found that 80% and 79% of A-grade restaurants maintained their A grade on their next cycle at 2 and 3 years after grading, respectively. Among B-grade restaurants, 53% and 54%

TABLE 1—Restaurant Characteristics Before and After Grading: New York City, NY, 2007–2013

Characteristic	Operating Between July 27, 2007, and July 26, 2010 (n = 31 226), No. (%)	Operating Between July 27, 2010, and July 26, 2013 (n = 32 700), No. (%)
Borough		
Bronx	3 267 (10)	3 222 (10)
Brooklyn	7 538 (24)	8 047 (25)
Manhattan	11 828 (38)	12 584 (38)
Queens	7 307 (23)	7 552 (23)
Staten Island	1 286 (4)	1 295 (4)
Chain restaurants		
Yes	3 393 (11)	3 627 (11)
No	27 833 (89)	29 073 (89)
Restaurant type^a		
Wait service restaurant or diner	8 589 (31)	10 564 (33)
Quick-service establishment with take-out or limited seating	12 706 (46)	14 443 (45)
Baked goods, ice cream, or cafe only	3 539 (13)	4 050 (13)
Bar or wine bar	1 206 (4)	1 289 (4)
Cafeteria and banquet-style service or deli buffet	992 (4)	1 236 (4)
Food service at attraction	534 (2)	662 (2)
Missing	3 660	456

Note. The city restaurant letter-grading program began on July 27, 2010. All gradable restaurants (or pregrading equivalent) in operation between July 27, 2007, and July 26, 2013, included.

^aPercentage excludes missing values.



Note. The city restaurant letter-grading program began on July 27, 2010. Pre-adjudicated score from initial inspection closest to end of each period for unique restaurants was included in the analysis. For the time before the letter grading program began, inspection scores before grading were adjusted to remove points given for nonsanitary administrative violations.

FIGURE 1—Inspection score category on recent initial restaurant inspection: New York City, NY, 2007-2013.

improved to an A grade on the next cycle as of the 2- and 3-year mark, respectively.

Public Perception Surveys

Results from 2 independent telephone surveys suggested that New Yorkers dine out frequently and support and use letter grades to help them decide where to eat. Among NYC adults, 67% (95% CI=63%, 71%) and 68% (95% CI=63%, 72%) reported eating meals from a restaurant, deli, coffee shop, or bar at least once per week at the 1-year and 18-month mark, respectively. At the 1-year mark, 90% (95% CI=87%, 93%) approved of the program and 71% (95% CI=66%, 74%) had seen a grade card in restaurant windows. At 18 months, support remained at 91% (95% CI=88%, 94%) and 81% (95% CI=77%, 84%) had seen grade cards. Among those who had seen grade cards, 88% (95% CI=85%, 92%) considered them in their dining decisions at the 1-year and 18-month mark.

Results suggested that grades reassure diners about food safety; 76% (95% CI=71%, 80%)

felt more confident in a restaurant's food safety when an A grade was posted. An estimated 70% (95% CI=66%, 74%) expressed concern about getting sick from eating from restaurants, delis, and coffee shops, with 38% (95% CI=34%, 43%) being very concerned. A majority of 88% (95% CI=85%, 91%) supported more frequent inspections for restaurants that do not earn an A grade.

DISCUSSION

The NYC Health Department launched the restaurant letter-grading program to motivate restaurants to improve food safety, inform the public about inspection results, and reduce illness associated with dining out. The program introduced multiple changes to the enforcement landscape, including the mandatory posting of letter grades summarizing sanitary inspection scores, a fine-tuned risk-based inspection schedule, and a revised policy on financial penalties. Survey results suggest that New Yorkers approve of the program

and use it when making dining decisions. Our restaurant hygiene analysis suggests that the program provided an effective incentive for operators to comply with regulations and improve practices. We also found that there is an incentive to maintain hygiene practices, with the majority of A-grade restaurants earning A grades on their next inspection cycle.

Our ultimate goal is to reduce foodborne illness, but evaluating the impact of 1 program on such a multifactorial outcome is challenging. Past foodborne illness studies have noted that case finding suffers from underreporting and potential misclassification.^{4,15} Among cases that are identified, it can be difficult to know if exposures occurred in a restaurant. Certain hygiene and food-safety conditions monitored in restaurants are known risk factors or environmental antecedents for foodborne illness outbreaks,^{7,16,17} so we think measurement of sanitary conditions alone serves as a good proxy for public health risks.

TABLE 2—Estimated Success in Scoring in the A-Range on Initial Inspection in Restaurants: New York City, NY, July 2007–July 2013

Indicator	Inspections, No.	Model I, ^a SR (95% CI)	Model II, ^b SR (95% CI)
Time period			
13–36 mo before grading (Ref)	42 016	1.00	1.00
0–12 mo before grading	26 200	1.05 (1.01, 1.09)	1.05 (1.01, 1.09)
0–12 mo after grading	32 594	0.86 (0.83, 0.89)	0.87 (0.84, 0.90)
13–24 mo after grading	38 339	1.24 (1.20, 1.29)	1.26 (1.22, 1.31)
25–36 mo after grading	32 918	1.33 (1.29, 1.38)	1.35 (1.31, 1.40)
Season			
July–September (Ref)	36 598	...	1.00
October–December	41 697	...	1.20 (1.16, 1.24)
January–March	45 825	...	1.30 (1.26, 1.35)
April–June	47 947	...	1.20 (1.16, 1.24)
Chain restaurant			
No (Ref)	151 374	...	1.00
Yes	20 693	...	3.46 (3.31, 3.61)

Notes. CI = confidence interval; SR = success ratio. The city restaurant letter-grading program began on July 27, 2010. Preadjudicated initial inspection scores for all restaurants in operation between July 27, 2007, and July 26, 2013, included. A-range is equivalent to ≤ 13 points.

^aModel includes random intercepts for unique restaurants.

^bModel includes random intercepts for unique restaurants and adjusts for chain restaurant status and season of inspection.

Improvement in hygiene conditions appeared to be driven by certain categories of violations. Having a certified kitchen manager on site is important because it has been associated with fewer critical violations on inspection^{18,19} and identified as an important factor for preventing foodborne outbreaks.²⁰ Decreases in violations for inadequate hand-washing facilities and worker hygiene and improper storage or use of equipment or utensils are also likely to decrease risk for foodborne illness.²¹ Decreases in presence and severity of vermin violations contributed in large part to improvements in inspection scores, but vermin violations remain the largest average contributors to inspection score on initial inspection, suggesting a need for more restaurant operator education on this topic. The increase in average violation points related to food contact surface maintenance was likely an artifact related to a tendency for inspectors to cite this violation under a “miscellaneous” section before grading.

Although overall inspection performance improved in the second and third year of grading, A-range scores (0–13 points) decreased slightly in the first year of grading compared with the year before. We believe this decrease reflects the method in which the

program was rolled out. The first restaurants inspected under the grading program were those that scored poorly under pregrading program rules. These poorer-performing restaurants were overrepresented during year 1.

We call attention to the strong association between chain restaurant status and A-range score on initial inspection. This finding is consistent with other studies that reported better sanitary conditions (i.e., fewer critical violations) in chain restaurants compared with non-chains.^{18,22,23} It is instructive to consider the mechanisms used by chains to ensure food safety, such as use of standardized procedures, specialized equipment, and additional worker training and internal mock inspections, when conducting educational outreach among nonchains.

New York City is not alone in requiring public disclosure of restaurant inspection results at the point of decision-making. This type of disclosure program is becoming more common in North America at the state, county, and local level and several jurisdictions have published program evaluation findings. Similar to our results, the Toronto and Los Angeles evaluations found their disclosure programs were used by consumers and led to improved restaurant sanitary practices.^{24–26} Jin and

Leslie²⁴ found that mandatory posting of grade cards in Los Angeles County improved inspection scores after they controlled for restaurant characteristics. Similar to our findings, Toronto Public Health found overwhelming program approval by diners and that diners felt safer making purchases with their program.²⁵ Both of these evaluations were also able to detect decreases in foodborne illness after program implementation.^{15,27}

A previous study of the NYC restaurant grading program analyzed a public-use restaurant inspection data set and concluded that the program was not associated with an improvement in scores.²⁸ However, the analysis included only 17 complete months of inspection data after grading. We identified improvements in sanitary conditions only after the 2-year mark, which may partially explain the inconsistency in results. The previous analysis also did not account for overrepresentation of poorer-performing restaurants resulting from more frequent inspection for poorer performers after grading. By contrast, our regression analysis addressed oversampling by including random intercepts for individual restaurants.

Limitations

This study has certain limitations. We compared inspection performance across time among inspected restaurants. In our earliest period (July 2007–July 2008), about 25% of restaurants were uninspected because of reduced staffing and other inspectional priorities. Because initial inspection assignment before grading was random, we believe inspections during this period were not biased toward poorer-performing restaurants. Use of inspection scores over time may have also been problematic. Subtracting administrative violation points from pregrading inspection scores to make them comparable with grading scores may have underestimated inspection scores pregrading, because the scoring system did not always include points from every violation to calculate inspection score. The impact would be an underestimate of the success of the program. We were unable to find an adequate comparison group (e.g., nongraded jurisdiction) because of jurisdictional differences in food-safety regulations and inspection scoring systems, but we used time and within-restaurant analysis as controls to isolate the impact of the program over time.

TABLE 3—Average Points per Inspection for Specific Violations Cited on Recent Initial Inspections in Restaurants: New York City, NY, 2008–2013

Violations	From 24 Mo to 13 Mo Before Grading (n = 21 208)	From 12 Mo Before to Start of Grading (n = 22 313)	From 13 Mo to 24 Mo After Grading (n = 24 942)	From 25 Mo to 36 Mo After Grading (n = 24 681)
Facility and worker violations				
Critical violations				
Improperly maintained food contact surfaces ^a	0.69	0.98	1.31	1.53
Inadequate worker hygiene	0.51	0.47	0.36	0.35
Public health hazards^b				
No food safety-certified supervisor on site	1.29	1.37	0.84	0.79
Inadequate hand-washing facilities	1.81	1.45	0.65	0.58
Food handling and holding violations				
Critical violations^c				
Improper storage of in-use utensil	0.83	0.76	0.62	0.58
Inadequate protection of food from contamination during storage, preparation, display, service	1.03	1.01	1.20	1.16
Public health hazards				
Food not held cold enough	2.40	2.59	2.52	2.75
Food not held hot enough	1.28	1.39	1.28	1.36
Cross-contamination of foods	0.69	1.05	0.80	0.82
Pest violations: all vermin violations ^d	3.47	3.33	2.97	2.95

Notes. The city restaurant letter-grading program began on July 27, 2010. Each time period covers 12 months. Preadjudicated results from initial inspection closest to the end of each period for unique restaurants. Average points per violation cited on all recent initial inspections used to quantify the severity of violation conditions.

^aViolation citation practices changed when grading started. Before grading, violation was cited in a miscellaneous violation category.

^bPublic health hazards point range is 7 to 28 points, except for "inadequate hand-washing facilities," which is 10 or 28 points, and "no food safety certified supervisor on-site," which is 10 points.

^cCritical violation range is 5 to 8 points.

^dVermin includes rats, mice, cockroaches, or flies; all vermin violations range from 5 to 28 points. Points were bundled together for multiple vermin types.

Finally, the NYC restaurant grading program involved multiple changes to the enforcement landscape—more nuanced risk-based inspection frequency, greater exposure of restaurants to the risk of fines, grade posting, improvements to online resources, and additional training opportunities.²⁹ We cannot tease out which factors contributed most to improving hygiene or grades.

Conclusions

The results from our analysis indicate that the NYC restaurant letter-grading program exhibited a positive impact on restaurant hygiene, food-safety practices, and public awareness, suggesting that the program is an effective tool for improving food safety. Our analysis also identified violation areas that can be targeted for improvement in future program operations. ■

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Contributors

M. R. Wong contributed to program evaluation design, performed analysis, and drafted the article. W. McKelvey contributed to program evaluation design and assisted with drafting the article. K. Ito and J. B. Jacobson conducted the analysis and assisted with drafting the article. C. Schiff and D. Kass conceptualized the program and assisted with drafting the article. All authors helped to interpret findings and review drafts of the article.

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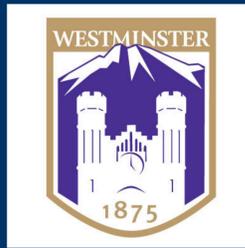
Human Participant Protection

The New York City Department of Health and Mental Hygiene institutional review board determined that the program evaluation protocol was not human participant research in accordance with 45 CFR Part 46.

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Feasibility of Restaurant Letter Grading in Utah

By: Breanna Peltekian, Heather Stuart, Ry Mount, and Lauren Martinez
Public Health Program, Westminster College - Spring 2015



Introduction

Utahns are in need of a transparent identification system to determine which restaurants are sanitary, based on the grade assigned by the health department, which would be conveyed to the public in a simplified format. This will create market pressure to improve safety and sanitation and to reduce the incidence of foodborne illness through informed consumer choice.

Overall, this proposal's main objective is to determine the feasibility of implementing a restaurant letter grading system in Utah. To achieve this objective, there are several sub-objectives:

- Survey the general public on their opinions and acceptance of the letter grading system
- Assess cost-effectiveness and success of other states' restaurant letter grading programs
- Discuss with health professionals the feasibility and limitations of our proposal
- Receive feedback from the Utah Restaurant Association and/or restaurant owners to determine the limitations of our proposal

Up to 70% of FBI is linked to food prepared at foodservice establishments (WHO, 2007). Determining the feasibility of this proposal is important to Public Health because implementing the letter grading system will potentially decrease the amount of foodborne illnesses and provide the public with information to help determine the health and safety of what they will be eating.



Sample Grade Card

Salt Lake County Health Department (SAMPLE)

On, (insert date here), (insert Restaurant/ facility name here/ address here)
EARNED THE FOLLOWING GRADE

A



Inspection Report Information



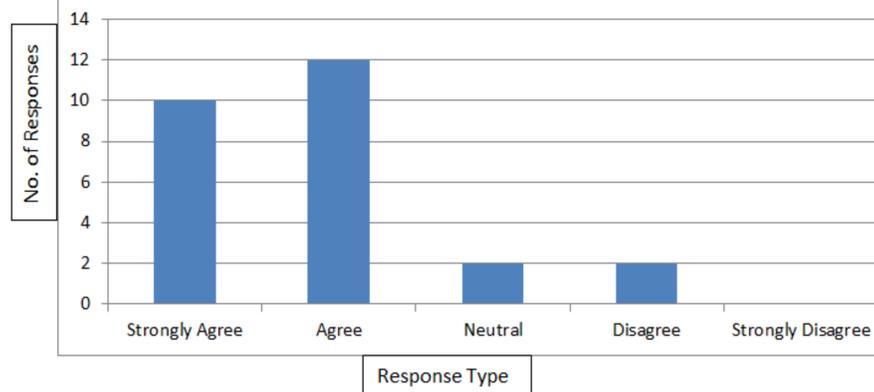
Inspection Report Information

If you have a question or concern, please contact the Environmental health Division at xxx-xxx-xxxx or visit www.xxxxxxx.com

NOT TO BE REMOVED BY ANYONE OTHER THAN HEALTH AUTHORITY

Results

Consumers concerned about not having a letter-grading system for restaurant inspections in Utah



Materials and Methods

Environmental health professionals, restaurant owners, and the general public were interviewed/surveyed. First, environmental health scientists discussed the process used in their specific Utah counties for food inspections and how the current food inspection scores are determined. They also gave their opinion on our letter-grading proposal and they answered, with their experience, if they believe restaurant letter grading would be effective in Utah.

Next, twenty five restaurant-goers from the general public were surveyed to determine if they would benefit from the restaurant letter grades being easily displayed. A Likert Scale was used to assess the opinions and desires from the public. Finally, restaurant owners were interviewed to see what their main concerns are in regards to letter grading and to answer any questions that they had. In the end, political feasibility will be determined by speaking with a Utah State Legislator, LaVar Christensen, who is interested in sponsoring and passing a bill regarding restaurant letter grading in Utah.

The letter grading systems that other states utilize were closely examined. It was researched whether the other states' systems are beneficial to reducing the incidence of foodborne disease, as well as improve business for the restaurants. The letter grading system in other states allowed us to compare Utah's system to theirs, to see the limitations that they faced, if any, and how they overcame those limitations.

Conclusion

By surveying the public and researching foodborne illness in Utah, it was determined that the existing programs that are implemented in Utah are insufficient in protecting the public. The programs in place now provide limited access to the public for them to see the results of inspections and to understand the risks they are taking when dining out. This research supports that a letter grading system would aid in lowering the rates of restaurant contracted food borne illnesses. It would not just come from simply changing the format of the grade card, but with the accountability that comes with this awareness. The letter grade would make consumers more aware of inspection reports and more selective in their choices.

This selectivity would make restaurant cleanliness a part of a business plan. It would mean that restaurants are no longer only being held accountable by the health department, but also by consumers. If a restaurant knows that their potential customers would be put off by a poor grade, it would be crucial to the business's survival to make sure that they were up to code. This would by default lower food borne illness rates and is why Utah should be in support of a restaurant letter grading system.

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