

# CONFERENCE FOR FOOD PROTECTION



**2004 Issues Submitted**

**Chandler, Arizona**

No.	Title
<b>Council I Issues</b>	
I-001	Variance Committee Final Report
I-002	Variances at Retail - Research Endorsement
I-003	Food Recovery Committee Report
I-004	Food Recovery Committee Continuation
I-005	Plan Review Committee Report
I-006	Final Recommended Guidance for Permanent Outdoor Cooking Operations - 2003
I-007	Plan Review Committee Continuation
I-008	Food Product Traceability Committee Final Report
I-009	Variances at Retail Committee Final Report
I-010	Variances at Retail Committee - AFDO Final Retail Meat & Poultry Processing Guidelines
I-011	Designation of Food Code Provisions as Critical and Non-Critical
I-012	Revising the definition of "Potentially Hazardous Food" in the Food Code
I-013	Person in Charge present during food production Section 2-101.11
I-014	Demonstration of Knowledge - "Compliance with the Food Code" Section 2-102.11
I-015	Definition of "Complying with this Code" - Supplement to the 2001 Food Code
I-016	Receipt of foods when person-in-charge or food employees are not present
I-017	Title: Molluscan Shellfish - clarify and expand when shucked shellfish may be removed from the container in which they were received
I-018	Revise paragraph 3-203.12(B)(2)(b) of the 2001 FDA Food Code to be consistent with the "Commingle" definition provided in paragraph 1-201.10(B)(13)
I-019	Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes
I-020	To protect food and beverages from contamination by removing the exemption which allows food in certain containers to be stored on the floor
I-021	Using Equipment for Intended Purpose
I-022	Inform consumers of the risk associated with consumption of fresh untreated juice
I-023	Cold Holding of Potentially Hazardous Food
I-024	Consumer Advisory Modification, Section 3-603.11 Supplement to the 2001 Food Code
I-025	Include Instructions for manual warewashing sink set-up
I-026	Clarify that walk-in coolers without prefabricated floors should not be considered equipment as defined in the 2001 Food Code, Paragraph 1-201.10(B)(28)(b) and specify allowances for installation of floor drains in coolers in the 2001 Food, Section 5-402.11 and the FDA Food Establishment Plan Review Guide
I-027	Standardization of chemical sanitizer concentration levels and inclusion into FDA Food Code
I-028	Labeling of irradiated raw ground beef reground with other non-irradiated beef for retail sale
I-029	Guidance for retail facilities regarding beef grinding logs tracking supplier information
I-030	Unsanitary Handling of Drinking Water Coolers
I-031	Reinforce Accountability Inferred By Active Managerial Control
<b>Council II Issues</b>	
II-001	Amendment to the Conference Constitution and Bylaws – Executive Director
II-002	Amendment to the Conference Procedures Manual – Executive Director
II-003	Amendment to the Conference Constitution and Bylaws – Article XVI
II-004	Amendment to the Conference Procedures Manual – Late-Breaking Issues and Supplemental Material
II-005	CFP Food Manager Training Testing and Certification Committee Report.
II-006	Conference Standards for Accreditation of Food Protection Manager Certification Programs Edits and Modifications
II-007	Conference Standards for Accreditation of Food Protection Manager Certification Programs Annex B Edit
II-008	Food Manager Training, Testing and Certification Committee Bylaws Modifications
II-009	Accredited Program Definition
II-010	On Line Food Manager Certification
II-011	Interdisciplinary training in foodborne illness investigations
II-012	Revision of Standard #5, Foodborne Illness Investigation and Response to include food security / food terrorism preparedness and response.

No.	Title
II-013	Food Security at retail.
II-014	Guidance regarding safety and security guidelines for the transportation and distribution of meat, poultry, and egg products
II-015	Certification of Food Safety Regulation Professionals
II-016	Certification of Food Safety Regulation Professionals
II-017	Certification of Health Officials- section 8-402.11
II-018	CFP Inspection Form Committee, Recommendation to accept committee report.
II-019	CFP Inspection Form Committee, Recommendation to accept Inspection Form and instructional documents.
II-020	Definitions for Risk Factor, Public Health Intervention and Good Retail Practice.
II-021	CFP Inspection Form Committee, Recommended Elements that should be on an Inspection Form and their Justification.
II-022	CFP Program Standards Committee, Recommendation to Accept Committee Report
II-023	Baseline Survey Frequency Change
II-024	Compliance and Enforcement Legal Remedies
II-025	CFP endorsement of FDA field testing of the draft Audit Manual For Conducting Voluntary National Retail Food Regulatory Program Standards Self-Assessment Evaluations, 12/03.
II-026	Extension of Phase-In Time for Compliance with Risk Factors and Interventions
II-027	Request to consider whether or not a minimum level of food allergy knowledge should be required for managers or persons in charge of retail food establishments.
II-028	Creation of Coordinated Educational or Instructional Materials for Emergencies
II-029	Special Issue: Amendment to the Constitution and Bylaws of the Conference – Article V
<b>Council III Issues</b>	
III-001	Acceptance of the Retail HACCP Committee report by the Conference for Food Protection.
III-002	Endorsement of the FDA HACCP guides by the Conference of Food Protection.
III-003	Completion of CFP Retail HACCP Committee Issue No. 02-III-03 to provide feedback to the FDA on the first Retail Food Program Database of Foodborne Illness Risk Factors report issued in 2000 that would help eliminate any confusion on terminology when the second report by the FDA is issued in 2004.
III-004	Continuation of the CFP Food Allergen Committee.
III-005	The 2004 CFP Date Marking Committee Report.
III-006	Update bibliography reference listed in Annex2, Section 3-501.17 of the 2001 FDA Food Code.
III-007	Update bibliography references listed in Annex 2, Section 30501.17 of the 2001 FDA Food Code.
III-008	Time Only as a Public Health Control Committee – Council III.
III-009	Time Only as a Public Health Control for 6 hours.
III-010	Modify § 3-501.19, Time as a Public Health Control to clarify the meaning and intent of "Immediate Consumption"
III-011	Expanding the Copper and copper alloy use limitation
III-012	Growing Sprouts in Retail Food Establishments
III-013	Date Marking of Refrigerated Ready-to-Eat Potentially Hazardous Food.
III-014	Addition of Cheese Date Marking Exemption to Section 3-501.17 (D)
III-015	Section 3-501.17 date marking violation to be identified as a non-critical violation.
III-016	Section 3-507.17 and 18 – Date marking violation to be identified as a non-critical violation.
III-017	Addition of exempt food to Section 3-501.17
III-018	The date Marking Provisions Should be Limited to High-Risk Foods, as Identified in the FDA's <i>Listeria monocytogenes</i> Risk Assessment.
III-019	Guidance to control the growth of <i>Listeria monocytogenes</i> in post-lethality exposed (ready-to-eat) RTE meat and poultry products at retail.
III-020	Identification of sanitation practices, standard operating procedures, and good retail practices to limit post-processing contamination with and growth of <i>Listeria monocytogenes</i> in food establishments.
III-021	Exception to 14 day shelf life limit
III-022	Regulatory for Cook Chill
III-023	Revise Reduced Oxygen Packaging, Criteria.*
III-024	Latex Gloves Prohibited
III-025	Short Task Food Gloves

No.	Title
III-026	Qualification of Gloves for Food Preparation to Prevent Contamination
III-027	Third Party Certification of Disposable Single Use Food Contact Gloves
III-028	Preventing Contamination from Hands, Section 3-301.11
III-029	Reducing Norovirus: Prevention of Bare Hand Contact with Ready-to-Eat Foods
III-030	Reducing Norovirus: Implementing Effective Employee Health Interventions
III-031	Allow Vacuum packaging of hard and semi-soft cheese at retail food establishments
III-032	Provide guidance to retail establishments and restaurants on the handling of steaks that have been blade tenderized.
III-033	Chemical Sanitization Using Quaternary Ammonium Compound Solutions
III-034	Modify cold food holding surface temperatures on open top prep tables and salad bars.
III-035	Ready to Eat Fruits and Vegetables Committee



## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-001  
Internal # 045

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Variance Committee Final Report

### 2. Issue you would like the Conference to consider:

Final Report covering 3-502.11 Variance Requirements.

### 3. Public Health Significance:

Food safety technology sometimes allows for food processing methods that are scientifically valid that may not be recognized by the current edition of the food code. In such instances variances may be required by the states that have adopted the code. Variances need to be scientifically evaluated through a fair and open process providing due process. This due process is spelled out by each of the states based on existing statutes. To help the regulatory authority determine if the applied process is scientifically valid many resources should developed. Please see the attached report.

### 4. Recommended Solution: The Conference recommends.....

To accept this report.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-002  
Internal # 070

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Variances at Retail - Research Endorsement

### 2. Issue you would like the Conference to consider:

Food safety technology sometimes allows for food processing methods that are scientifically valid that may not be recognized by the current edition of the food code. In such instances variances may be required by the states that have adopted the code. Variances need to be scientifically evaluated through a fair and open process providing due process. This due process is spelled out by each of the states based on existing statutes. To help the regulatory authority determine if the applied process is scientifically valid many resources should developed. Please see the attached Variance Committee report.

### 3. Public Health Significance:

Additional research is needed to provide guidance documents based on science to assure safe retail-level food processing.

### 4. Recommended Solution: The Conference recommends.....

The Conference recommends that the Chair write a letter of support to AFDO encouraging them to seek additional CREES grants to expand the research and production of guidance documents in the area of food processing at retail.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-003  
Internal # 066

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Food Recovery Committee Report

### 2. Issue you would like the Conference to consider:

Attached is a status report from the Food Recovery Committee showing FDA's and the CFP's committee responses to the CFP 2002 charge to review comments received via the FDA's "Good Guidance Practices" notice and comment process for the CFP "Food Recovery Guidelines." The committee was also charged to use the authorization to revise the "guidelines" as posted on the CFP website. The committee is by way of this report fulfilling its commitment to report all such revisions to the CFP Executive Board via the chair of Council I and reporting proposed revisions back to the full council via issue submission to the 2004 conference. [2002-I-22]

### 3. Public Health Significance:

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.

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. Please see the attached report.

### 4. Recommended Solution:

The Conference recommends acceptance of this Food Recovery Committee report.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
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Internal # 067

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Food Recovery Committee Continuation

### 2. Issue you would like the Conference to consider:

Recreation of a committee to continue review and discussion of the work summarized in the Food Recovery Committee Report.

### 3. Public Health Significance:

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.

### 4. Recommended Solution: The Conference recommends...

creating a Food Recovery Committee to continue to consider further revisions recommended by the FDA which will allow appropriate parts of the Food Recovery Guidelines to be used in sections of the FDA Model Food Code and its annexes and appendices.

### 5. Submitter:

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**CONFERENCE FOR FOOD PROTECTION**

**2004 ISSUE FORM**  
**Deadline Feb 2, 2004**

**Issue # 2004 I-005**  
**Internal # 071**

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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**1. Title:**

Plan Review Committee Report

**2. Issue you would like the Conference to consider:**

Attached is a status report from the Plan Review Committee showing completion of the committee charge on the development of the "Recommended Guidance for Permanent Outdoor Cooking Establishments - 2003". [2002-I-23]

Additional time is needed to address the remaining issues in the guidance document on mobile food units and pushcarts. [2002-I-24]

**3. Public Health Significance:**

Retail food operations are increasing their service and sales by taking the food to where their customers are located. Venues now include permanent outdoor cooking operations, mobile food units, and pushcarts. The committees work has been to address food safety and facility concerns through the production of guidance documents for the regulatory and industry officials developing and conducting these operations outside the traditional four-walled retail food establishments.

**4. Recommended Solution: The Conference recommends.....**

The Conference recommends acceptance of the Plan Review Committee report and adding the "Recommended Guidance for Permanent Outdoor Cooking Establishments" to FDA plan review training programs.

<b>5. Submitter:</b>	
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-006  
Internal # 072

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Final Recommended Guidance for Permanent Outdoor Cooking Establishments - 2003

### 2. Issue you would like the Conference to consider:

Attached are the Final Recommended Guidance for Permanent Outdoor Cooking Establishments - 2003 and Plan Review Committee Report indicating completion of the charge from the 2002 CFP to review and finalize the Permanent Outdoor Cooking Committee Guidance document.

This charge [2002-I-23] was:

1. "Recommended Guidance for Food Establishments with Permanent Outdoor Cooking Operations" be forwarded to the Facility Plan Review Committee for content review and formatting into a joint CFP/FDA guidance document.
2. The current co-chairs of the Outdoor Cooking Committee will work with Facility Plan Review Committee through the 2004 Conference for the purpose of participating in and facilitating the completion of the development of the guidance document.

### 3. Public Health Significance:

Retail food operations are increasing outreach by taking the food to where their customers are located. Venues now include permanent outdoor cooking operations as a part of traditionally operated food service establishments. The construction and operational considerations set forth in this document clarify applicable parts of the Food Code and serve as further guidance for regulatory and industry personnel in any of these operations.

### 4. Recommended Solution: The Conference recommends.....

The Conference recommends acceptance of the Final Recommended Guidance for Permanent Outdoor Cooking Establishments -2003 and adding the document to the FDA Food Code annex.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-007  
Internal # 073

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Plan Review Committee Continuation

### 2. Issue you would like the Conference to consider:

Attached is a status report from the Plan Review Committee showing that additional time is needed to address the remaining issues in the guidance document on mobile food units and pushcarts. [2002-I-24]

### 3. Public Health Significance:

Retail food service operations use an increasing number and more complex mobile food units and pushcarts in their marketing and delivery efforts to serve the demands of people for a wide variety of fare where they gather for work and play. Food Code provides general guidance on the construction and operation of these units within the broad definition of food establishment and general details for design, construction, operation, and maintenance. Regulatory officials and industry need a condensation of these requirements as they relate to this specific area of retail-level operations.

### 4. Recommended Solution: The Conference recommends.....

creation of a 2004 plan Review committee to resolve outstanding issues in the Mobile Food Units and Pushcarts guidance document and other matters referred to it at the 2004 CFP meeting.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-008  
Internal # 065

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Food Product Traceability Committee Final Report

### 2. Issue you would like the Conference to consider:

Final Report covering review of legislation and consideration of needed recommendations for the food manufacturing industry to attain greater uniformity in the identification of products for traceability. [CFP Issue 2002-I-27]

### 3. Public Health Significance:

Food product traceability responsibilities are incumbent on all levels of the food production, distribution, and sales or service. This area has been thoroughly addressed by recent legislation. Please see the attached report.

### 4. Recommended Solution: The Conference recommends.....

The Conference recommends acceptance of this Food Traceability Committee final report and dissolution of this committee.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-009  
Internal # 074

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Variances at Retail Committee Final Report

### 2. Issue you would like the Conference to consider:

The fulfillment of the CFP 2002 issue [2002-I-15] charges:

1. The Committee continue and finish review of AFDO's Guideline document 'Retail Meat and Poultry Processing Guidelines' in concert with AFDO.
2. Upon completion of the review and agreement by both AFDO and the Committee, the finished report should be sent to the CFP Executive Board for its acceptance and to AFDO.
3. If the CFP Board accepts the report, the Board should forward the report to AFDO and to FDA recommending that the report be referenced in, or placed in its entirety, into Annex 6 of the Food Code.

### 3. Public Health Significance:

These guidelines provide sound scientific support for the production at retail level of meat and poultry products such as ground meats, cured and smoked meat or poultry products, dry and semi dry fermented sausage, and meat jerky. These guidelines are to assist both the establishment and state or local government to provide guidance for the processing of meat and poultry at retail.

### 4. Recommended Solution: The Conference recommends.....

The Conference recommends acceptance of this Variances at Retail Committee final report and dissolution of this committee.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-010  
Internal # 075

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Variances at Retail Committee - AFDO Final Retail Meat & Poultry Processing Guidelines

### 2. Issue you would like the Conference to consider:

Acceptance of Final Retail Meat & Poultry Processing Guidelines to fulfill the CFP 2002 issue [2002-I-15] charges. Attached references are also included as attachments to this document.

### 3. Public Health Significance:

These guidelines provide sound scientific support for the production at retail level of meat and poultry products such as ground meats, cured and smoked meat or poultry products, dry and semi dry fermented sausage, and meat jerky. These guidelines are to assist both the establishment and state or local government to provide guidance for the processing of meat and poultry at retail.

### 4. Recommended Solution: The Conference recommends.....

The Conference recommends acceptance of the Variances at Retail Committee - AFDO Final Retail Meat & Poultry Processing Guidelines. The Conference recommends sending letters to FDA and USDA to recommend incorporating these guidelines into the appropriate documents including the FDA Food Code.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-011  
Internal # 083

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Designation of Food Code Provisions as Critical and Non-Critical

### 2. Issue you would like the Conference to consider:

All codified provisions in the Food Code are currently designated as either "critical", "non-critical" or "swing" items. Enforcement provisions in the Food Code are based on these designations. FDA plans to reevaluate the existing designations in relation to the risk factors most commonly associated with foodborne illness. The most significant risk factors include unsafe food sources, inadequate cooking, improper holding temperatures, contaminated equipment and poor personal hygiene.

CFP issue 2002-I-18 and the final report of the CFP Criticality Committee suggested that designating items as "critical" in the Food Code and on many inspection reports may be misunderstood in relation to the severity and importance of violations, as well as the HACCP term "critical control point". FDA is considering eliminating the use of the terms "critical" and "non-critical" in the Food Code and instead categorizing items using more descriptive terminology that relates to their potential for contributing to or causing foodborne illness. FDA plans to make the terminology consistent with other FDA and CDC documents issued in recent years that focus on foodborne illness risk factors, public health interventions and good retail practices. These documents include:

- Draft Voluntary National Retail Food Regulatory Program Standards,
- FDA's Retail Food Program Database of Foodborne Illness Risk Factors
- FDA's Procedures for Standardization and Certification of Retail Food Inspection Officers
- FDA's Managing Food Safety (Retail HACCP Guides); and
- CDC's EHS-Net Data Collection Methodology and Instrument for Outbreak and Non-Outbreak Evaluations.

FDA will also consider the CFP Inspection Form Committee's model inspection form that highlights the important elements of a high quality inspection.

### 3. Public Health Significance:

Although the Food Code addresses controls for risk factors and interventions, the current definition and usage of "critical item" is not consistent with that approach. The term "critical item" may have been appropriate for the earlier versions of the Food Code, but FDA, in its other core guidance documents, now focuses on those risk factors identified as contributing to foodborne illness based on epidemiological outbreak data.

Emphasizing inspection and enforcement activities on the risk factors will focus limited public health and industry resources where they are most effective.

**4. Recommended Solution: The Conference recommends.....**

based on discussion and deliberation that FDA move forward with updating the Food Code usage and application of the term "Critical Item."

The Conference further recommends that FDA:

1. remove the term "critical item" from the Food Code and replace it with a more appropriate term or terms;
2. redesignate Food Code provisions in terms of their relationship to the risk factors most likely to contribute to foodborne illness and the public health interventions and good retail practices that result in safer food and protect the consumer; and
3. seek review and comment from the CFP on draft proposals of these changes and consider the CFP input in its revision.

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Revising the definition of "Potentially Hazardous Food" in the Food Code.

### 2. Issue you would like the Conference to consider:

The term "Potentially Hazardous Food" (PHF), first used in the 1962 Food Service Sanitation Manual and now in Subparagraph 1-201-10 (B)(65) of the Food Code, has evolved as new science and epidemiology became available but has some shortcomings. Several foods have been added to the definition of PHF on an individual basis (garlic-in-oil, sprouts, sliced melon, shell eggs) but the identity of others remain unclear, i.e., sliced tomatoes. The current definition addresses food that supports rapid and progressive growth of infectious or toxigenic microorganisms, growth of *Clostridium botulinum* or *Salmonella* in eggs but not the slow growth of *Listeria monocytogenes*. The current definition of PHF also considers water activity and pH, but not the interaction of these factors or other factors that could make a food non-PHF.

FDA contracted with the Institute of Food Technologists (IFT) to provide a scientific review and analysis of several questions related to potentially hazardous foods. The IFT Report, "Evaluation and Definition of Potentially Hazardous Foods," can be found on the CFP website, <http://www.foodprotect.org>, under Other Documents. IFT developed a framework for decision-making to determine whether time/temperature control is required for food safety instead of defining it in terms of pathogens, food types, water activity or pH. The report provided a complete process but only part of the process is addressed in this issue. The remainder of their process, including product assessment using pathogen modeling programs and challenge testing, requires further review and additional research.

### 3. Public Health Significance:

The proposed changes in the definition of PHF, based on the conclusions from the combined expertise of the IFT Scientific and Technical Panel, provide a clearer understanding and way to determine whether foods require time/temperature control for safety. The changes, based on two tables developed by IFT, allow for the interaction of pH and water activity as well as each factor alone to determine whether the food is PHF and refrigeration is required. Other recommendations in the report such as the use of other factors in the evaluation process, pathogen modeling programs, and challenge studies remain available for use on a case-by-case basis.

### 4. Recommended Solution: The Conference recommends.....

A) Based on discussion and deliberation, that FDA revise the definition of "Potentially

Hazardous Food," subparagraph 1-201.10 (B)(65), in the following ways:

1). Delete the existing (a)(i-iii) and replace it with a new (a) "Potentially hazardous food" means a food that requires time and temperature control for safety (TCS) to limit pathogen growth or toxin formation that constitutes a threat to public health." Keep the existing language regarding raw shell eggs and move it to subparagraph (b).

2). Revise (c)(v) to replace the first phrase "A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of S. Enteritidis in eggs or C, botulinum can not occur," with the phrase "A food for which laboratory evidence demonstrates that time and temperature control for safety is not required,"

3). Revise the definition to also allow for the interaction of water activity and pH to determine whether a food is not a potentially hazardous food (PHF), based on Table A or Table B on page 8-5 of the IFT Report, "Evaluation and Definition of Potentially Hazardous Foods" (attached).

B) That a PHF Committee be named to work with the FDA on this issue, charged to consider the best implementation strategy for state/local regulators and the retail industry to determine whether a food is PHF or not, based on the IFT Report, to determine whether the term PHF or TCS is preferred and to report back to the CFP Executive Board by the 2004 Fall Board Meeting.

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

*All information above the line is for conference use only.*

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### 1. Title:

Person in Charge present during food production. Section 2-101.11.

### 2. Issue you would like the Conference to consider:

The FDA 2001 Food Code, Section 2-101.11 states a person in charge (PIC) must be present during all hours of operation. This PIC may be the actual permit holder or a designee assigned the responsibilities as the PIC. For many retail grocery operations that person should be allowed to be the Manager-on-Duty (MOD) who has administrative management responsibilities for the entire store during off-peak production hours. The production departments have a "certified" knowledgeable person present and in charge of a department during their major production periods and preparation of potentially hazardous food. However, after production many departments are now "service counters" with no actual production-taking place (i.e. donuts boxed for customers).

Many health jurisdictions require each department within a grocery store be individually licensed and therefore, require each department to have a certified "person in charge" during all hours of operation, e.g., one store operating a deli, produce, seafood and meat department would be required to have a minimum of four (4) certified persons in charge. Some of these jurisdictions do not allow the Manager-on-Duty who is responsible for the entire store to be the certified "person in charge" for departments.

### 3. Public Health Significance:

Restaurants and Grocery stores are different when it comes to public health risks for the all hours of operation. Grocers do not perform production during all hours of operation; however, many stores are 24-hour facilities. The Manager-on-Duty has complete administrative management responsibility for the entire operation in a grocery store. Any issue, problem, complaint, or major decision for the facility would be made by the MOD. He/she is also responsible for food safety for the entire operation and to ensure that programs are in place for crisis situations. Thus, this person would meet the Public Health Reasons as explained in the Food Code Annex 2, as "someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled." This person would be immediately available and knowledgeable in both operational and Code requirements, can respond to questions and concerns and can resolve problems.

During major production periods and hours of high risk processes involving potentially hazardous food the individual departments usually have a certified "person in charge" that is certified by an approved program in food safety. During the off-hours or non-peak

hours (i.e. early mornings, late afternoon, or evenings) a store may have part-time associates in departments for service functions. The bakery may have someone behind the counter with knowledge and training in basic food safety, but not be “manager certified”. If a jurisdiction requires all licensees to have a certified person in charge during all hours of operation, most grocers would have to cease department services after 3 or 4 pm. If a certified person (MOD) is available under the same roof of a grocery store they should be allowed to be the person in charge for the entire facility. A clarification on the person in charge for the type of operation and/or production periods would provide greater uniformity throughout the country and guard against the individual regulatory imposition of varying standards and intent of the FDA Food Code.

What is the practicality or public health significance of having more than 80 people meet the requirement of a manager’s certification for “person in charge” under one roof of one grocery store? Logic provides that companies cannot be in business long if every associate must be trained to manager level competency because they may be the only person in a department of the store at some point during a 24 hour day.

**4. Recommended Solution: The Conference recommends.....**

the Conference Chair send a letter to the FDA Commissioner to urge one of the three following changes to the FDA 2001 Food Code, Section 2-101.11:

1. Change the language from the “person in charge is present during all hours of operation” to “present during high risk operation of potentially hazardous foods”.
2. Recognize the difference in operational types and production practices of food establishments by allowing the MOD to be the person in charge for grocery operations, especially where local jurisdictions require individual licenses for each department. This can be accomplished by changing the “permit holder....” to “the retail facility, under one operator and one roof regardless of individual permits for departments, shall be the person in charge or shall ....” or
3. A combination of 1 & 2.

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

*All information above the line is for conference use only.*

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### 1. Title:

Demonstration of Knowledge - "Compliance with the Food Code." Section 2-102.11.

### 2. Issue you would like the Conference to consider:

CFP Issue 2002-I-28, as approved by the State Voting Delegates during the 2002 CFP requested that the FDA provide a "clear and logical", written definition for compliance with the Code for the purpose of demonstration of knowledge be included in Part 1-2 [2-1] of the FDA Food Code. This request was sought in order to provide clarification surrounding one of the ways in which establishments could satisfy the demonstrate knowledge criteria of the Code.

In response to Issue 2002-I-28, the FDA adopted the language and position that an establishment can only meet the Demonstration of Knowledge - Compliance with the Code (Section 2-102-11) with the following language: "The person in charge shall demonstrate this knowledge by: (A) "Complying with this Code by having no violations during the current inspection;"

While this definition is "clear" it is not "logical" as required by the Conference recommendation. The CFP Forms Committee presented on page 14 of their report to Council II that compliance with the Code can be demonstrated by "verifying that there are no risk factors or GRP [Good Retail Practice] critical item violations, or if there are violations, the person in charge demonstrates knowledge by taking corrective action to correct the violation." This report seems to have provided both a clear and logical definition and one in which the FDA could have used as a base to adopt or build upon.

### 3. Public Health Significance:

By adopting the language of having no violations as a way to demonstrate knowledge to comply with the Food Code, the FDA has positioned all establishments to fail the Demonstration of Knowledge section of the Food Code. Since it is the rare exception that any establishment would receive no violations, (this includes operations in which the management staff has been certified in food safety in accordance with CFP standards) the vast majority of well run, safe establishments, would be non-compliant with the knowledge section of the Food Code.

In addition, State and local regulatory agencies would not be compliant with meeting their own mandates for Code enforcements and satisfactorily meeting the needs of the consuming public if virtually all establishments fail to properly demonstrate knowledge of the Food Code given the current definition.

**4. Recommended Solution: The Conference recommends.....**

that the Conference Chair send a letter to the FDA Commissioner requesting FDA re-define "compliance with the Code" for the purpose of demonstration of knowledge in Section 2-102.11 of the Food Code to the language previously submitted by the CFP Forms Committee. Specifically, "compliance with the Code can be demonstrated by "verifying that there are no risk factors or GRP [Good Retail Practice] critical item violations, or if there are violations, the person in charge demonstrates knowledge by taking corrective action to correct the violation."

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## CONFERENCE FOR FOOD PROTECTION

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**Deadline Feb 2, 2004**

**Issue # 2004 I-015**  
**Internal # 061**

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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**1. Title:**

Definition of "Complying with this Code" - Supplement to the 2001 Food Code

**2. Issue you would like the Conference to consider:**

2-102.11 Demonstration  
 The "Supplement to the 2001 Food Code" has amended Section 2-102.11 of the 2001 Food Code by revising paragraph (A) to read: "Complying with this Code by having no violations during the current inspection...." In essence, this section strictly defines "Compliance with the Code" as an inspection with no violations. This overly restrictive definition is impossible for operators to meet as we believe there are very few inspections conducted nationwide where the food facility is not cited for at least a non-critical violation. As written, it requires perfection at all times on the part of the retail and restaurant sector operators.

**3. Public Health Significance:**

The current means for "complying with the code" noted in the 2001 Food Code Supplement may impose a "de facto" requirement at the state and local level for mandatory manager certification when an establishment is cited for a violation, either critical or non-critical during an inspection. The 2001 Food Code offers foodservice operators three ways to demonstrate their knowledge to a health inspector: compliance with the Code, being a certified food protection manager or by responding correctly to inspector's questions as they relate to the specific food operation. Under the new Supplement requirements, if a violation is noted during the inspection and the operator is unable to answer an inspector's questions to his/her satisfaction, then the only way for the person in charge to comply is through manager certification. This severely restricts options for foodservice operators who are working to comply with the demonstration requirements yet offers no additional public health protection.

**4. Recommended Solution: The Conference recommends.....**

... that Section 2-102.11(A) of the Supplement to the 2001 Food Code be revised to read "(A) substantially complying with this Code by passing the current inspection;"

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Receipt of foods when person in charge or food employees are not present

### 2. Issue you would like the Conference to consider:

FDA Food Code 2-103.11(E) Person In Charge shall ensure that employees are visibly observing foods as they are received.

### 3. Public Health Significance:

Many food establishments receive deliveries from suppliers when no employee is present. It would be a huge burden to food establishments to require the presence of an employee whenever deliveries are made. It is also impractical to require that all suppliers make deliveries only when food establishment employees are present. A common sense approach must be developed to allow these "key drop" type deliveries. Some type of documentation or verification could be provided by the supplier indicating that the food was checked for requirements under 2-103.11(E).

### 4. Recommended Solution: The Conference recommends.....

Change Food Code Section 2-103.11(E) to read:  
  
Foods are received from APPROVED sources, delivered at the required temperatures, protected from contamination, free of visible ADULTERATION, and accurately presented, by establishing a system where the employee or the supplier physically verifies these requirements, and by routinely monitoring the effectiveness of the system and periodically evaluating foods upon their receipt.

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## CONFERENCE FOR FOOD PROTECTION

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Internal # 050

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Molluscan Shellfish - clarify and expand when shucked shellfish may be removed from the container in which they were received.

### 2. Issue you would like the Conference to consider:

FDA Food Code, Section 3-203.11 C, specifies that shucked shellfish remain in same container in which they were received, then removed and dispensed only in response to a consumer's request. This issue will provide the retailer an option to repack into consumer size packages prior to consumer's request, but require the retailer to provide important label tracking information on each consumer package.

### 3. Public Health Significance:

Lot separation is critical to isolating shellfish and tracking them to their source. Clarifying and expanding Section 3-203.11 language will maintain this ability to isolate & track, allow the retail food operator flexibility, and reflect current retail practices.

### 4. Recommended Solution: The Conference recommends.....

Modify 3-203.11 by modifying (A) by simply adding reference to newly created (D) and then creating (D).

MODIFY A, to read: (A) Except as specified in (B), (C) and (D) of this section.

CREATE D, to read: (D) SHUCKED SHELLFISH may be removed from the container in which they were received and repacked in consumer self service containers if:

- (1) The labeling information for the shellfish on each container as specified under 3-202.17,
- (2) The labeling information as specified under 3-202.17 is retained in a written log which correlates with the date when, or dates during which, the shellfish are sold or served,
- (3) The written log is maintained for 90 days, and
- (4) The shellfish are protected from contamination...

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## CONFERENCE FOR FOOD PROTECTION

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**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Revise paragraph 3-203.12(B)(2)(b) of the 2001 FDA Food Code to be consistent with the "Commingle" definition provided in paragraph 1-201.10(B)(13).

### 2. Issue you would like the Conference to consider:

Revise paragraph 3-203.12(B)(2)(b) of the 2001 FDA Food Code to be consistent with the "Commingle" definition provided in paragraph 1-201.10(B)(13). Contradicting intent and language exist between the meaning of "commingle" with the display of shellstock from different containers harvested from the same growing areas on the same date as identified on required shellstock tags or labels. This contradiction stems from existing language in paragraph 3-203.12(B)(2)(b) vs. the definition provided in paragraph 1-201.10(B)(13).

1-201.10(B)(13) reads "Commingle means: (a) To combine SHELLSTOCK harvested on different days or from different growing areas as identified on the tag or label, or (b) To combine SHUCKED SHELLFISH from containers with different container codes or different shucking dates." This definition is consistent with language in the National Shellfish sanitation Program Guide for the Control of Molluscan Shellfish (NSSP).

3-203.12(B)(2)(b) reads "Ensuring that SHELLSTOCK from one tagged or labeled container are not COMMINGLED with SHELLSTOCK from another container before being ordered by the consumer."

The definition of "Commingle" does not prohibit the display or combining of Shellstock harvested from the same growing areas and date as identified on the tag or label. However, paragraph 3-203.12 (B)(2)(b) of the FDA Food Code (Shellstock, Maintaining Identification) prohibits the display of two or more containers of shellstock, even if the shellstock originates from the harvesting growing areas on the same harvesting date as identified on the tag or label.

### 3. Public Health Significance:

The important food safety control interventions surrounding the handling and sale of shellstock are rapid and accurate lot identification. This certainly can be managed and maintained through good retail practices even though multiple containers from the same harvesting area on the same date are displayed at the same time. As long as shellstock lots sold on a particular day are identified and documented record retention (shellstock tags) occurs as prescribed in the FDA Food Code, trace back of original lots sold on any particular day is achievable. Outbreak or illness associated with hepatitis A virus may not

be immediate and could take as long as 90 days to be reported and investigated. During the foodborne illness investigation, months after the purchase and consumption of shellfish, the primary focus lies with identifying all shellfish sold on a particular day based on retained shellstock tags, and to determine the original source. The food establishment's record keeping system to reflect lots displayed and sold is the important food safety issue, not separating each container on display, especially when product more than likely are derived from the same lot.

The proposed rewording of paragraph 3-203.12(B)(2)(b) incorporates the intent and language of "Commingle" without eliminating any requirements for maintaining shellstock protection, identification and record retention for traceability, or compromising the public health protection guidelines as identified in the FDA Food Code and the National Shellfish sanitation Program Guide for the Control of Molluscan Shellfish (NSSP).

**4. Recommended Solution: The Conference recommends.....**

the Conference Chair send a letter to the FDA Commissioner recommending the rewording of paragraph 3-203.12(B)(2)(b) of the 2001 Food Code to be consistent with the definition and intent of "COMMINGLED" provided in Chapter 1 of the Food Code and the NSSP. The rewording should read:

"3-203.12(B)(2)(b) Ensuring that SHELLSTOCK from tagged or labeled container are not COMMINGLED with SHELLSTOCK from another container harvested on a different day and from different growing areas as identified on the tag or label."

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes

### 2. Issue you would like the Conference to consider:

FDA Food Code Section 3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.\* states "Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and egg-fortified beverages that are not: (A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2); or (B) Included in 3-401.11(D)."

During June and July of 2003 in Ohio a local health department jurisdiction and the Ohio Department of Health investigated a Salmonella Serotype Enteritidis foodborne outbreak. The food product implicated in the outbreak was coconut pie that contained meringue prepared with raw shell eggs that was determined to be lightly cooked. A total of 17 people met the case definition.

During the course of the investigation it was revealed there was some confusion among local health department officials and the food service operator as to if meringue is considered to be a lightly cooked product.

In FDA Code section 3-801.11 meringue is already identified as a lightly cooked food that may not be served or offered for sale in ready to eat form to highly susceptible populations unless pasteurized egg products are substituted.

The implicated food service establishment did not fall under the definition of highly susceptible population in the code. What happened with this foodborne outbreak demonstrated that the general population as well as highly susceptible populations are at risk.

### 3. Public Health Significance:

Raw or undercooked eggs that are used in certain recipes are particularly hazardous because the virulent organism Salmonella Enteritidis may be present in raw shell eggs.

### 4. Recommended Solution: The Conference recommends.....

that the conference chair send a letter to the FDA Commissioner to urge the following changes to the food code : For clarification purposes add "meringue" to the language in section 3-302.13 so that the code states:

Section 3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.\*  
Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, "meringue" eggnog, ice cream, and egg-fortified beverages that are not: (A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2); or (B) Included in 3-401.11(D).

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## CONFERENCE FOR FOOD PROTECTION

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Internal # 007

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

To protect food and beverages from contamination by removing the exemption which allows food in certain containers to be stored on the floor.

### 2. Issue you would like the Conference to consider:

Section 3-305.11 B and C Allows Food in packages, working containers and cased Food in waterproof containers such as bottles and cans, and milk containers in plastic crates to be stored on a floor that is clean and not exposed to floor moisture.

### 3. Public Health Significance:

Deleting Sections 3-305.11 B and C would eliminate the exemption for food in packages and working containers and cased Food in waterproof containers such as bottles and cans, and milk containers in plastic crates to be stored on a floor that is clean and not exposed to floor moisture.

### 4. Recommended Solution: The Conference recommends.....

The Conference Chair send a letter to the FDA Commissioner to urge the following changes to the Food Code:

Amend the 2001 Food Code, Section 3-305.11, Food Storage, to read:

FOOD shall be protected from contamination by storing the FOOD:

- (1) In a clean, dry location;
- (2) Where it is not exposed to splash, dust, or other contamination; and
- (3) At least 15 cm (6 inches) above the floor.

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-021  
Internal # 078

Council Recommendation:      Accepted as Submitted \_\_\_\_\_      Accepted as Amended \_\_\_\_\_      No Action \_\_\_\_\_

Delegate Action:      Accepted \_\_\_\_\_      Rejected \_\_\_\_\_

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### 1. Title:

Using Equipment for Intended Purpose

### 2. Issue you would like the Conference to consider:

Approved methods for reheating potentially hazardous foods (PHF's) to the proper temperature/time within 2 hours are not addressed in the current Food Code. Frequently, retail and food service operators use holding equipment such as steam tables and crock pots that may or may not be designed to reheat PHF's to the proper time/temperature within the 2 hour time frame. Given the limited duration time of inspections, it is extremely difficult for an inspector to verify whether such equipment is capable of properly reheating foods. If an inspection is less than 2 hours in duration, it is impossible for an inspector to accurately quantify where the establishment has control of reheating processes. In contrast, the Food Code provides a section on Cooling Methods (3-501.15) to allow an inspector to provide feedback to the operator in cases where he or she is unable to effectively quantify cooling as out of control due to the limited duration of the inspection.

### 3. Public Health Significance:

Inadequate holding temperatures, including inadequate reheating, is a risk factor identified by CDC as a major contributor to foodborne illness. It is essential that the Food Code provide a reference to using equipment for its intended purpose to allow an inspector to provide feedback to retail and food service operators when reheating may be out of control. If an operator can provide evidence from the equipment manufacturer that it is capable of reheating food as specified under § 3-403.11, then the equipment would be considered used for its intended purpose.

### 4. Recommended Solution: The Conference recommends.....

that a letter be written to FDA recommending that a new section be added to the FDA Food Code to address using equipment for its intended purpose as follows:

4-204.124- Intended Purpose

Equipment used for reheating potentially hazardous foods as specified under § 3-403.11 shall be used in accordance with the manufacturer's operating instructions based on the proper use of equipment in conjunction with the type of food being reheated.

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Inform consumers of the risk associated with consumption of fresh untreated juice.

### 2. Issue you would like the Conference to consider:

It is recommended that Section 3-404.11 of the FDA Model Food Code, "Treating Juice", include a provision that addresses the food safety concerns regarding selling fresh juice by the glass.

### 3. Public Health Significance:

The 21 CFR 120 Juice HACCP Regulation applies to products sold as juice or used as an ingredient in beverages, however the regulation exempts retail operations from the requirements. Section 3-404.11 addresses fresh juice packaged in a food establishment/retail operation by requiring a HACCP plan which attains a 5-log reduction, which is equal to a 99.999% reduction of the most resistant microorganisms of public health significance or that the product be labeled, if not treated to yield a 5-log reduction of the most resistant microorganisms of public health significance. The labeling requirement are as specified under 3-602.11, and as specified in 21 CFR 101.17(g) with the phrase, "Warning: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

The public health rationale for providing the consumer with information about the risks associated with drinking unpasteurized/untreated juice is the same regardless whether the juice is packaged or not.

### 4. Recommended Solution: The Conference recommends.....

The Conference recommends that Section 3-404.11 delete Packaged and read Juice in a FOOD Establishment shall be:

and expand section 3-404.11 (B) to include

(2) Fresh packaged juice that is sold to the consumer without a 5-log reduction shall be labeled "Warning: This product has not been pasteurized and therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

(3) Fresh juice that is sold to the consumer without a 5-log reduction shall have a placard with the Warning notice conspicuously placed at point of sale.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Cold Holding of Potentially Hazardous Food

### 2. Issue you would like the Conference to consider:

The Food Code currently allows a regulatory jurisdiction to give a five-year phase-in time period from the date the local jurisdiction adopts the Food Code, for replacement of refrigeration equipment that fails to meet the refrigeration standard of 41°F but can meet the 45°F requirement. With improvements in commercial refrigerator design and enhanced equipment standards, FDA believes this exemption is no longer necessary and is detrimental to public health protection in light of what has been learned about the growth and survival of *Listeria monocytogenes* in refrigerated foods.

### 3. Public Health Significance:

Foodborne illness associated with *Listeria monocytogenes* (LM) in certain types of refrigerated ready-to-eat foods continues to be a significant problem in the US, especially among highly susceptible populations. Foods can become contaminated with LM a number of places along the path from farm to table and appropriate control measures should be put in place whenever possible. Keeping product temperatures as low as possible is the most effective means of limiting the growth of LM in foods that have been contaminated.

For most foods, maintaining a product temperature of 5°C (41°F) or less should limit the growth of LM and other pathogens. The retail food, food service, and vending industries have demonstrated the capability to routinely maintain foods at 5°C (41°F) or less with the proper equipment and food storage practices. Under an exemption established in the 1997 Food Code to address concerns about older equipment in place in food establishments at the time, the Food Code currently permits cold holding of food at temperatures of up to 7°C (45°C).

### 4. Recommended Solution: The Conference recommends.....

Based on discussion and deliberation that FDA delete §3-501.16(A)(2)(b) and §3-501.17(A)(2)(a)-(b) to remove the exemption allowing food to be stored at 7°C (45°F) for a maximum of 4 days in existing refrigeration equipment that is not capable of maintaining the food at 5°C (41°F).

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Consumer Advisory Modification, Section 3-603.11 Supplement to the 2001 Food Code

### 2. Issue you would like the Conference to consider:

This section requires a mandatory written consumer warning if the establishment serves undercooked (or cooked to order) meats, poultry, fish, eggs, etc. Current research shows that there is little danger when intact meats, fish or eggs are cooked rare or medium rare. In a striking contradiction, other non-animal, potentially hazardous foods which are generally consumed without cooking pose a significant risk to "especially vulnerable" consumers and do not require any warning. Furthermore, FDA research on consumer advisories has shown that consumer advisories in general impart little useful information to consumers and are generally unwanted by consumers at retail.

At the 1998 CFP, a general consensus concerning this issue was reached and was outlined on the page preceding the "Consumer Advisory" section of the 2001 Food Code. The guidance was then included in codified language in the Supplement to the 2001 Food Code. The Supplement requires that food establishments serving raw or undercooked products meet two requirements, disclosure and reminder. Operators are required to disclose that menu items contain raw or undercooked animal products and remind vulnerable consumers of the increased risks associated with consumption of these food products. One option for reminding consumers allows operators to provide informational brochures upon request. However, during the past six years, the FDA has been unable to successfully develop an acceptable consensus brochure for "vulnerable consumers" as identified in the FDA Food Code section 3-603.11.

We strongly feel that to be effective, consumer education must move beyond simple warning statements and scare tactics involving specific food groups at the retail level. Public health education, as related to foodborne illnesses, is a shared responsibility of the government, food industry, the medical and health care professionals (doctors, nutritionists and dietitians), and all levels of academia and public interest groups. It should not be placed solely on the industry with simple point of sale warnings in restaurants and/or supermarkets for only specific stigmatized foods.

### 3. Public Health Significance:

It is important for foodservice operators to inform consumers when a potentially hazardous, raw or undercooked animal protein is available for sale through disclosure on the menu. For example, when raw eggs are used in a caesar salad, the menu should denote "raw egg caesar salad" or have some other description informing the consumer

that raw eggs are an ingredient for that particular menu item. The disclosure of undercooked animal foods on menus is sufficient in effectively communicating with a vulnerable consumer eating in a foodservice operation so that they may make an informed choice when ordering.

FDA's own Working Group's findings indicate that disclosure is sufficient enough, at the restaurant level, to inform the consumer of hazards associated with consuming raw or undercooked animal foods with no other reminder needed.

#### **4. Recommended Solution: The Conference recommends.....**

The Conference recommends revising Section 3-603.11(A) of the Supplement to the 2001 Food Code to read: (A) Except as specified in Section 3-401.11(C) and Subparagraph 3-401.11(D)(3) and under Section 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 that these foods are a food choice by way of a DISCLOSURE, as specified in paragraph (B) of this section, using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.

The Conference also recommends that 3-603.11(C) be deleted.

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## CONFERENCE FOR FOOD PROTECTION

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**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Include instructions for manual warewashing sink set-up

### 2. Issue you would like the Conference to consider:

Include in the FDA Food Code instructions and references for correct manual warewashing sink set-up.

### 3. Public Health Significance:

Although the code talks about washing, rinsing and sanitizing it provides no direction for how manual warewashing sinks must be set-up. This would eliminate any confusion on proper utensil wash set-up.

### 4. Recommended Solution: The Conference recommends.....

FDA Food Code 4-301.12 rename title and add (F)

4-301.12      Manual Warewashing, Sink Compartment Requirements [and Set-Up].

(F) A 3-compartment sink used for utensil washing shall be set-up as follows:

(1) The first sink shall be designated as the wash compartment and the wash solution shall meet the requirements as specified in 4-501.17 and 4-501.19.

(2) The second sink shall be designated as the rinse compartment and shall follow the procedures specified in 4-603.16.

(3) The third sink shall be designated as the sanitizer compartment and shall follow the requirements specified in 4-501.114 or 4-501.111, and 4-703.11

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

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**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Clarify that walk-in coolers without prefabricated floors should not be considered equipment as defined in the 2001 Food Code, Paragraph 1-201.10(B)(28)(b) and specify allowances for installation of floor drains in coolers in the 2001 Food, Section 5-402.11 and the FDA Food Establishment Plan Review Guide.

### 2. Issue you would like the Conference to consider:

The definition of "Equipment" provided in paragraph 1-201.10(B)(28), and application of backflow prevention guidance provided in section 5-402.11 of the FDA 2001 Food Code, and corresponding guidance in the FDA 2000 Food Establishment Plan Review Guide have resulted in a lack of uniform interpretation and enforcement by regulatory agencies. Some agencies interpret these references as meaning drains cannot be installed inside walk-in coolers, defining walk-in coolers as "Equipment" or confusing the definition of what constitutes an indirect waste connection.

Paragraph 1-201.10(B)(28) of the FDA 2001 Food Code defines equipment and what is not considered as equipment. Section 6-201.13(B) of the same Code states "The floors in FOOD ESTABLISHMENTS in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and SEALED." The FDA 2000 Food Establishment Plan Review Guide, Section III, Part 10, Floors, #4 states "Properly installed trapped floor drains shall be provided in floors that are water flushed for cleaning or that receive discharges of water or other liquid waste from equipment or in areas where pressure spray methods for cleaning equipment are used." Section 5-402.11 of the Food Code states "a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment or utensils are placed." Section III, Part 12 of the Plan Review Guide reiterates that "a direct connection may not exist between the sewage system and any drains originating from equipment in which food, portable equipment, or utensils are placed except if otherwise required by state plumbing codes." Section III, Part 2, I of the Plan Review Guide states "if walk-in (cooler) floors are water flushed for cleaning or receive discharge of liquid waste or excessive melt water, the floors should be...and sloped to drain. Local jurisdictions may require drains to be located outside of the cooler within 5 feet of the cooler box."

Confusion and lack of uniform interpretation is compounded by NSF International Standard 7, Section 4.16.4, requirement which outlines "Drains, other than condensate, shall be eliminated from the food zone." NSF considers the inside of a walk-in cooler as a food zone. However, NSF addresses coolers with prefabricated floors and not coolers

which are extensions of food preparation areas that have concrete or equivalent type floor bases. This confusion and lack of uniform interpretation has resulted in a variation of agencies and ordinances requiring:

- If a floor drain is desired (or required) then the drain may be installed outside of the cooler and the floor shall be graded to the drain, or
- Specific requirements for direct and indirect connections, or
- Detailed requirements for floor drains provided in walk-in coolers by way of air gaps or air breaks.

### **3. Public Health Significance:**

The retail food industry is confronted with the paradox of not being permitted by individual local plumbing authorities to install floor drains in coolers while at the same time floor drains are permitted to be installed in food prep areas (refrigerated or non-refrigerated). In several situations, the walk-in coolers in retail supermarkets are extensions of food prep areas because food operations may occur inside these coolers to maintain product temperatures, equipment/environment temperatures and reduce microbial hazards. Examples include grinding operations in walk-in meat coolers, and ice production located within produce and seafood coolers. The food industry considers large refrigerated walk-in storage coolers essential for food safety in areas of market operations for dairy, deli and bakery. However, many retail food establishments incur objections from local regulators when trying to create a safer, more sanitary design by installing floor drains in coolers.

Many retail food establishments are utilizing approved and recognized wet cleaning or high pressure cleaning for equipment and facility, such as those described in Part 4-6 or Chapter 6 of the FDA Food Code. The USDA FSIS Food Safety Hand Book, Part VI, Section 416.2 (e)(4) states "Plumbing systems must be installed and maintained to provide adequate floor drainage in all areas where floors are subject to flood type cleaning or where normal operations release or discharge water or other liquid waste on to the floor." Prohibiting floor drains in coolers creates unsafe conditions. There's a greater occupational risk and safety hazards from slips and falls due to excessive floor pitch. This is magnified in coolers where ice is manufactured or where drainage occurs for melting ice used for cooling exterior surfaces of foods, such as seafood and produce. Waste water must be squeegeed to floor drains installed outside of coolers creating potential flooding, occupational (slipping) and environmental cross contamination hazards in the food establishment. Pooling water in low spots also provides bacteria niches. Additional safety and structural hazards are created by placing storage and operating equipment on excessively pitched, uneven floor surfaces located in walk-in refrigerated coolers.

Many regulatory authorities allow floor drains, which are trapped and indirectly connected to sewage lines, to be installed in prep areas but restrict those same drains from being installed inside walk-in coolers where the potential risk for back flow is the same. A solution to this is to tie all floor drains in both prep areas and coolers into a single collection pit which is indirectly connected to the main sewer system by an air gap. The pit is trapped and has a vented receptor and an alarm system which alerts of potential back flows. This pit design was submitted to Robert Warren, Code Secretary of the National Association of Plumbing, Heating & Cooling Contractors and Ray Beaulieu, FDA



Assistant Director of Code & Practices of Retail Food Protection – both commented in favor of use (see attached). In 1998, a similar issue, CFP Issue 1998-I-02, was presented and was approved by the State Voting Delegates (see attached). However, modifications or Plan Review Development Committee recommendations were never included in the 1999 Food Code or later Codes, or into the 2000 FDA Food Establishment Plan Review Guide.

#### **4. Recommended Solution: The Conference recommends.....**

the Conference Chair send a letter to the FDA Commissioner recommending expanding the list of equipment specified in Paragraph 1-201.10(B)(28)(b) for equipment, and add clarification Section 5-402.11 and corresponding FDA Food Establishment Plan Review Guide for use of floors drains in walk-in coolers.

1. Paragraph 1-201.10(B)(28)(b) should read:

“(b) “Equipment” does not include walk-in coolers which do not have prefabricated floors and items used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.”

2. Add a new paragraph to Section 5-401.11 and the FDA 2000 Food Establishment Plan Review Guide, Section III, Part 12:

“Floor drains are allowed in walk-in coolers which do not have prefabricated floors and are used for the storage and/or preparation of food or other products used for human consumption providing that the drains are indirectly connected through an air gap or air break to a sanitary drainage system which is properly trapped and vented as required by law. Pipes from floor drains may discharge effluent into a single easily cleanable collection pit or catch basin of adequate size to remove the routinely generated water out of it. The main sewer line shall be located at the base of the pit and effluent pipes from drains entering the pit shall be elevated above the base of the pit to create an air gap.” See attached diagram.

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## CONFERENCE FOR FOOD PROTECTION

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**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Standardization of chemical sanitizer concentration levels and inclusion into FDA Food Code.

### 2. Issue you would like the Conference to consider:

21 CFR 178.1010 & FDA Food Code Section 4-501.114 is not consistent in noting minimum and maximum concentration requirements. No maximum concentration is noted for Chlorine in section 4-501.114 (A) of the FDA Food Code. No minimum or maximum concentrations are noted for Quaternary solutions in section 4-501.114 (C) of the FDA Food Code.

### 3. Public Health Significance:

A determination of sanitizer range is necessary for proper restaurant monitoring and execution. If the FDA Food Code remains the "reference manual" for the restaurant industry, then we recommend that it contains the sanitizer information referenced above.

### 4. Recommended Solution: The Conference recommends.....

That a letter be written to FDA with the following recommendation: 1) Content from 21 CFR 178.1010 should be reformatted in an easy to read matrix in FDA Food Code Section 7-204-11 to include minimum and maximum concentrations of sanitizer for each sanitizer used based on no-rinse requirements and scientific validation.

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## CONFERENCE FOR FOOD PROTECTION

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**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Labeling of irradiated raw ground beef reground with other non-irradiated beef for retail sale.

### 2. Issue you would like the Conference to consider:

Raw ground beef that has been irradiated to destroy pathogenic bacteria and that is then reground and packaged for sale with non-irradiated beef trim, could lose the intended effect of the irradiation process [21 CFR 179, 9 CFR 424.22 ( c)] . However, the mixed product would still retain a label to reflect that the package contains irradiated beef. The consumer may be misled about the enhanced safety afforded by the irradiation process in these mixed products.

On December 23, 1999, FSIS issued a final rule (64 Federal Register 72150) to permit the use of irradiation to kill pathogenic bacteria, including *E. coli* O157:H7, and to extend the shelf life in raw refrigerated and frozen meat (up to 4.5kGy and 7kGy, respectively) and meat products. In the final rule, FSIS required that irradiated meat and poultry, including beef, must bear labeling that reflects that the product was irradiated or that the product contains an irradiated meat or poultry product. This labeling requirement is applicable even at retail where coarse ground irradiated product might be finely ground for retail sale, or irradiated product is combined with other non-irradiated product at retail.

The labeling must bear the international symbol, the radura. Unless the word "irradiated" is part of the product name, the labeling must bear a disclosure statement, either "treated with irradiation" or "treated by irradiation." If irradiated meat or poultry products are part of a multi-ingredient product, the irradiated meat or poultry product must be identified as such in the ingredient statement, in the proper order of predominance.

Irradiation at the approved levels is expected to significantly reduce the levels of pathogens but is not a guarantee that the product is free of pathogens unless, a claim to this effect is stated on the label and substantiated by the producer of the irradiated product. Consequently, irradiated meat or poultry products handled by retail operations should be stored and handled in the same manner as other raw products that would need to undergo further treatment by the consumer to make them safe.

FSIS conducts verification testing of ground beef to detect whether the product is adulterated with *Escherichia coli* O157:H7. This verification testing is primarily conducted at Federally inspected facilities, but some verification testing does occur at retail operations. FSIS is assessing how it will more fully implement a risk-based verification

testing program. Because of the potential public health impact of mixing irradiated and non-irradiated beef (i.e., product treated to significantly reduce the levels of *E. coli* O157:H7, if it were present, with product not specifically treated), FSIS is assessing the feasibility of targeting for verification testing operations that regrind or mix irradiated and non-irradiated beef. However, another option under consideration is to provide guidance in the Food Code to state that such practice is not a recommended good manufacturing practice and to discourage such practices.

### 3. Public Health Significance:

The use of irradiation as an antimicrobial treatment greatly increases the chances of producing a product that has a substantially lower level of pathogenic bacteria. These products will only lead to a reduction in foodborne illnesses and deaths if handled, cooked, and served properly. However, mixing irradiated and non-irradiated beef may negate the benefits of irradiation.

### 4. Recommended Solution: The Conference recommends.....

USDA, in consultation with FDA, develop guidance to be included in the Annex of the Food Code regarding: 1) labeling requirements for truthfully labeling irradiated meat or poultry products with added non-irradiated meat or poultry product mixed at retail operations; 2) the public health significance of adding irradiated raw ground beef to non-irradiated raw ground beef; and 3) the potential ramifications for verification testing by FSIS of retail operations that mix irradiated and non-irradiated beef at retail.

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## CONFERENCE FOR FOOD PROTECTION

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**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Guidance for retail facilities regarding beef grinding logs tracking supplier information

### 2. Issue you would like the Conference to consider:

In an effort to improve public health by ensuring that product is quickly removed from the market if product is determined to be adulterated after it has been inspected and passed by FSIS, FSIS explained in the Federal Register (67 FR 62332) on October 7, 2002, that, under 9 CFR 320.1(b)(1), Federally inspected establishments and retail facilities are required to keep records of each transaction involving their purchasing or receiving any meat or meat food product. These records must show the name or description of the articles they purchase or receive (9 CFR 320.1(b)(1)(i)) and the name and address of the seller of the articles they purchase (9 CFR 320.1(b)(1)(iv)). Federally inspected establishments and retail facilities must provide FSIS access to these records (9 CFR 320.4, 21 U.S.C. 642).

As is stated in 67 FR 62332, "at the time FSIS collects samples of ground beef from retail facilities, FSIS will obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of ground beef sampled, the supplier lot numbers and production dates, and any other information that would be useful to suppliers if they are later notified of an *E. coli* O157:H7 positive finding."

Finally, in the October 7, 2002, issue of the Federal Register, FSIS also stated that the Agency expects that supplier lot numbers and production dates are normally available at Federal grinding establishments and retail facilities. In addition, FSIS stated that it expects that retail facilities would normally obtain the contact information that FSIS is collecting when it collects samples of ground beef from retail facilities.

Therefore, retail facilities should consistently maintain adequate records concerning suppliers of source material for ground beef products, as required by regulations and the Federal Meat Inspection Act.

### 3. Public Health Significance:

Adequate business records are critical in any investigation related to public health, food safety, or misbranding of meat products. Should an *E. coli* O157:H7 outbreak occur associated with consumption of ground beef, accurate grinding logs tracking supplier information in retail meat markets and retail stores will be crucial in tracing the source of *E. coli* O157:H7 and preventing further illnesses.

#### 4. Recommended Solution: The Conference recommends.....

USDA develop, and FDA include as an Annex to the Food Code, guidance for retail facilities to be included in the Annex of the Food Code recommending that retail grinders maintain the following information:

- names and identification numbers of the inspected establishments supplying the source materials for each lot of raw ground beef produced at the retail store;
- if store-generated trim is used to produce the ground beef, names and identification numbers of inspected establishments supplying source material for the store-generated trim used for each lot of raw ground beef produced at the retail store;
- suppliers' (inspected establishments') lot number and production date for the source material used for each lot of ground beef produced at the retail store;
- other information concerning the supplier that would be useful to the supplier if it is later notified of any food safety hazard in the source materials used for a particular lot of ground beef produced at the retail store.

<b>5. Submitter:</b>			
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## Conference for Food Protection

2004 ISSUE FORM

Deadline Feb 2, 2004

Issue # 2004 I-030

Internal # 056

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_      **Accepted as Amended** \_\_\_\_\_      **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_      **Rejected** \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Unsanitary Handling of Drinking Water Coolers

### 2. Issue you would like the Conference to consider:

The service of drinking water in 5 and 10-gallon coolers is a common practice by licensed food establishments in a wide variety of applications including golf courses, schools and universities. This practice however, has been largely mishandled and overlooked as a health and safety hazard. The practices being utilized often include the use of non-food grade fill hoses that are also used for cleaning equipment and filling chemical tanks, improper cooler cleaning and storage, and no sanitation procedures.

### 3. Public Health Significance:

An extreme example of the impact of this issue, In 2002 a 15-year-old boy died and more than 80 others contracted the Norwalk virus after consuming water from contaminated coolers at a golf course in Arizona. "The outbreak sparked an inspection of 157 courses in Maricopa County, Ariz. Health officials found that 63 percent of the facilities failed to handle drinking water and ice properly. The only courses that passed the health inspection didn't use jugs to dispense drinking water..." - Superintendent News. With 100% of the facilities in this sampling that use water coolers failing the health code inspection, it is apparent that this issue is wide spread and in need of attention and guidance offered for safe water service.

On the surface this appears to be a matter of relative insignificance. However, please consider the 26 million golfers in the US, countless student athletes and other consumers who rely on coolers for hydration that are routinely exposed to potentially hazardous drinking water. These consumers are assuming that health guidelines are being followed and the service of water regulated to protect their well being.

### 4. Recommended Solution: The Conference recommends.....

1. The Conference distributes guidelines for proper water and cooler handling through their network of food industry, government, academia, and consumer organizations.
2. Encourage health regulatory agencies that inspect facilities utilizing insulated coolers to enforce proper water handling to the same standards applied to all other areas of food and beverage service as stated in their respective food codes.

Attached is a sample of guidelines for proper cooler handling produced by the Washington County, MN Health Department. This Fact Sheet mirrors the guidelines established in Maricopa County, AZ following the Norwalk incident. Some local health

regulators recognize this as a concern and are acting on it, however most are not aware that there is a problem. This sheet could be used as a model for distribution through the Conference's established network to raise awareness of this issue on a national scale.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 I-031  
Internal # 093

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

*All information above the line is for conference use only.*

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### 1. Title:

Reinforce Accountability Inferred By Active Managerial Control.

### 2. Issue you would like the Conference to consider:

Who's in charge of food safety? Who's in charge of handwashing? Active Managerial Control (AMC) points out that THE PERMIT HOLDER bears the primary accountability to serve safe food. AMC defines the role of the Person-In-Charge (PIC) as does the Food Code in section 2-101.11. Regulators help operators "safeguard public health and provide to CONSUMERS FOOD that is safe, UNADULTERATED, and honestly presented." Local inspectors help by consulting, training, auditing and if necessary, suspending permits. Inspectors are most effective in preventing foodborne illness when in their consultative mode, guiding the operators in their awesome responsibility. The enforcement role of the inspectors also serves both the operator and the public when a major breakdown of the food safety system occurs.

Richard Barnes' response to a delegate question in the 2002 delegate voting on the recurring "no bare-hand contact" issue provides an important context for consideration of this accountability issue:

The Chair recognizes Richard Barnes.

Richard Barnes (FDA): Richard Barnes, FDA. Thank you. There are a lot of issues here that we're talking about, but I guess I'm going to talk primarily about the issue of Active Managerial Control of the risk factors.

We have reached consensus, I believe, among all of us that the goal of the retail program is managerial control of the risk factors that lead to foodborne illness. What we have done with this issue is taken language that existed in the previous Code in an annex and put it directly into the Code language itself which puts the onus on the operator of an establishment to manage the risk factor in his establishment which is what we say is the goal of this program.

If we are going to say that the manager is responsible for managing those risk factors, then we also must follow that in the language of the Code. We do not believe that there is any difference in what we have done previously in exception by taking the language from the annex and putting it in the Code and putting it back onto the manager of the establishment to do it, for him to maintain a plan, to develop a plan, to implement a plan.

Our goal as regulators then is to insure that he implements that plan, takes appropriate compliance actions when they do not - to go back to no bare-hand contact.

So, if truly our goal of the retail program is Active Managerial Control of the risk factors in the establishment, this is one issue that puts it directly back on the manager to control.

### 3. Public Health Significance:

Clarifying operator accountability focuses their response to the food safety challenge and accelerates a path forward for their multidisciplined teams to work together from design through operations. This clarity folds in regulatory resources, knowledge and experience into a single-minded, operation-specific plan based on risk. The Plan Review process can now be jointly focused on risk with legal minimums as a safety net (e.g. number/location of hand sinks).

This integration cuts the timeline between discovery and implementation. It speeds State adoption and implementation of The Food Code and its updates. The sum of accelerated actions is the metric for the improvement in public health.

### 4. Recommended Solution: The Conference recommends.....

... the Conference Chair send a letter to the FDA Commissioner to urge the following change to the Food Code:

Restate section 1-102.10: "The purpose of this code is to guide FOOD ESTABLISHMENTS and their regulatory allies to safeguard public health and provide to CONSUMERS FOOD that is safe, UNADULTERATED, and honestly presented."

5. Submitter:			
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**CONFERENCE FOR FOOD PROTECTION**

**2004 ISSUE FORM**  
**Deadline Feb 2, 2004**

**Issue # 2004 II-001**  
**Internal # 008**

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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**1. Title:**

Amendment to the Conference Constitution and Bylaws – Executive Director

**2. Issue you would like the Conference to consider:**

The following Sections of the Conference Constitution and Bylaws and corresponding sections of the Appendix should be amended changing the words Executive Secretary to Executive Director.

Article II - Sections 1 and 3 (twice)  
 Article III - Sections 1, 2 and 3  
 Article IV - Section 1, Subsection 4; and Section 4 (twice)  
 Article V - Section 5 and 10 (twice)  
 Article VI - Section 2  
 Article VIII - Opening Paragraph; Sections 1, 2, 3, 4 (twice), 5, 6, 7  
 Article XIII - Section 2 (twice)  
 Article XIV - Opening Paragraph;  
 Article XVI - Section 2, Subsection 4; Section 4 (twice); Section 6 (twice); Sections 7 and 8  
 Article XVIII – Section 1

**3. Public Health Significance:**

Since the duties and responsibilities of the position of Executive Secretary have expanded as the Conference has taken on a larger role in food safety, the title of Executive Secretary is no longer appropriate. Therefore, the Executive Board and the Constitution and Bylaws Committee of the Conference recommend that the title Executive Secretary be changed to Executive Director

**4. Recommended Solution: The Conference recommends.....**

That the Articles and Appendix of the Conference Constitution and Bylaws set forth in Section 2 of this Issue form be amended as proposed.

<b>5. Submitter:</b>			
<b>Name:</b>	Larry Eils, Constitution and Bylaws Committee chair		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-002  
Internal # 038

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Amendment to the Conference Procedures Manual – Executive Director

### 2. Issue you would like the Conference to consider:

The following Sections of the Conference Procedures Manual should be amended changing the words Executive Secretary to Executive Director:

Article IV – Section A, Subsection 3  
Article V – Section A, Subsection 2 (twice); Section B  
Article VIII – Section H

### 3. Public Health Significance:

These proposed changes follow the request of another Issue from the Conference Constitution and Bylaws Committee changing Executive Secretary to Executive Director in the Conference Constitution and Bylaws. These changes would bring both documents into conformance with each other.

### 4. Recommended Solution: The Conference recommends.....

That the Articles of the Conference Procedures Manual set forth in Section 2 of this Issue form be amended as proposed.

### 5. Submitter:

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**CONFERENCE FOR FOOD PROTECTION**

**2004 ISSUE FORM**  
**Deadline Feb 2, 2004**

**Issue # 2004 II-003**  
**Internal # 009**

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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**1. Title:**

Amendment to the Conference Constitution and Bylaws – Article XVI

**2. Issue you would like the Conference to consider:**

Article XVI, Section 4 of the Conference Constitution and Bylaws should be amended to read as follows (addition shown in CAPS): “At least one hundred . . . a notice of the forthcoming meeting. Each notice shall include a current copy of Article II, Section 3 and Article XVI, SECTIONS 2, 3, 4 AND 5 of the Constitution and Bylaws.”

**3. Public Health Significance:**

Currently the Executive Secretary is required to send all of Article XVI - Rules of Assembly when contacting state regulatory agencies. Since only Sections 2, 3, 4 and 5 in Article XVI pertain to the regulatory agencies being contacted; it is the belief of the Executive Secretary and the Constitution and Bylaws Committee that the other Sections in the Article do not need to be sent

**4. Recommended Solution: The Conference recommends.....**

That the Conference Constitution and Bylaws be amended as set forth in Section 2 of this Issue form.

<b>5. Submitter:</b>			
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**CONFERENCE FOR FOOD PROTECTION**

**2004 ISSUE FORM**  
**Deadline Feb 2, 2004**

**Issue # 2004 II-004**  
**Internal # 062**

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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**1. Title:**

Amendment to the Conference Procedures Manual – Late-Breaking Issues and Supplemental Material

**2. Issue you would like the Conference to consider:**

The following Sections of the Conference Procedures Manual should be amended as follows: (see attachment for specific wording)

- Article IV – Section A: delete the word Form
- Article IV – Section A, Subsection 3: add new sentence
- Article IV – Section A, Subsection 3: add new subsection a.
- Article IV – Section A, add new Subsection 4
- Article IV – Section B, add new Subsection 3
- Article IV – add new Section G and Subsections 1 and 2
- Article IV – Change old Section G to new Section F

**3. Public Health Significance:**

These proposed changes follow the request of the Council Chairs and Vice Chairs and the Executive Board to explain how the Conference will handle late-breaking food safety Issues and supplemental material submitted during the Conference relating to Issues being considered. Therefore, the Executive Board and the Conference Constitution and Bylaws Committee recommend these changes as set forth in the attachment.

**4. Recommended Solution: The Conference recommends.....**

That the Articles of the Conference Procedures Manual set forth in Section 2 of this Issue form be amended as proposed.

**5. Submitter:**

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**CONFERENCE FOR FOOD PROTECTION**

**2004 ISSUE FORM**  
**Deadline Feb 2, 2004**

**Issue # 2004 II-005**  
**Internal # 091**

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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**1. Title:**

CFP Food Manager Training Testing and Certification Committee Report.

**2. Issue you would like the Conference to consider:**

Acceptance of the Committee's Report to the Conference

**3. Public Health Significance:**

Continued support of the Accreditation process.

**4. Recommended Solution: The Conference recommends.....**

Accept the Committee's Report to the Conference

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-006  
Internal # 034

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title: [Briefly describe the purpose of this Issue.]

Conference Standards for Accreditation of Food Protection Manager Certification Programs Edits and Modifications

### 2. Issue you would like the Conference to consider:

To amend the Conference Standards for Accreditation of Food Protection Manager Certification Programs. Modifications and edits are based on two years of work by the Conference Food Manager Training, Testing, and Certification Committee to refine the standards and develop the Accreditation Program.

Many of the changes are minor wording edits based upon feedback from the American National Standards Institute (ANSI) as the third party accreditor of Food Protection Manager Programs against the Conference Standards. In some cases, the ANSI auditors felt the standards were ambiguous and in other cases, the change from the test recognition program to the ANSI-CFP Accreditation Program made some of the standards obsolete. Finally, some of the changes are designed to clarify confusing terms and/or standards.

### 3. Public Health Significance:

The Conference has supported the development and ongoing maintenance of both the Standards for Accreditation of Food Protection Manager Certification Programs and the ANSI-CFP Accreditation Program. By supporting the Standards and the Accreditation Program, the Conference has improved Food Safety by promoting the standardization of Food Manager Certification Programs and ensuring that Food Protection Managers Certified by Accredited Organizations are evaluated using psychometrically valid, reliable and legally defensible programs. The continued support of the Standards and the ANSI-CFP Accreditation Program will enhance Food Protection Manager Certification in the United States.

### 4. Recommended Solution: The Conference recommends.....

To amend the Conference Standards for Accreditation of Food Protection Manager Programs as attached (see attached Standards):

All edits are marked in red. Those terms to be removed are in strikeout format. Those terms to be added are in red and underlined.



The Conference Food Manager Training, Testing and Certification Committee has approved all edits/modifications to the Standards.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-007  
Internal # 035

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Conference Standards for Accreditation of Food Protection Manager Certification Programs Annex B Edit

### 2. Issue you would like the Conference to consider:

To amend the Conference Standards for Accreditation of Food Protection Manager Certification Programs to remove the Elements of Knowledge from Annex B of the Conference Standards.

The Elements of Knowledge in Annex B have been misused by regulatory agencies and others as defining the content that should be incorporated into Food Manager Certification Programs. The Standards State that Food Manager Certification Programs should be based on a valid job/task Analysis. No job/task analysis was conducted to arrive at the Elements of Knowledge listed in Annex B. Therefore, the requirement that Food Manager Certification Programs be developed based on a job/task analysis and the listing of the Elements of Knowledge in Annex B conflict with each other.

Additionally, many providers of training for Food Protection Managers use the Elements of Knowledge listed in Annex B as the basis for the development of training. However, this may result in an unfair process for candidates as they are trained using the Elements of Knowledge and tested based on the knowledge needed for competent practice as identified by a valid job/task analysis. No study has ever been conducted to compare the Elements of Knowledge with a valid job/task analysis or even to verify if the elements of knowledge are indeed the critical issues associated with safe food delivery. Therefore candidates may be trained in one area and tested in another.

### 3. Public Health Significance:

Food Manager Training Programs use the Elements of Knowledge listed in Annex B as a basis for training programs for Food Managers. They often believe that because the Elements of Knowledge are listed in Annex B, that they have been developed according to standards and reflect real world practice. However, this is an incorrect assumption. The Elements of Knowledge were not developed using standard task identification practices and no study has ever been conducted to determine if the Elements of Knowledge relate in any way to the job/task analyses conducted for Food Managers. Using the Elements of Knowledge as a basis for anything is poor practice and may contribute to the mis-education of Food Managers. By leaving the Elements of Knowledge in Annex B, the Conference is contributing to this injustice.

**4. Recommended Solution: The Conference recommends.....**

To remove the Elements of Knowledge from Annex B (see attached Standards)

**5. Submitter:**

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-008  
Internal # 036

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Food Manager Training, Testing and Certification Committee Bylaws Modifications

### 2. Issue you would like the Conference to consider:

To amend the Food Manager Training, Testing, and Certification Committee's Bylaws to add Section 4 and Section 5 to the Objectives of the Committee. (see attached Bylaws)

### 3. Public Health Significance:

The Conference has charged the Food Manager Training, Testing, and Certification Committee with the task of developing and maintaining Standards for Accreditation of Food Protection Manager Certification Programs and to establish and maintain an accreditation program for Food Safety Manager Certification Programs. As a result of this continued charge, the Food Manager Training, Testing, and Certification Committee was named a standing Committee to the Executive Board and during the 2002 Conference, the Bylaws for the committee were submitted and approved.

The proposed additions to the Bylaws add objectives that were not originally listed in the Bylaws however were included in the Standards (see attached Bylaws and Annex D of the Standards). The Committee has determined that the objectives of the Food Manager Training, Testing, and Certification Committee are best listed in the Bylaws rather than the Standards.

By incorporating the additional objectives of the Food Manager Training, Testing, and Certification Committee into the Bylaws (rather than having them as Annex D of the Standards) they are more appropriately positioned.

### 4. Recommended Solution: The Conference recommends.....

To change the Food Protection Manager Training, Testing and Certification Committee Bylaws to add to Article I - Objectives, the following:

Section 4. Promote Strategies to enhance equivalence among food protection manager certificates issued by certification organizations.

Section 5. Establish and refine policies and standards to which certifying organizations shall conform.

The Conference Food Manager Training, Testing, and Certification Committee has

approved all proposed edits to the Bylaws.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-009  
Internal # 037

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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**1. Title:**

Accredited Program Definition

**2. Issue you would like the Conference to consider:**

To amend section 1-201.10 (B)(1)(a) of the 2001 FDA Food Code in the next revision to specify in more detail the definition of "Accredited Program" with regards to the Food Protection Manager Certification Program.

Current 1-201.10 (B)(1)(a) of the 2001 FDA Food Code reads:

"Accredited Program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

**3. Public Health Significance:**

Currently the FDA Food Code does not specify what type of accrediting agency is acceptable for accrediting the Food Protection Manager program used to fulfill demonstration of knowledge for the Person in Charge in a food operation establishment. However, the FDA Food Code does specify the type of accreditation agency when referring to certified equipment. Failure to specify type of accrediting agency for Manager Certification may result in:

- Food Protection Manager Certification programs/providers accredited by agencies not reviewed or approved by the Conference for Food Protection (CFP).
- Accrediting agencies using Food Protection Manager Certification program standards that have not been developed, reviewed or approved by the Conference for Food Protection (CFP).

Over the past 10+ years the CFP Food Protection Manager Certification Committee has worked diligently to develop, maintain and continuously improve the standards for Manager Certification Programs. In addition, during the last 2 years, the Committee has recommended a single accrediting agency (ANSI) and presented the recommendation to the CFP Board for approval. ANSI (American National Standards Institute) was approved by the CFP Board for accrediting Food Protection Manager Certification Programs. Currently there are 3 such accredited provider programs.

The benefits of specifying a CFP approved accrediting agency for accrediting Food Protection Manager Certification programs are:

- The unique Food Protection Manager program standards developed by the CFP Food Protection Manager Certification Committee are specific to food safety as many vested interest groups have input into the standards, including: certification providers, industry (food service and retail), academia, regulatory (state and local and “at large”), and consumer organizations/independents.
- There is a need for these standards to be very specific as there is a wide diversity of stakeholders.
- The years of work developing these standards by the CFP Food Protection Manager Certification Committee ensures that they are practical and acceptable by the stakeholders.
- CFP approved accrediting agency (ANSI) uses these standards to accredit Food Protection Manager Certification provider programs by reviewing the psychometric properties of the examinations used in the Food Manager Certification process.
- ANSI provides both on-site dimensions of audits as well as bench audits, unlike many other accreditation agencies.
- The unique relationship between ANSI and the CFP provides a forum (CFP Accreditation Committee) to monitor accreditation activities and problem solving.
- CFP accredited programs already have a very large candidate base and trusted by many regulatory agencies who already specify to use CFP accredited programs.
- Clearly stating the approved CFP accreditation protocol will ensure reciprocity between states/jurisdictions that adopt the FDA Food Code, which is a key objective of accreditation of the Food Protection Manager exam.

#### **4. Recommended Solution: The Conference recommends.....**

...to change (current) Section 1-201.10 (B)(1)(a) of the 2001 FDA Food Code to read:

(a) “Accredited program” means a food protection manager certification program that has been evaluated and listed by a Conference for Food Protection recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs

- Add “Conference for Food Protection recognized” before accrediting agency.
- Deleting “national standards for organizations that certify individuals” and replacing with “Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs”.

- If approved, addressing corresponding changes if needed in Annex 3, Chapter One.

The CFP Food Protection Manager Training, Testing and Certification Committee Meeting approved the above recommendation on December 16, 2003.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-010  
Internal # 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.*

### 1. Title:

On Line Food Manager Certification

### 2. Issue you would like the Conference to consider:

Jurisdictions around the US have requirements for food manager certification based on local laws and rules. Currently CFP recognizes exams that have met the standards of CFP/ANSI. Local jurisdictions have the option of referencing these CFP/ANSI recognized programs as meeting eligibility requirements. On line examinations are common for a variety of professions including CEU's for physicians, certifications for realtors, attorneys, law enforcement, etc. The same security issues exist whether the exam is paper based or taken via a secure Internet connection. Testing companies typically require a proctor to be present to administer an exam. Internet based exams should be given the same treatment as paper based exams, as there is inherently no more risk of security breaches, as the current system of testing is one based on the honor system. Internet based exams that have met the tests for reliability, fairness, validity and relevance should be afforded the same accreditation as paper ones.

### 3. Public Health Significance:

Online learning systems coupled with online examinations have the ability to reach far more persons, and result in higher rates of retention of food safety information than similar paper based exams and learning systems. The public health impact of this would be to improve the sanitation of facilities by providing accessible, relevant and reliable information through Internet learning, and make certification far easier to candidates who now must either hire a trainer and/or proctor. Employers may be more likely to comply with certification requirements when the exam and learning materials are easily accessible.

### 4. Recommended Solution: The Conference recommends.....

The Conference recommends that Internet based exams be given the same accreditation as paper based exams as long as they meet CFP/ANSI standards.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-011  
Internal # 064

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Interdisciplinary training in foodborne illness investigations

### 2. Issue you would like the Conference to consider:

The successful, rapid investigation of potential foodborne illness outbreaks, determination of source(s), containment, media response, and follow-up, requires a combination of governmental disciplines, including field inspectors, registered nurses, physicians, epidemiologists, communications specialists, and State, Local and Federal management, along with industry, academia, and others. The importance of the desired smooth interaction, and pre-planned and practiced series of processes, is made even more critical as a result of the threat of foodborne bio-terrorism and tampering. It is likely that the extent of a problem could hinge on the knowledge and action of first responders, the local health officials and food establishment operators.

While sources of information on epidemiology exists in various venues, including publications, the internet, FDA training sites, etc., based on discussions between Federal, State and Local agencies, and industry, a need exists to educate the various governmental agencies and industry counterparts, to improve and optimize food borne illness investigations, and responses. For this purpose, a pilot program titled "Epi-Ready - Foodborne Illness Response Strategies" was developed. It was funded by CDC, under the auspices of the National Environmental Health Association, and involved numerous agencies and individuals including FDA. The pilot program is under way at the time of this submission (in early 2004).

This submitter, and others from various agencies and from industry, would like the Conference to consider the importance of this training and materials, determine how this information relates to the FDA Standards, and make recommendations as to the contents, training, certification of individuals and/or agencies, and support the further development of the materials and programs.

### 3. Public Health Significance:

The rapid investigation of foodborne illness outbreaks and identification of source(s) is critical to protection of the public. In this age of potential food related bioterrorism and product tampering, the ability of all governmental agencies and industry to work together will be of national concern to the health and welfare of the public. The ability of all disciplines to work well together will be fundamental to providing accurate information to epidemiologists and those who monitor the nation's health. It is critical that early in the

investigation, specific assessment to be made of industry's systems/procedures (restaurant, distribution and supplier) to determine any potential and actual risk to determine the cause/source of the outbreak.

#### **4. Recommended Solution: The Conference recommends.....**

The Conference recommends

- 1) that the importance of smooth functioning, interdisciplinary efforts of foodborne illness investigations and response be given the highest priority,
- 2) that the potential for foodborne bioterrorism and tampering adds a new and broader range of complexities and considerations to foodborne illness investigations,
- 3) that significant interdisciplinary training is needed at both the local level and between governmental agencies and industry,
- 4) that a Conference for Food Protection committee under Council II be formed with a recommended title "Foodborne Illness Interdisciplinary Investigation and Response Training",
- 4) that the Epi-Ready Program is a starting point for discussion of this committee,
- 5) that the core of the committee be formed to include representatives of FDA Training, NEHA, Council of State & Territorial Epidemiologists (CSTE), CDC, certain other State, Local and Federal agency individuals that have been involved with the Epi-Ready programs, and Food Safety professionals from industry and academia, and
- 6) that the charges to the committee be
  - a) to meet telephonically with support of CFP funding,
  - b) survey information that currently exists,
  - c) prepare a written report with recommendations on the Epi-Ready and other programs to the Conference Board by the August-September 2004 Board meeting.Additionally,
  - d) that the committee include in its recommendations whether a basic certification program of governmental officials and industry food safety professionals should occur, and in what form,
  - e) and make other recommendations as the committee feels necessary as to the content of training, delivery methods and oversight organization(s).

#### **5. Submitter:**

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-012  
Internal # 032

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Revision of Standard #5, Foodborne Illness Investigation and Response to include food security / food terrorism preparedness and response.

### 2. Issue you would like the Conference to consider:

The current Standard #5 applies to the surveillance, investigation, response, and subsequent review of alleged food-related emergencies, either unintentional or deliberate, that results in illness or outbreaks. The CFP Program Standards Committee seeks the endorsement of the Conference that the Committee work with the FDA Clearinghouse Work Group to revise Standard #5 to include food security / food terrorism preparedness and response.

### 3. Public Health Significance:

Post September 11, 2001, the concern of deliberate contamination of the food supply has increasingly become an area for attention by each regulatory food jurisdiction. Each jurisdiction must assume responsibility for maintaining the safety of the food supply within its state and received via interstate transport. Federal recommendations are one resource to jurisdictions for development of a food security program within its areas of responsibility.

A revised Standard #5 that addresses food security would make available to enrolled jurisdictions a marker for developing their food security measures. The areas of Investigative Procedures, Reporting, Laboratory Support, Traceback Procedures, Recalls, and Program Outcomes are all potential sections of the Standard to update.

The latest revision from the Clearinghouse is attached as Attachment 1.

### 4. Recommended Solution: The Conference recommends.....

that the CFP Program Standards Committee work with the existing FDA Program Standards Clearinghouse Work Group to revise Standard #5 to include food security / food terrorism preparedness and response.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-013  
Internal # 002

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Food Security at retail.

### 2. Issue you would like the Conference to consider:

It is recommended that the preface of the FDA Food Code, offer a discussion on Food Security issues at retail.

### 3. Public Health Significance:

Recent events have made it necessary to consider food security (the intentional contamination of food) as important as food safety issues. Consideration of both food safety and food security need to be considered when assessing the public health issues regarding the safety of the food supply. Numerous guidance documents have been written by regulatory, academia and industry trade groups addressing this issue.

### 4. Recommended Solution: The Conference recommends.....

that the preface of the FDA Food Code, offer a discussion on Food Security issues at retail. It is also recommends Annex 2 of the FDA Food Code include a reference section that would provide a summary (website and contact information) of available resources on food security for retail. This should include but not be limited to guidance documents provided by regulatory authorities, academia, and industry groups.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-014  
Internal # 055

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Guidance regarding safety and security guidelines for the transportation and distribution of meat, poultry, and egg products

### 2. Issue you would like the Conference to consider:

On August 4, 2003, FSIS published a notice of availability regarding new safety and security guidance materials associated with meat, poultry, and egg products in the Federal Register (68 FR 45789). FDA has prepared similar guidance for other food commodities. The guidance materials are specifically designed for food processors and can be adapted for use by retail and food service providers. As stated in the Federal Register, the guidelines were developed to assist facilities and shippers of all sizes, as well as Federal, State, and local authorities, to improve food safety and security in the handling of FSIS-regulated products at every step in the transportation and distribution process. While these guidelines are voluntary, and parties may choose to adopt measures suggested by many different sources, it is vital that all parties in the transportation and distribution process for meat, poultry, and egg products take steps to ensure the security of their operations, the integrity of their processes and products, and the continued safety of the products that they handle.

### 3. Public Health Significance:

American food producers and retailers have a vested interest in making biosecurity a priority. The potential for unintentional and intentional contamination is of significant concern to public health. The transportation and handling of food result in the movement of billions of pounds of product each year. The potential for public harm is significant. Diligence regarding awareness about food security risk potential is critical for maintaining biosecurity and safety. Thus, awareness by all sectors of the food industry is an important step in improving public health.

### 4. Recommended Solution: The Conference recommends.....

The Conference recommends that FDA in consultation with USDA develop guidance for retail establishments to be included in the Annex of the Food Code, which incorporates information on biosecurity and safety of food.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-015  
Internal # 019

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Certification of Food Safety Regulation Professionals

### 2. Issue you would like the Conference to consider:

Work Group 1 of the Program Standards Committee (Council II) was assigned to investigate options for addressing the charge imposed by Issue 02-02-14 (CFP 2002) in regards to the credentialing of regulatory food inspection personnel. A detailed report is attached which outlines the key Work Group discussion points for a multi-tiered approach to training and/or credentialing; issues for Council II deliberation and a cooperative review of the FDA ORA University program.

### 3. Public Health Significance:

The food service industry and regulators recognize the need for a model credentialing program for food inspection personnel that is equal to or exceeds the requirements for food protection managers. While many variations of programs exist, there is a strong desire for the Conference to help facilitate adoption of a model format for the training or credentialing of food safety regulation professionals.

### 4. Recommended Solution: The Conference recommends.....

adoption of the Program Standards Committee Work Group 1 report relative to the certification of food safety regulation professionals.

### 5. Submitter:

<b>Name:</b>	Lee Cornman & Jorge Hernandez, Co-Chairs		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-016  
Internal # 044

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Certification of Food Safety Regulation Professionals

### 2. Issue you would like the Conference to consider:

Work Group 1 of the Program Standards Committee (Council II) was assigned to investigate options for addressing the charge imposed by Issue 02-02-14 (CFP 2002) in regards to the credentialing of regulatory food inspection personnel. Group discussions and research has resulted in a series of six recommended actions specific to this issue for Conference consideration. These recommended actions are as follows:

1. In future Conference discussions relative to training or credentialing of individuals responsible for the regulation of retail food establishments, these members of the regulatory authority should be referred to as "food safety regulation professionals".
2. That the Conference
  - a. develop a multi-tiered approach to the credentialing of regulatory officials and
  - b. evaluate the potential incorporation of existing training and/or certification programs.
3. That the Conference charge the Program Standards Committee with using the FDA Program Standards - Standard No. 2 as the model for the evaluation of other training or credentialing programs for food safety regulatory professionals.
4. That the Conference request FDA provide guidance on how subpart 8-402.10 can be practicably implemented within a regulatory food program and what may be the resulting legal ramifications to state or local jurisdictions that have adopted Chapter 8 by reference.
5. That the Conference charge the Program Standards Committee with conducting a joint review with FDA of the FDA ORA University training curriculum as it pertains to Standard No. 2.
6. That the Conference charge the Program Standards Committee with formally approaching FDA on the concept of forming a cooperative partnership with a focus on training, standardization and/or certification of food safety regulation professionals.

A detailed report is attached which outlines the key Work Group discussion points for a multi-tiered approach to training and/or credentialing; issues for Council II deliberation and a cooperative review of the FDA ORA University program.



### 3. Public Health Significance:

The food service industry and regulators recognize the need for a model credentialing program for food inspection personnel that is equal to or exceeds the requirements for food protection managers. While many variations of programs exist, there is a strong desire for the Conference to help facilitate adoption of a model format for the training or credentialing of food safety regulation professionals.

### 4. Recommended Solution: The Conference recommends.....

that the Conference create a 2004 Program Standards Committee and that they be charged with facilitating the recommendations contained within the 2002 Program Standards Committee Work Group report.

<b>5. Submitter:</b>			
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**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**1. Title:**

Certification of Health Officials- section 8-402.11

**2. Issue you would like the Conference to consider:**

There is no national requirement that outlines a minimum educational component for regulatory officials.

The current food code language in section 8-402.11 is not specific and does not provide the regulatory official with the elements they need to know in order to have the knowledge, skills and ability to adequately perform their required duties. Although there are programs available to the regulatory official that would provide the necessary training, many are not feasible while being specific to food safety.

In order to focus the inspection efforts on food safety and sanitation and to better communicate the results of the inspection to the establishment, regulatory officials should possess, at a minimum, the same level of food safety knowledge as the industry it is regulating. Regulatory persons that possess a credential in food safety and sanitation will better assess the food safety knowledge of the person in charge and the conditions of the establishment.

Montana state officials recognized this fact and passed legislation in the State setting minimum requirements for inspector certification and training. More states should take this lead.

**3. Public Health Significance:**

Regulatory officials that earn a food safety credential before they begin conducting inspections on their own, and as a start to their training curriculum, will be able to apply their knowledge immediately and better assure the protection of the public's health.

**4. Recommended Solution: The Conference recommends.....**

Regulatory officials who conduct inspections of food establishments should be required to take and pass, at a level that will allow the Regulatory Official to be eligible for trainer status, a food protection manager certification examination that is accredited by ANSI/CFP.

Additionally, the Regulatory Officials must have completed state training that "standardizes" the inspector on methods of inspections prior to conducting foodservice

audits on their own. Standardization programs support uniformity of applying the Food Code within and among local health departments.

As such section 8-402.11 be amended to read:

B. Any individual intending to inspect the facilities, equipment, processes, premises, records or other information of a food establishment for compliance with food safety standards on behalf of the jurisdiction, must have shown proficiency in food safety and sanitation practices through passing a food protection manager certification examination that is accredited through ANSI/CFP at a level that will allow the Regulatory Official to become eligible for trainer status with the organization providing the exam and must have been standardized by the state prior to conducting inspections.

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-018  
Internal # 040

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

CFP Inspection Form Committee, Recommendation to accept committee report.

### 2. Issue you would like the Conference to consider:

During the 2000 CFP, the Inspection Form Committee (hereafter referred to as the Committee) was formed. Charges included working on the elements and concepts that should be included on an inspection form and bringing the form to the 2002 CFP. These charges were fulfilled at the 2002 CFP; the 2004 Committee was asked to continue their work. The Committee was given four tasks to complete their charge. These tasks were:

- a. Designing an instructional document to assist inspectors and other individuals in properly completing the proposed inspection forms, presented by the Committee; and
- b. Developing a field test of the proposed inspection forms and instructions to be conducted in coordination with volunteers from industry and federal, state and local regulatory agencies; and
- c. Posting the latest version of the inspection form and instructions on the CFP website [www.foodprotect.org](http://www.foodprotect.org); and
- d. Working with FDA to refine the attached elements and justifications for addition to Annex 4, Section 6, Inspection Report of the FDA Food Code.

This issue presents the report of the Committee and the summary of the two pilot tests that were conducted in order to test and improve the proposed inspection form. This issue addresses and fulfills all charges a, b, c and d as listed above. This issue seeks acceptance of the committee's report and pilot test.

FDA Food Code, Annex 4, Sections 5, 6 and 11 and Annex 7, Form 3-B; FDA Recommended National Retail Food Regulatory Program Standards.

### 3. Public Health Significance:

An inspection form is critical to all regulatory agencies to document violations in food establishments and to provide information to the industry to help them resolve identified violations. It further assists in the collection and evaluation of inspection data that can help identify trends that may need to be addressed throughout a program. These trends can identify training needs at the inspector level, chain establishment level or on a jurisdiction level for all establishments.

Although a check-off style form facilitates collection and categorization of data for analytical purposes, the industry finds specific, written comments to be more helpful in identifying and resolving the specific opportunities noted in their establishment.

The Committee's report documents the steps taken to ensure the form developed is: 1) thorough, user friendly and a valuable tool in helping to provide a safe food supply to consumers, 2) beneficial in helping jurisdictions meet the FDA's program standards, and 3) valuable in helping industry to identify food safety opportunities. The report shows we had moderate to good acceptance of the form initially, and dramatically improved acceptance after the form was revised based on the first pilot test's comments.

**4. Recommended Solution: The Conference recommends.....**

...that the attached report of the Inspection Form Committee be accepted.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-019  
Internal # 020

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

CFP Inspection Form Committee, Recommendation to accept Inspection Form and instructional documents.

### 2. Issue you would like the Conference to consider:

During the 2000 CFP, the Inspection Form Committee (hereafter referred to as the Committee) was formed. Charges included working on the elements and concepts that should be included on an inspection form and bringing the form to the 2002 CFP. These charges were fulfilled and at the 2002 CFP the Committee was asked to continue their work and was given four tasks to complete their charge. These tasks were:

- a. Designing an instructional document to assist inspectors and other individuals in properly completing the proposed inspection forms, presented by the Committee; and
- b. Developing a field test of the proposed inspection forms and instructions to be conducted in coordination with volunteers from industry and federal, state and local regulatory agencies; and
- c. Posting the latest version of the inspection form and instructions on the CFP website [www.foodprotect.org](http://www.foodprotect.org); and
- d. Working with FDA to refine the attached elements and justifications for addition to Annex 4, Section 6, Inspection Report of the FDA Food Code.

This issue presents the inspection form, the marking instructions and the food code citations for each of the items on the form. This issue fulfills charge 'a.' as listed above. This issue seeks acceptance of these documents.

FDA Food Code, Annex 4, Sections 5, 6 and 11 and Annex 7, Form 3-B; FDA Recommended National Retail Food Regulatory Program Standards.

### 3. Public Health Significance:

The recommended form emphasizes the risk factors and interventions for foodborne illness so that the inspector's attention is focused on those items that will have the greatest impact on reducing foodborne illness. This form does not focus specifically on critical items, although they are identified on the code citation reference sheets. Some critical items are seldom identified as contributing to foodborne illness, often due to good controls that have been put into place nationwide. Our goal was to focus the inspector's, as well as the operator's, attention on those things which are most commonly associated with foodborne illness—specifically, employee knowledge, health and hygiene, and food source, contamination and temperature. Using a standard inspection form nationally helps both regulatory agencies and industry (especially, multi-state chains) track progress

in minimizing risk factors for foodborne illness. These forms were designed to also assist jurisdictions in meeting FDA's Program Standards, specifically standards 3, 4 and 6.

The reverse side of the check-off form has code citations for each of the Risk Factor and Intervention items. A similar code citation reference sheet for the Good Retail Practices (GRP) items is also provided in the marking instructions. This facilitates both industry and regulatory familiarization with the food code and its requirements. The blank addendum sheet allows inspectors the flexibility to be more specific and thorough in explaining opportunities found during inspections. Industry often finds specific, detailed comments more effective in helping correct violations and understanding code requirements than a check-off sheet. The attached marking instruction's document further defines when and where an item is to be documented on the inspection form. These marking instructions and code citations will help inspectors and the regulated community understand how to avoid and correct violations. Additional information on form design and logic is provided in the Committee's report.

#### **4. Recommended Solution: The Conference recommends.....**

that the Conference Chair send a letter to the FDA Commissioner to urge the following changes to the Food Code:

1. Incorporate the attached Inspection Form into the Food Code as Annex 7, Form 3-B, and;
2. Incorporate the Marking Instructions and Risk Factors/Interventions and GRP Code Citations into Annex 4 of the Food Code.

#### **5. Submitter:**

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**CONFERENCE FOR FOOD PROTECTION**  
**2004 ISSUE FORM**      Issue # 2004 II-020  
Deadline Feb 2, 2004      Internal # 021

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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**1. Title:**

Definitions for Risk Factor, Public Health Intervention and Good Retail Practice.

**2. Issue you would like the Conference to consider:**

The terms 'risk factor' and 'public health intervention' are used in the preface of the food code; these terms, along with 'good retail practice,' are also defined in the 'Voluntary National Retail Food Regulatory Program Standards;' and the proposed Model Inspection Form is designed with these three terms and their concepts as the basis for the form. These definitions should be included in section 1-201.10 of the Food Code.

**3. Public Health Significance:**

These terms need to be defined to help regulatory agencies, industry and the consumer understand which items are a focus or point of emphasis in the food code, program standards and on the food establishment inspection report.

**4. Recommended Solution: The Conference recommends.....**

....the Conference Chair send a letter to the FDA Commissioner to urge the following definitions be incorporated into Section 1-201.10 of the food code:

"PUBLIC HEALTH INTERVENTION" means one of the preventive measures to protect consumer health as stated below:

- i. Management's demonstration of knowledge;
- ii. Employee health controls;
- iii. Controlling hands as a vehicle of contamination;
- iv. Time / temperature parameters for controlling pathogens; and
- v. Consumer advisory.

"RISK FACTOR" means one of the improper practices or procedures as stated below which are most frequently identified by epidemiological investigation as a cause of foodborne illness or injury:

- i. Improper holding temperature;
- ii. Inadequate cooking;
- iii. Contaminated equipment;
- iv. Unsafe source; and
- v. Poor personal hygiene.



"GOOD RETAIL PRACTICE or (GRP)" means a preventive measure that includes practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that is prerequisite to instituting a HACCP or Risk Control Plan, and is not addressed by a public health intervention or risk factor.

<b>5. Submitter:</b>			
<b>Name:</b>	Lorna Girard, Chair, Inspection Form Committee		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-021  
Internal # 022

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

CFP Inspection Form Committee, Recommended Elements that should be on an Inspection Form and their Justification.

### 2. Issue you would like the Conference to consider:

During the 2000 CFP, the Inspection Form Committee was formed. Charges included working on the elements and concepts that should be included on an inspection form and bringing the form to the 2002 CFP. This was accomplished and at the 2002 CFP the inspection form committee was asked to further refine their justification. This issue presents the justification for the elements that are included on the current inspection form. When designing and refining the actual form, these elements were used to determine which Food Code items should be on the inspection form and a justification was written to explain why they should be on the form. Additional justifications could be taken from the Public Health Reasons, Annex 3, of the FDA Food Code. FDA Food Code, Annex 3; Annex 4, Sections 5, 6 and 11; and Annex 7, Form 3-B; FDA Voluntary National Retail Food Regulatory Program Standards.

### 3. Public Health Significance:

The Inspection Form Committee worked closely with FDA to identify items that should be on the inspection form. The goal of our Committee was to identify items in the Food Code that are more likely than others to cause foodborne illness and to provide a one page inspection sheet that would help focus the inspector's time and efforts on those items. The attached Justification paper explains why the items that are on the inspection sheet were selected.

### 4. Recommended Solution: The Conference recommends.....

....the Conference Chair send a letter to the FDA Commissioner requesting that the attached justification be incorporated into Annex 4, Section 6, Inspection Report of the FDA Food Code.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-022  
Internal # 028

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

CFP Program Standards Committee, Recommendation to Accept Committee Report

### 2. Issue you would like the Conference to consider:

The CFP Program Standards Committee seeks Council II's acceptance of its committee report.

### 3. Public Health Significance:

In addition to its summary report, the Program Standards Committee has submitted six issues for consideration at the 2004 meeting of the Conference for Food Protection. These issues have been studied carefully, and the members of the Program Standards Committee believe the recommendations offered in the issues will enhance the criteria and protocol of the FDA's Voluntary National Retail Food Regulatory Program Standards.

### 4. Recommended Solution: The Conference recommends.....

acceptance of the CFP Program Standards Committee report and the continuation of the Program Standards Committee at least through the 2006 meeting of the CFP.

### 5. Submitter:

<b>Name:</b>	Diann Worzalla and David McSwane		
<b>Organization:</b>	CFP Program Standards Committee Co-Chairs		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-023  
Internal # 029

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Baseline Survey Frequency Change

### 2. Issue you would like the Conference to consider:

The CFP Program Standards Committee seeks the Conference's approval to change the "Voluntary National Retail Food Regulatory Program Standards" baseline survey frequency from a 3-year to a 5-year cycle to match FDA's national survey cycle.

### 3. Public Health Significance:

In 1998 the Food and Drug Administration (FDA) developed the Draft Voluntary National Retail Food Regulatory Program Standards (hereafter called the Standards) which consists of nine components. The last component, Standard No. 9 - Program Assessment, establishes how a jurisdiction can measure the effectiveness of its program. One of the essential program elements required to meet this Standard is for the jurisdiction to conduct a baseline survey and report on the occurrence of risk factors and the use of Food Code interventions. As currently written, the baseline information is to be updated at least once within every three-year audit interval to measure trends.

The intent of establishing a baseline of current compliance with Food Code provisions that address the CDC-identified risk factors is to track the change in the occurrence of risk factors through future comparison studies.

The initiative to create the FDA Retail Food Program Database of Foodborne Illness Risk Factors began in January 1997, and is ongoing. The project's purpose is to establish a baseline against which industry and regulatory efforts to change behaviors and practices directly related to foodborne illness will be measured. It recognizes the need to fill a void that currently exists in the assessment of program effectiveness for controlling these risk factors.

By establishing a baseline, the information gathered from future field inspections can be used to measure trends in terms of compliance with specific requirements of the Food Code. It is expected that an improvement in compliance with the Food Code provisions that address these risk factors will have a direct impact on the occurrence of foodborne illness.

Completion of the baseline surveys requires a major resource commitment by the jurisdiction. The FDA national surveys are being conducted at 5-year intervals. The Standards Committee and the Clearinghouse Work Group both endorse changing the baseline survey frequency in Standard No. 9 from a 3-year to a 5-year cycle to match FDA's national survey cycle.

**4. Recommended Solution: The Conference recommends.....**

changing FDA's Voluntary National Retail Food Regulatory Program Standards, STANDARD NO. 9, baseline survey frequency to a 5-year cycle to match the national survey interval.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-024  
Internal # 030

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Compliance and Enforcement Legal Remedies

### 2. Issue you would like the Conference to consider:

The CFP Program Standards Committee seeks the Conference's approval to change the "Voluntary National Retail Food Regulatory Program Standards", Standard No. 1 and reflected Appendix A-5 so that criminal OR injunctive OR civil penalties are combined in the same line item (12, 13, 14) and rename it "Legal Remedy".

### 3. Public Health Significance:

In 1998 the Food and Drug Administration (FDA) developed the Draft Voluntary National Retail Food Regulatory Program Standards (hereafter called the Standards) which consists of nine components. The first component, Standard No. 1 - Regulatory Foundation, establishes the essential program elements required to meet acceptable regulatory oversight of the retail food industry.

One essential element of Standard No. 1 is for a jurisdiction to have compliance and enforcement provisions at least as stringent as Annex 1 of the Food Code as shown in Standard 1, Appendix A, Table A-5. The criteria for compliance with this element are for the jurisdiction to meet all 15 of the items listed on Table A-5.

Items 12, 13 and 14 currently read:

- 12 - Criminal Proceedings
- 13 - Petitions for Injunction
- 14 - Civil Penalties provided

Passing for the "Compliance and Enforcement" component requires a "Yes" for each of the 15 Compliance and Enforcement requirements.

The Standards Committee and Clearinghouse Work Group both agree that a foundation for an effective enforcement program does not necessarily need to contain both criminal and civil penalties in order to meet the intent of the FDA Food Code.

The desired outcome of Standard No. 1 is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

**4. Recommended Solution: The Conference recommends.....**

changing FDA's Voluntary National Retail Food Regulatory Program Standards, Standard No. 1 and reflected Appendix A-5 so that criminal OR injunctive OR civil penalties are combined in the same line item (12, 13, 14) and rename it "Legal Remedy".

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-025  
Internal # 031

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

CFP endorsement of FDA field testing of the draft Audit Manual For Conducting Voluntary National Retail Food Regulatory Program Standards Self-Assessment Evaluations, 12/03.

### 2. Issue you would like the Conference to consider:

The CFP Program Standards Committee seeks the Conference's endorsement of FDA field testing of the draft Audit Manual for conducting Voluntary National Retail Food Regulatory Program Standards Self-Assessment Evaluations. The manual is a 'how-to' guide written to auditors for their use in conducting verification audits of the self-assessments completed by jurisdictions. Audit forms and directions for auditing each of the nine Standards are included in each chapter numbered to correspond with one of the Standards.

### 3. Public Health Significance:

In 1998 the Food and Drug Administration (FDA) developed the Draft Voluntary National Retail Food Regulatory Program Standards (hereafter called the Standards) with input from federal, state and local regulatory officials, industry, trade associations, academia and consumers. The purpose of the Standards is to serve as a guide to regulatory retail food program managers in the design and management of a retail food program and to provide a means of recognition for those programs that meet the Standards. The Standards provide jurisdictions with a framework upon which to build their programs so that the focus is on the reduction of risk factors known to cause foodborne illness. The Standards require regulatory programs to assess the retail food industry's level of active managerial control over these risk factors, offer intervention strategies to aid industry in compliance and to track the occurrence of the risk factors over time. The Standards consist of nine components. The last component, Standard No. 9 - Program Assessment, establishes how a jurisdiction can measure the effectiveness of its program and describes how the Standards' process is implemented. Firstly, Standard No. 9 requires the regulatory program manager to conduct an initial self-assessment of their retail food safety program within 12 months of enrolling in the Standards and every 36 months thereafter. A self-assessment is an internal review by program management to determine whether their existing program meets each of the Standards. The Standards are intended to provide the goals and criteria for a continuous improvement process. Following self-assessment, jurisdictions are encouraged to establish action plans that suit their resources and priorities and that will help them move steadily toward attainment of each of the Standards. Participation in the Standards is voluntary, and a jurisdiction may work at its own pace, with the ultimate goal of achieving all nine of the program Standards.



One aspect of Standard No. 9 is a verification audit, which is the subject and purpose of the manual. A verification audit is a systematic, independent examination by an external party to confirm the accuracy and completeness of the regulatory program's self-assessment. The audit may be performed by any authorized city, county, district, state, federal, tribal official or other third party who has no responsibilities for the day-to-day operations of the program being audited and is charged with conducting a verification audit. The auditor must be able to perform his or her duties objectively and without any conflict of interest. The first verification audit must be conducted within 36 months following the initial self-assessment and every 3 years thereafter following subsequent self-assessments. The verification audit confirms and reports on the accuracy of the self-assessment. The findings of the audit will determine whether a jurisdiction will maintain its national listing as having met an individual Standard as reported by the jurisdiction. Continued enrollment in the Standards as an active participant, as attested by the website posting of self-assessment results and audit verification, is dependent upon regular self-assessments and verification audits as stated in the Standards. The verification audit lends credibility to the information reported by a jurisdiction and is essential to the integrity of the national Standards listing.

**4. Recommended Solution: The Conference recommends.....**

Endorsement of FDA field testing of the draft Audit Manual to address its effectiveness, process, and application; FDA report back at the 2006 CFP meeting its findings and consideration of state and tribal feedback.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-026  
Internal # 033

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Extension of Phase-In Time for Compliance with Risk Factors and Interventions

### 2. Issue you would like the Conference to consider:

The CFP Program Standards Committee seeks the Conference's approval to change the "Voluntary National Retail Food Regulatory Program Standards", Standard No. 1 and reflected Appendix A-1 to extend the phase-in time for compliance with 11 of the 11 risk factors and interventions in nine-years (by the third audit).

### 3. Public Health Significance:

In 1998 the Food and Drug Administration (FDA) developed the Draft Voluntary National Retail Food Regulatory Program Standards (hereafter called the Standards) which consists of nine components. The first component, Standard No. 1 - Regulatory Foundation, establishes the essential program elements required to meet acceptable regulatory oversight of the retail food industry.

One essential element of Standard No. 1 requires that the regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the Food Code. To meet this element of the Standard, regulations must have a corresponding requirement for the Food Code sections as listed in Appendix A, Table A-1 and summarized in Table A-2, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations."

For initial listing, the regulatory foundation must contain at least 9 of the 11 interventions and risk factor controls. Currently, in order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the second audit. This issue involves extending the period for compliance with all eleven of the risk factors and interventions from two assessment cycles (six years) to three assessment cycles (nine years).

The Standards Committee supports this phase-in extension understanding that modification to law or regulation can be a lengthy and time-consuming process. The Standards are intended to provide the goals and criteria for a continuous improvement process and designed for jurisdictions to work at their own pace, with the ultimate goal of achieving all aspects of the Standards.

The desired outcome of Standard No. 1 is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

**4. Recommended Solution: The Conference recommends.....**

changing the "Voluntary National Retail Food Regulatory Program Standards", Standard No. 1 and reflected Appendix A-1 to extend the phase-in time for compliance with 11 of the 11 risk factors and interventions to nine-years (by the third audit).

**5. Submitter:**

<b>Name:</b>	Diann Worzalla and David McSwane		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-027  
Internal # 047

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Request to consider whether or not a minimum level of food allergy knowledge should be required for managers or persons in charge of retail food establishments.

### 2. Issue you would like the Conference to consider:

Food allergy is increasing and accounts for 30,000 emergency room visits and up to 200 deaths each year. The current consensus among scientists is that about 7 million Americans suffer from food allergy. Several published studies have shown that reactions occur in restaurants, some leading to death. One study of 32 fatal reactions showed that 47% of the deaths occurred as a result of restaurant meals. In a study of peanut and tree nut reactions scientists learned that reactions were caused by server error, ingredient switches, lack of communication between the kitchen staff and the wait staff, and cross contact between allergy-free and allergy-containing food. A survey of 490 attendees to Food Allergy and Anaphylaxis Network's (FAAN) conferences in '03 showed 93% had eaten in a restaurant in the past year, 47% reported having a reaction. Major concerns included cross contact and knowledge and training of restaurant staff regarding food allergy. This survey showed that food-allergic consumers are frequenting restaurants. Industry leaders have told us that very little training and education is provided to employees in this field. Education of the industry will protect everyone--the consumers and the industry. A small group of industry leaders, working as advisors to FAAN, have agreed that a minimum level of knowledge on food allergy information would be advisable for managers or persons in charge of retail food establishments.

### 3. Public Health Significance:

A minimum level of food allergy knowledge will allow managers or persons in charge of food service, retail food or vending operations to understand the potential seriousness of food allergy and how they can help save a life by providing accurate information to consumers with food allergies. Currently, the training and certification materials for certified food managers being used by the industry offer alarmingly different levels of food allergy information. At least one training program provides extensive, accurate information about food allergy. Other training and certification programs provide almost no information, or it is incorrect and misleading. A standard minimum level of food allergy knowledge for managers or persons in charge of retail food establishments would ensure that the training and education of the staff is consistent within the retail food industry.

**4. Recommended Solution: The Conference recommends.....**

We respectfully request that the CFP Manager Training, Testing, and Certification Committee or other suitable committee determine the minimum level of food allergy knowledge necessary for managers or persons in charge of retail food establishments and that this information be included as part of the Certified Food Manager exam recognized by the Conference for Food Protection.

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 II-028  
Internal # 092

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**1. Title:** [Briefly describe the purpose of this Issue.]

Creation of Coordinated Educational or Instructional Materials for Emergencies

**2. Issue you would like the Conference to consider:**

There is a critical need for consistent and scientifically sound guidance that both regulators and food industry decision-makers can use during emergencies involving the retail segment. The purpose of the FDA Model Food Code is to provide guidance needed to ensure the safety and protection of food offered at retail. Yet neither the Code nor the Annexes currently address public and private sector coordination during food emergencies.

**3. Public Health Significance:**

The widespread power outage and associated water interruption that occurred throughout the northeastern U.S. in August 2003 revealed dramatic public health vulnerabilities. State and local regulatory officials did not have uniform policies/procedures in place for dealing with an event simultaneously involving thousands of facilities. This was exacerbated by the inability to communicate when phone and computer systems went down. Food establishments also lacked information about how to operate safely during the power outage and water supply interruption. Many continued to use untreated water as a food ingredient during the boil-water alert. Results from a non-random sample of Michigan inspections documented 36% of grocery and convenience stores offering at least some temperature-abused, perishable food for sale a day after power was restored.

**4. Recommended Solution: The Conference recommends.....**

The Conference For Food Protection should form a work group to recommend uniform educational and instructional materials that communicate emergency procedures for the retail segment including:

- a. A generic emergency management framework with recommended roles and responsibilities for both public and private sectors during imminent health hazards,
- b. Specific guidance for the specific scenarios identified in the FDA Model Food Section 8-404.11, Ceasing Operations & Reporting, and
- c. Tools that assist retail food managers to participate in coordinated public and private sector responses to food emergencies.

Michigan regulators and retail food industry leaders are developing working draft guidance documents that could serve as a starting point for further discussion (examples attached). These documents will be further refined prior to the CFP Meeting in April. We welcome collaboration from out-of-state retail food organizations.

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM

Deadline Feb 2, 2004

Issue # 2004 III-001

Internal # 004

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Acceptance of the Retail HACCP Committee report by the Conference for Food Protection.

### 2. Issue you would like the Conference to consider:

The Retail HACCP Committee requests that the Conference for Food Protection accept the final report inclusive of several documents: 1) the two (2) draft guidance documents developed by FDA and reviewed by the CFP Retail HACCP Committee. "Managing Food Safety: A Guide for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments" which provides to retail and food service operators a step-by-step procedure for developing a voluntary food safety management system based on HACCP principles with the goal is for the operator to achieve active managerial control of risk factors identified by CDC as major contributors to foodborne illness; 2) "Managing Food Safety: A Regulator's Guide for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems" which provides guidance to regulators of retail and food service on conducting risk-based inspections. In addition, it provides intervention strategies that can be developed with operators to assist them in their efforts to achieve active managerial control of foodborne illness risk factors, and 3) recommendations to the FDA regarding the foodborne illness risk factor database. The committee carefully reviewed both HACCP guides for clarity and accuracy.

### 3. Public Health Significance:

The wide variety of practices in retail and food service establishments do not always lend themselves to a "one-size-fits-all" approach to managing food safety. Implementation of the FDA guidance provides the retail and food service industries with a valuable tool that can be customized by individual operations to increase food safety. Additionally, the development and acceptance of the guidance for regulators for applying HACCP principles to risk-based retail and food service inspections will allow resources to be focused on the prevention of factors that might lead to foodborne illness outbreaks.

The safety of foods, as they flow from farm to table, benefit from focused attention on those steps in the path that have a greater risk of contributing to hazards in food that could cause foodborne illness. By voluntarily incorporating HACCP principles, greater attention can be given to controlling the steps and activities which will most likely cause foodborne illness. Additionally, the FDA Foodborne Illness Risk Factor Database is another tool for both industry and regulatory to use and allows both to focus resources in the prevention of foodborne illness outbreaks.



**4. Recommended Solution: The Conference recommends.....**

The Retail HACCP Committee respectfully requests that the Conference for Food Protection accept the committee's report. (see attachments).

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-002  
Internal # 005

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Endorsement of the FDA HACCP Guides by the Conference of Food Protection.

### 2. Issue you would like the Conference to consider:

The Retail HACCP Committee requests that the Conference of Food Protection endorse two guidance documents developed by FDA and reviewed by the CFP Retail HACCP Committee. "Managing Food Safety: A Guide for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments" provides to retail and food service operators a step-by-step procedure for developing a voluntary food safety management system based on HACCP principles. The goal is for the operator to achieve active managerial control of risk factors identified by CDC as major contributors to foodborne illness. "Managing Food Safety: A Regulator's Guide for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems" provides guidance to regulators of retail and food service on conducting risk-based inspections. In addition, it provides intervention strategies that can be developed with operators to assist them in their efforts to achieve active managerial control of foodborne illness risk factors.

### 3. Public Health Significance:

The safety of foods, as they flow from farm to table, benefit from focused attention on those steps in the path that have a greater risk of contributing to hazards in food that could cause foodborne illness. By voluntarily incorporating HACCP principles, greater attention can be given to controlling the steps and activities which will most likely cause foodborne illness.

The wide variety of practices in retail and food service establishments do not always lend themselves to a "one-size-fits-all" approach to managing food safety. Implementation of the FDA guidance provides the retail and food service industries with a valuable tool that can be customized by individual operations to increase food safety.

The development and acceptance of the guidance for regulators for applying HACCP principles to risk-based retail and food service inspections will allow resources to be focused on the prevention of factors that might lead to foodborne illness outbreaks. The Retail HACCP Committee is comprised of members of state and local regulatory, academia, and industry. The committee conducted a thorough review of both documents to assure consistency and accuracy.

#### 4. Recommended Solution: The Conference recommends.....

The Retail HACCP Committee respectfully requests that the Conference of Food Protection endorse both documents with a recommendation that both industry and regulatory consider implementing the principles of the documents into their respective food safety programs (see attachments).

<b>5. Submitter:</b>			
<b>Name:</b>	Pam Williams, Debra K. Williams Co-Chairs		
<b>Organization:</b>	CFP Retail HACCP Committee		
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<b>City/State/Zip:</b>	Tallahassee, FL 32399-1650		
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**CONFERENCE FOR FOOD PROTECTION**

**2004 ISSUE FORM**  
**Deadline Feb 2, 2004**

**Issue # 2004 III-003**  
**Internal # 006**

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

*All information above the line is for conference use only.*

**1. Title:**

Completion of CFP Retail HACCP Committee Issue No. 02-III-03 to provide feedback to the FDA on the first Retail Food Program Database of Foodborne Illness Risk Factors report issued in 2000 that would help eliminate any confusion on terminology when the second report by the FDA is issued in 2004.

**2. Issue you would like the Conference to consider:**

The Retail HACCP Committee reviewed the first Retail Food Program Database of Foodborne Illness Risk Factors report that was issued by the FDA in 2000. There were some areas of the report that generated confusion due to terminology or lack of explanation which resulted in mis-information or mis-reporting regarding the industry's compliance to regulatory standards as reported by the media.

The Retail HACCP Committee is comprised of members from state and local regulatory, academia, and industry. The committee conducted a thorough review of the report as well as comments that were previously submitted to the FDA by other interested parties. The recommendations were summarized and were submitted to the CFP Executive Board who then forwarded the comments to FDA for consideration and inclusion in the development of their second report to be issued in 2004.

**3. Public Health Significance:**

The retail and food service establishments must utilize their resources to focus on those areas which would pose the greatest risk of contributing to foodborne illness. The FDA Database of Foodborne Illness Risk Factors provides direction for retail and food service operations to increase focus on food safety in those areas which pose the greatest risk. The report provides a tool for industry and the regulatory community focused on the prevention of factors that might lead to foodborne illness outbreaks.

**4. Recommended Solution: The Conference recommends.....**

The Retail HACCP Committee respectfully requests that the Conference for Food Protection accept the committee's comments as provided to the FDA as they have been sent the comments and suggestions from the committee. (see attachment)

**5. Submitter:**

<b>Name:</b>	Pam Williams, Debra K. Williams, Co-Chairs		
<b>Organization:</b>	CFP Retail HACCP Committee		
<b>Address:</b>	3280 Merganser Lane		
<b>City/State/Zip:</b>	Alpharetta, GA 30022		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-004  
Internal # 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.*

### 1. Title:

Continuation of the CFP Food Allergen Committee

### 2. Issue you would like the Conference to consider:

In 2002 the Conference for Food Protection established a committee with representatives from the various stake holders to work with FDA on food allergens. The Committee was charged with reporting back to the Executive Board the results of their work not later than the 2004 Conference. The Executive Board was to then immediately report to the FDA the results of the Committee's work.

The Committee was formed in the fall of 2002 with representatives from state and local regulatory agencies, the FDA, industry, consumers, and an academic expert.

In July 2003, the Committee agreed to the following consensus recommendations and transmitted them to the CFP Executive Board in August:

1. In Section 2-102.11 of the 2001 FDA Model Food Code add item (16) to read:  
Explaining the significance of the relationship between food allergens and allergic reactions.
2. The CFP Allergen Committee recommends that the FDA develop and clearly define the term "food allergen" in the FDA Model Food Code.
3. The CFP Allergen Committee recommends the FDA require that all food ingredient statements identify in common language that an ingredient is itself or is derived from one of the 8 major food allergens.
4. The CFP Allergen Committee recommends that the FDA further expand the food allergen commentary in the Annexes of the 2001 FDA Model Food Code based upon available food allergen science.
5. The CFP Allergen Committee recommends that the FDA develop a food allergen training program for state and local regulatory officials.

While the Committee unanimously agreed on the above recommendations, it also discussed other possible changes to the Food Code without reaching consensus. With this in mind, the Committee should be recreated to continue the deliberations.

### 3. Public Health Significance:

A food-induced allergic reaction can be a very serious medical problem for those who suffer from food allergies. It is important that the foodservice, retail and vending industries work to understand food allergies. The Committee's recommendations can further food allergen knowledge among employees of these sectors.

### 4. Recommended Solution: The Conference recommends.....

that a 2004 Allergen Committee be created to continue the work of the 2002 Committee. The new Committee should also be charged with reporting any additional recommendations to the Executive Board prior to the 2006 CFP meeting.

<b>5. Submitter:</b>			
<b>Name:</b>	Steven F. Grover, R.E.H.S. Dr. Benjamin Cohen		
<b>Organization:</b>	Co-Chairs, Food Allergen Committee		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-005  
Internal # 023

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

The 2004 CFP Date Marking Committee Report

### 2. Issue you would like the Conference to consider:

The Date Marking Committee was formed to resolve the date marking issue. The Committee reviewed FDA Food Code section 3-501.16, 3-501.17, 3-501.18, Annex 2 & 3, and current available scientific Lm data listed in the report.

### 3. Public Health Significance:

Listeriosis is a relatively rare but very serious foodborne illness. The Date Marking Committee is submitting this report and four additional issues. These Issues, which are based on current science, will preserve public health principles, be reasonable for industry to implement, and be capable of being evaluated by the applicable regulatory agency.

### 4. Recommended Solution: The Conference recommends.....

1. The acceptance of the Date Marking Committee report.
2. The Committee's 2004 report be used as the background for deliberation on the 4 additional issues presented by the Committee. The Committee strongly recommends that each of the issues be deliberated and voted on separately.

### 5. Submitter:

<b>Name:</b>	Cas Tryba & Frank Greene		
<b>Organization:</b>	Co-Chair of CFP Date Marking Committee		
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<b>City/State/Zip:</b>	Springfield, MA 01102/ Hartford CT 06106		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-006  
Internal # 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.*

### 1. Title:

Update bibliography references listed in Annex 2, Section 3-501.17 of the 2001 FDA Food Code.

### 2. Issue you would like the Conference to consider:

The current FDA Food Code (2001 Version with supplemental changes) provides only limited scientific references for Section 3-501.17, Ready-to-Eat, Potentially Hazardous Food, Date Marking (four references). The CFP Date Marking Committee reviewed numerous scientific papers, research documents, government risk assessments and policies, and previous CFP recommendations as part of its charge from the 2002 CFP. Many of the reviewed resources were not available for review prior to the 2002 CFP, but provide valuable scientific references for public health reasons applicable to Section 3-501.17. The following resources should be added to Annex 2 of the current FDA Food Code, Section 3-501.17:

- Chen, Y., Ross, W.H., Scott, V.N. and Gombas, D.E. 2003. Listeria monocytogenes: Low Levels Equal Low Risk. J. Food Protection, 66(4):570–577.
- Code of Federal Regulations, Title 9, Part 430. Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products. June 6, 2003.
- Food and Drug Administration (FDA), 2000. FDA's Response to CFP Recommendations, August 8, 2000.
- FDA/Center for Disease Control and Prevention (CDC), 2003 Update of the Listeria Action Plan, November 2003. <http://www.cfsan.fda.gov/~dms/lmr2plan.html>
- FDA/United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS)/CDC, Quantitative Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods, September 2003. <http://www.foodsafety.gov/~dms/lmr2-toc.html>
- FDA Docket No. 99N-1168 and FSIS Docket No. 00-048N. Draft Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods. <http://www.foodsafety.gov/~dms/lmrisk.html>.
- Genigeorgis, C., Carniciu, M., Dutulescu, D. and Farver, T.B. 1991. Growth and Survival of Listeria monocytogenes in Market Cheeses Stored at 4 to 30°C. J. Food Protection, 54(9):662-668.
- Gombas, D.E., Chen, Y., Clavero, R. and Scott, V.N. 2003. Survey of Listeria monocytogenes in Ready-to-Eat Foods. J. Food Protection, 66(4):559–569.
- Institute of Food Technologist (IFT), 2003. Evaluation and Definition of Potentially Hazardous Foods. IFT/FDA Contract No. 223-98-2333, Task Order No. 4. National Institute of Standards and Technology, Handbook 130, Uniform Open Dating Regulation. <http://www.nist.gov>.
- Peterson, B, Ph.D., Barraj, N, Ph.D., Rachman, N, Ph.D. Watters, J, MPH, Novigen



Sciences, Inc. International. USDHHS-FDA-CFSAN and USDA-FSIS's "Draft assessment of the Relative Risk to Public Health From foodborne Listeria monocytogenes among Selected Categories of Ready-to-Eat Foods – A Review Prepared for Members of the L. M. Working Group. 2001, Washington, D.C. (unpublished).

- Ryser, E.T. Marth, E.H. 1987. Behavior of Listeria monocytogenes During the Manufacture and Ripening of Cheddar Cheese. J Food Protection, 50(1):7-13.
- United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS), 2001. Consumer Education and Information. Focus on: Food Product Dating. <http://www.fsis.usda.gov/oa/pubs/dating.htm>.
- USDA ARS Eastern Regional Research Center, Pathogen Modeling Program, Version 7.0. Microbial Food Safety Research Unit, Philadelphia, PA. <http://www.arserrc.gov/mfs/pathogen.htm>
- USDA FSIS, Directive 10,240.4., 2003. Verification Procedures for the Listeria monocytogenes Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program. <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240-4.pdf>
- Wallace, F.M., Call, J.E., Porto, A.C.S., Cocoma, G.J., ERRC Special Project Team and Luchansky, J.B. 2003. Recovery Rate of Listeria monocytogenes from Commercially Prepared Frankfurters during Extended Refrigerated Storage. J. Food Protection, 66(4):584–591.
- Yousef, A.E. and Marth, E.H. 1988. Behavior of Listeria monocytogenes During the Manufacture and Storage of Colby Cheese. J. Food Protection, 51(1):12-15.

### 3. Public Health Significance:

The addition of these references to Annex 2 will provide the most current and applicable science, risk assessment research and recommended control interventions for risk factors associated with time-temperature variables associated with Listeria monocytogenes and date marking under Section 3-501.17. These additions promote a uniform understanding and communication reference point that is scientifically sound and up-to-date, and a national tool long recognized by industry and government officials.

### 4. Recommended Solution: The Conference recommends.....

the Conference Chair send a letter to the FDA Commissioner recommending that FDA:

1. Update bibliography references provided in Annex 2 of the current FDA 2001 Food Code, Section 3-501.17, by adding the references listed in 2 above, and
2. These references be used to update date marking guidelines under Section 3-501.17, and
3. These references be used to update the public health reasons for date marking found in the FDA 2001 Food Code, Annex 3 (Public Health Reasons).

<b>5. Submitter:</b>			
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-007  
Internal # 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.*

### 1. Title:

Update bibliography references listed in Annex 2, Section 3-501.17 of the 2001 FDA Food Code.

### 2. Issue you would like the Conference to consider:

The current FDA Food Code (2001 Version with supplemental changes) provides only limited scientific references for Section 3-501.17, Ready-to-Eat, Potentially Hazardous Food, Date Marking (four references). The CFP Date Marking Committee reviewed numerous scientific papers, research documents, government risk assessments and policies, and previous CFP recommendations as part of its charge from the 2002 CFP. Many of the reviewed resources were not available for review prior to the 2002 CFP, but provide valuable scientific references for public health reasons applicable to Section 3-501.17. The following resources should be added to Annex 2 of the current FDA Food Code, Section 3-501.17:

- Chen, Y., Ross, W.H., Scott, V.N. and Gombas, D.E. 2003. Listeria monocytogenes: Low Levels Equal Low Risk. J. Food Protection, 66(4):570–577.
- Code of Federal Regulations, Title 9, Part 430. Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products. June 6, 2003.
- Food and Drug Administration (FDA), 2000. FDA's Response to CFP Recommendations, August 8, 2000.
- FDA/Center for Disease Control and Prevention (CDC), 2003 Update of the Listeria Action Plan, November 2003. <http://www.cfsan.fda.gov/~dms/lmr2plan.html>
- FDA/United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS)/CDC, Quantitative Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods, September 2003. <http://www.foodsafety.gov/~dms/lmr2-toc.html>
- FDA Docket No. 99N-1168 and FSIS Docket No. 00-048N. Draft Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods. <http://www.foodsafety.gov/~dms/lmrisk.html>.
- Genigeorgis, C., Carniciu, M., Dutulescu, D. and Farver, T.B. 1991. Growth and Survival of Listeria monocytogenes in Market Cheeses Stored at 4 to 30°C. J. Food Protection, 54(9):662-668.
- Gombas, D.E., Chen, Y., Clavero, R. and Scott, V.N. 2003. Survey of Listeria monocytogenes in Ready-to-Eat Foods. J. Food Protection, 66( 4):559–569.
- Institute of Food Technologist (IFT), 2003. Evaluation and Definition of Potentially Hazardous Foods. IFT/FDA Contract No. 223-98-2333, Task Order No. 4.
- National Institute of Standards and Technology, Handbook 130, Uniform Open Dating

Regulation. <http://www.nist.gov>.

- Peterson, B, Ph.D., Barraji, N, Ph.D., Rachman, N, Ph.D. Watters, J, MPH, Novigen Sciences, Inc. International. USDHHS-FDA-CFSAN and USDA-FSIS's "Draft assessment of the Relative Risk to Public Health From foodborne Listeria monocytogenes among Selected Categories of Ready-to-Eat Foods – A Review Prepared for Members of the L. M. Working Group. 2001, Washington, D.C. (unpublished).
- Ryser, E.T. Marth, E.H. 1987. Behavior of Listeria monocytogenes During the Manufacture and Ripening of Cheddar Cheese. J Food Protection, 50(1):7-13.
- Seman, D.L., A.C. Borger, J.D. Meyer, P.A. Hall, and A.L. Milkowski. 2002. Modeling the growth of Listeria monocytogenes in cured ready-to-eat processed meat products by manipulation of sodium chloride, sodium diacetate, potassium lactate, and product moisture content. J. Food Protect. 65: 651-658.
- United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS), 2001. Consumer Education and Information. Focus on: Food Product Dating. <http://www.fsis.usda.gov/oa/pubs/dating.htm>.
- USDA ARS Eastern Regional Research Center, Pathogen Modeling Program, Version 7.0. Microbial Food Safety Research Unit, Philadelphia, PA. <http://www.arserrc.gov/mfs/pathogen.htm>
- USDA FSIS, Directive 10,240.4., 2003. Verification Procedures for the Listeria monocytogenes Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program. <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240-4.pdf>
- Wallace, F.M., Call, J.E., Porto, A.C.S., Cocomo, G.J., ERRRC Special Project Team and Luchansky, J.B. 2003. Recovery Rate of Listeria monocytogenes from Commercially Prepared Frankfurters during Extended Refrigerated Storage. J. Food Protection, 66(4):584–591.
- White, C.H. and Custer, E.W. 1976. Survival of Salmonella in Cheddar Cheese.. J. Milk Food Tech. 39(5):328-331.
- Yousef, A.E. and Marth, E.H. 1988. Behavior of Listeria monocytogenes During the Manufacture and Storage of Colby Cheese. J. Food Protection, 51(1):12-15.

### **3. Public Health Significance:**

The addition of these references to Annex 2 will provide the most current and applicable science, risk assessment research and recommended control interventions for risk factors associated with time-temperature variables associated with Listeria monocytogenes and date marking under Section 3-501.17. These additions promote a uniform understanding and communication reference point that are scientifically sound and up-to-date - a national tool long been recognized by industry and government officials.

### **4. Recommended Solution: The Conference recommends.....**

that FDA update bibliography references provided in Annex 2 of the current FDA Food Code, Section 3-501.17, by adding the references listed in 2 above to provide current and up-to-date references taken into consideration in developing guidelines for Section 3-501.17.

<b>5. Submitter:</b>			
<b>Name:</b>	Timothy Weigner/Sheri Dove		
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-008  
Internal # 048

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Time Only as a Public Health Control Committee - Council III.

### 2. Issue you would like the Conference to consider:

This committee was established to develop a report reviewing and summarizing information regarding the rate of growth of pathogens in food between

- 7 degrees C (45F) and 21 degrees C (70F), and
- 21 degrees C (70F) and 60 degrees C (140F)

The committee was also charged with presenting that report at the next CFP Conference along with their recommendations for changes, if any, in the time allowances for the use of Time as a Public Health Control.

The overall goal of this committee was to examine the role of temperature AND time combinations on the growth of bacterial pathogens in foods. A specific aim was to determine time limits for a temperature range between 41-140F (5-60C). The critical question that was addressed to the committee was: Can guidelines be provided to utilize time as a public health control for food products stored in the temperature range between 41-140F (5-60C). In particular, there was an interest to look at a temperature range of 41-70F (5-21C) and 70-140F (21-60C).

Our committee was broadly representative of regulatory, industry, consumer groups, consultants, and academia. Most of the committee work was performed through conference calls and collection of science-based information (peer reviewed journal articles, growth modeling programs, science-based reports, etc.). This report (attached) provides a collection of science-based information that was available and the committee's recommendation for potential use of time (at different temperatures) as a public health control.

### 3. Public Health Significance:

Temperatures below 41F (5C) and above 135 (57C) have long been recognized as boundaries of retail food safety because they effectively prevent the growth of foodborne pathogens ((below 41F (5C) and above 135F (57C)) or lead to microbial inactivation (above 135F). In almost all cases where temperature is used as an intervention to growth/survival of foodborne pathogens, time is also used as an important parameter for safety. The combination of time AND temperature should also considered for any step in the flow of food where potentially hazardous foods will be exposed to temperatures above 41F and below 135F. Guidelines are needed for the use of time alone as a public health control when foods are held between 41-135F (5-57C).

1 As with many other Food Code public health recommendations, credible science forms the basis for regulatory decisions and uniform implementation, with an overlay of public health principles and practical applications.

2 The committee recognizes that FDA sets the Food Code recommendations to control the worst time/temperature scenario. The Agency's guidance must also protect the immuno-compromised and other highly susceptible populations.

3 There is scientific consensus regarding the critical limit of a) a 1-log growth of *L. monocytogenes* for foods that are held at cold temperatures and b) a 1-log growth of *C. perfringens* for foods that are held at hot temperatures or foods that are cooled after cooking or hot-holding. More research is recommended to further understand acceptable levels of growth during holding and initial levels of pathogens on potentially hazardous foods.

4 In general, the committee feels that the current hot-holding and cold-holding parameters for holding potentially hazardous foods are more than adequate to ensure safety and are justified by the literature.

5 The science presented in this report suggests that potentially hazardous foods held at cold temperatures, using time only as a public health control, may be safely held for more than 4 hours without temperature control not to exceed 1 log growth of *L. monocytogenes*. As a supplement to the committee report, this committee will be submitting an issue related the use of time alone as a public health control at different temperatures.

6 The USDA Pathogen Modeling Program can be used as a tool for scientific agreement – however, estimates for growth are generally conservative using this approach. The only way to specifically determine growth and inactivation of specific pathogens is to test them within the specific food matrix.

#### **4. Recommended Solution: The Conference recommends.....**

The committee recommends that the Conference accept the attached report indicating that the charge to this committee has been completed.

<b>5. Submitter:</b>			
<b>Name:</b>	Rich Linton, Chair		
<b>Organization:</b>	Time as a Public Health Control Committee of Council III		
<b>Address:</b>	745 Agricultural Mall Drive		
<b>City/State/Zip:</b>	West Lafayette, IN 47907		
<b>Telephone:</b>	765-494-6481	<b>Fax:</b>	765-494-7953
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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-009  
Internal # 049

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Time Only as a Public Health Control for 6 hours.

### 2. Issue you would like the Conference to consider:

Section 3-501.19 of the FDA Model Food Code allows food to be held at any temperature for up to 4 hours under certain conditions. Existing science suggests that the holding of potentially hazardous foods for 6 hours without refrigeration is safe. The CFP Committee for Time as a Public Health Control recommends that there be no more than one log growth of pathogens during holding.\* Further, the Committee report shows that the growth of pathogenic organisms below 70 degrees F is very slow. At 70 F the fastest growing pathogen, *Yersinia enterocolytica*, takes 5.9 hours to reach one log growth. Therefore, for products which have been held refrigerated at 41 F or below, in compliance with 3-501.16 of the Food Code, and are then removed from refrigeration, these foods can safely be held for up to 6 hours without exceeding one log growth.

The Time as a Public Health Control Committee Report, Appendix 1, identifies specific pathogens and the time it takes to reach 1 log growth. Based on the most conservative approach using *Yersinia enterocolytica* as the target organism and an ambient temperature of 70 F, 6 hours would maintain the necessary level of food safety.

\*Reference: CFP Committee Report: Time as a Public Health Control, Appendix 1, January 5, 2004.

### 3. Public Health Significance:

Each day food establishments discard foods that have been held in the danger zone after 4 hours has passed because it is assumed that they are unsafe, but in fact existing science indicates that this is incorrect. Allowing food establishments to hold foods which have been removed from refrigeration for up to 6 hours unrefrigerated, will still assure food safety, will reduce the amount of wasted food, will save energy and will encourage the use of science based food safety principles and programs.

### 4. Recommended Solution: The Conference recommends.....

... that the Conference Chair send a letter to the FDA Commissioner recommending the following changes to section 3-501.19 of the FDA Model Food Code.

3-501.19 Time as a Public Health Control.\*

(A) If time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of READY-TO-EAT POTENTIALLY HAZARDOUS FOOD which has just been cooked, reheated, hot held or otherwise is above 135°F and that is displayed or held for service for immediate consumption:

(Subparagraphs 1-3 remain unchanged.)

(4) Written procedures shall be maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that ensure compliance with Subparagraphs (A) (1)-(4) of this section.

(B) Except as specified under (C) of this section, if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of POTENTIALLY HAZARDOUS FOOD, or for READY-TO-EAT POTENTIALLY HAZARDOUS FOOD which is at a temperature of 41° F, or below and that is displayed or held for service for immediate consumption:

(1) The FOOD shall be marked or otherwise identified to indicate the time that is 6 hours past the point in time when the FOOD is removed from temperature control,

(2) The FOOD shall be cooked and served, served if ready-to-eat, or discarded, within 6 hours from the point in time when the FOOD is removed from temperature control,

(3) The FOOD in unmarked containers or packages or marked to exceed a 6 hour limit shall be discarded, and

(4) Written procedures shall be maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request, that ensure compliance with:

(a) Subparagraphs (B)(1)-(4) of this section; and

(b) § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control.

(C) In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, time only, rather than time in conjunction with temperature, may not be used as the public health control for raw EGGS.

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Modify § 3-501.19, Time as a Public Health Control to clarify the meaning and intent of "Immediate Consumption."

### 2. Issue you would like the Conference to consider:

The 2001 FDA Food Code, § 3-501.19, Time as a Public Health Control (TPHC) includes the phrase "immediate consumption." The current interpretation of "immediate consumption" by some jurisdictions prohibits the use of TPHC at supermarket/retail establishments where seating isn't available for the food.

### 3. Public Health Significance:

Many retail establishments recognize there are shoppers and consumers who prefer not to cook or prepare meals/products. These establishments have developed business models that incorporate the theme of "Home Meal Replacement" or "Meal Solution" operations to provide consumers with ready-to-eat, ready-to-consumer foods, such as salad bars, pizza shops, sandwich shops, specialty cafes, and soups and cooked chickens - a business of \$9-\$20 million annual sales in the United States. Data provided in "Trends 2002" portray consumer shopping trends and the types of foods they purchase:

- 74% of consumers eat out every week.
- 26% of the total population consumes meals at home that are not prepared at home, like takeout or home delivery.
- Sources of Takeout Foods:
  - Fast food restaurants: 25%
  - Restaurants: 14%
  - Supermarkets: 17%
  - Deli/pizza/bagel shop/coffee shop/donut shop: 28%

Some regulatory jurisdictions prohibit the use of TPHC at supermarket/retail establishments where seating is not available for the food to be consumed immediately on the premises. The FDA has set precedence in defining "Immediate Human Consumption" in 21 CFR 101.9(j)(2)(ii), which deals with the nutritional labeling requirements of foods, as meaning:

"Served in other establishments in which food is served for immediate human consumption (e.g., institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; bakeries, delicatessens, and retail confectionery stores where there are facilities for immediate

consumption on the premises; food service vendors, such as lunch wagons, ice cream shops, mall cookie counters, vending machines, and sidewalk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices)..."

The definition of "Immediate Human Consumption" provided in 21 CFR 101.9(j)(2)(ii) includes establishments where foods are generally consumed immediately where purchased or while the consumer is walking away – not as an establishment where seating is provided. Supermarket/retail food establishments should be permitted the opportunity to comply with the provisions of FDA Food Code § 3-501.19 dealing with TPHC regardless of whether or not seating is available. Some restaurants and food service establishments that offer take out or fast food that is not consumed at the point of purchase currently use TPHC for products that are awaiting customer purchase, pickup or delivery.

The 2001 FDA Food Code provides model language of a system of prevention and safeguards designed to minimize foodborne illnesses at food establishments, e.g., restaurants, catering, markets, vending locations, institutions, food banks grocery/supermarkets or take-outs. There is no available science to support prohibiting supermarket/retail establishments from utilizing TPHC as provided in § 3-501.19 of the 2001 FDA Food Code while allowing food service establishments to use TPHC. There is no available science to corroborate that there is an increase in risks for similar food handling and display processes based on whether the establishment is a food service facility vs. a retail facility.

#### **4. Recommended Solution: The Conference recommends.....**

the Conference Chair send a letter to the FDA Commissioner recommending that FDA reword 3-501.19(A) of the 2001 FDA Food Code to prevent the misinterpretation of "Immediate Consumption" and provide consistency and uniformity with the language in 21 CFR 101.9(j)(2)(ii). The recommended changes to this paragraph should read:

"(A) Except as specified under (B) of this section, if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of POTENTIALLY HAZARDOUS FOOD before cooking, or for READY-TO-EAT POTENTIALLY HAZARDOUS FOOD that is displayed or held for service or sale where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where READY-TO EAT FOODS are delivered to homes or offices."

or , add a new paragraph (B):

"(B) Take out operations, including retail stores, can use time as a public health control for food purchased that are intended to be consumed near the time of purchase in addition to the FOOD ESTABLISHMENT complying with subparagraphs (A)(1)-(4) of 3-501.19."

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## CONFERENCE FOR FOOD PROTECTION

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Internal # 057

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Expanding the Copper and copper alloy use limitation

### 2. Issue you would like the Conference to consider:

FDA Food Code, Section 4-101.14 (A) limits the use of copper and copper alloys that come in contact with food products that have a pH below 6.

### 3. Public Health Significance:

Individuals producing food products, such as apple butter and molasses, at festivals, carnivals, fairs, etc. should be afforded the opportunity to develop procedures or plans that minimize the time food comes in contact with copper materials and thereby produce a product which is not adulterated with excessive levels of metal contamination.

Discussions with the Center for Food Safety and Applied Nutrition (FDA) have revealed that there is no restriction at the manufacturing level on the use of copper kettles and pans in the production of apple butter and molasses, and that FDA would have no concern about such a practice unless finished product sampling revealed excessive levels of copper.

Although apple butter and molasses both have pH ranges below 6 (apples and apple products - 3.00 to 4.00; molasses - 4.90 to 5.40), there does not appear to be any scientific evidence that processing these products in copper kettles or pans under typical processing conditions and times contributes to significant elevated levels of copper in finished products. Unless solid evidence can be provided to prohibit such activity, processing (i.e. mixing, cooking and cooling) apple butter and molasses in copper kettles or pans should not be restricted by the Food Code, although the Food Code should prohibit the storage of such products in copper. Such a change will bring the Food Code into alignment with FDA's policy for dealing with this issue in food manufacturing environments.

### 4. Recommended Solution: The Conference recommends.....

that the Conference Chair send a letter to the FDA Commissioner to urge the following changes to the Food Code:

1. Section 4-101.14 (A) of the Food Code should be modified by inserting after the "paragraph" symbol a second "paragraph" symbol, and after "(B)" insert "and (C)"; and,
2. Add a paragraph (C): "Copper and copper alloys may be used in contact with apple butter and molasses during the typical processing times (i.e. mixing, cooking and

cooling) for these products. However, these products may not be stored in copper for time periods any longer than the typical processing times for these products.

**5. Submitter:**

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Growing Sprouts in Retail Food Establishments.

### 2. Issue you would like the Conference to consider:

In 1999, the U.S. Food and Drug Administration (FDA) developed guidance for the commercial sprouting industry because of the number of outbreaks associated with raw sprouts. FDA's guidance was based, largely, on recommendations from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

Following the 2002 Conference for Food Protection, the voting delegates approved a recommendation for issue 02-III-01, Reduced Microbial Risk through Alternative Intervention Processes for the Retail Sprout Industry. CFP sent a letter to FDA, requesting that "FDA develop recommendations for growing sprouts or treatment of raw sprouts at food establishments for the safe microbial intervention processes for sprouts." FDA's response to this request is below.

### 3. Public Health Significance:

Many factors contribute to the problem of E. coli O157:H7 or Salmonella outbreaks associated with consumption of raw sprouts. Contamination may be introduced anywhere along the farm to table continuum. Many types of seeds are rough or wrinkled which offers harborage for bacteria, making disinfection or sanitizing more difficult.

Microorganisms, even at very low numbers and sporadic distribution on seeds, grow quickly during the ideal conditions of the germination and sprouting process. There is no step in the production of raw sprouts such as cooking or pasteurization to reduce or eliminate pathogens before consumption. The seed is the preferred site for disinfection treatment rather than sprouting or the finished sprouts. Seeds are easier to disinfect than sprouts because contamination levels are lower, there is less debris present and seeds are generally more resistant to treatments than delicate sprouts. Also, the roots of some sprouts take up bacteria from irrigation water, making pathogens inaccessible to any sanitizer/disinfectant. Biofilm formation, identified on some sprouts, may also protect pathogens from sanitization/disinfection.

No single treatment is equally effective and commercially feasible for all seeds because of the variation in sensitivity or resistance. FDA recommends that seeds for sprouting be grown using Good Agricultural Practices (GAPs), that they receive an approved seed disinfection treatment and that microbial testing of the sprouts or irrigation water be conducted. The testing is used to validate the treatment and to prevent contaminated

product from entering the food supply. Any chemical treatment to reduce pathogens must receive approval from EPA under FIFRA requirements and have the specific treatment listed on the product label. To date, only calcium hypochlorite has an approved application on file. New technologies such as pulsed light, ultrasound, high hydrostatic pressure or pulsed electrical fields may not be commercially available.

**4. Recommended Solution: The Conference recommends.....**

Based on discussion and deliberation, that FDA amend Food Code Section 3-502.11 Variance Requirement to add a new subparagraph (H), "Sprouting seeds or beans in a retail food establishment." Because the variance application requires a HACCP Plan, the attached information for retail sprouters is provided as assistance to the food establishment operator who seeks to submit a variance application and HACCP plan to the regulatory authority and to the regulator who will be reviewing the application and plan and inspecting the sprouting process. This solution, both the amendment to the Food Code and the attached information, was chosen to maintain a consistent approach with the guidance already issued by FDA to the commercial sprouting industry, to identify applicable Food Code provisions and to identify EPA/FDA approved treatments which do not have an adverse impact on the germination, sprouting and yield of the sprouts.

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Date Marking of Refrigerated Ready-to-Eat Potentially Hazardous Food

### 2. Issue you would like the Conference to consider:

FDA is proposing changes to the date marking requirements in light of the findings in FDA's Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (Risk Assessment) (<http://www.foodsafety.gov/~dms/lmr2-toc.html>) and other recent research. Specifically, FDA is recommending several additional categories of food products be exempted from date marking requirements.

### 3. Public Health Significance:

Certain categories of ready-to-eat (RTE) potentially hazardous food, based on their intrinsic properties, are more likely to support the growth of *Listeria monocytogenes* (LM), even at temperatures of 5°C (41°F) or less. Over a period of extended refrigerated storage, LM may grow in these products to levels that will cause illness or death. Data from FDA's Risk Assessment, as well as other current research, has indicated that limiting the storage times of certain categories of RTE PHF, will significantly reduce the growth of LM.

The 2001 Food Code currently requires a system for date marking of all refrigerated, RTE PHF that are held on-site for more than 24 hours after opening or preparation. While the FDA believes a good date marking system can be an effective tool for preventing foodborne illness when applied to all types of PHF, the Agency is recommending that certain additional categories of low-risk foods be exempted from the date marking requirements, based on the results of the risk assessment. Certain categories of products, such as hard and semisoft cheeses, and fermented sausages have previously been exempted from date marking. These additional exemptions will allow operators and regulators to concentrate their efforts on those foods that are more likely to support the growth of LM. This should result in more effective and manageable methods for limiting the storage times of these foods. This, in combination with a maximum cold holding temperature of 5°C (41°F) will protect against substantial growth of LM, if present.

### 4. Recommended Solution: The Conference recommends.....

Based on discussion and deliberation that FDA amend the Food Code as follows:

A. Amend §3-501.17(E) to exempt from date marking, ready-to-eat products that are opened and held for more than 24 hours and which are included within the following food categories:



1. Deli-type salads processed in a FOOD PROCESSING PLANT with added antimicrobials or preservatives shown to control *Listeria monocytogenes*– such as pasta salad, potato salad, tuna salad, chicken salad, ham salad, macaroni salad, and seafood salad;
2. Preserved Fish – such as pickled herring, ceviche, and dried or salted cod; or
3. Cultured Dairy Products – meaning the product produced by culturing one or more dairy ingredients (21 CFR 131.200, 131.203, 131.206), such as yogurt;

B. The exemptions listed in paragraph (A) are not intended to apply to foods that are prepared or assembled on-site in a food establishment, or foods processed in a FOOD PROCESSING PLANT, to which one or more ingredients are added in a FOOD ESTABLISHMENT.

C. The exemptions in paragraph (A) should be added to those already listed in §3-501.17(D)-(E), as well as the exemptions for hard and semi soft cheeses as recommended in CFP 2002-III-37 and described in the 1999 FDA Program Information Manual (<http://www.cfsan.fda.gov/~ear/ret-chdt.html>).

D. Add additional references to Annex 2 of the Food Code to support the science behind amending the date marking provision.

E. Amend Annex 3 of the Food Code to state the scientific rationale that supports a targeted date marking approach and list some common preservatives that have been shown to inhibit LM growth (e.g., sorbate, benzoate).

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
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Issue # 2004 III-014  
Internal # 013

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Addition of Cheese Date Marking Exemption to Section 3-501.17(D)

### 2. Issue you would like the Conference to consider:

The FDA has identified specific hard and semisoft cheeses and pasteurized process cheese, each manufactured according to 21 CFR 133 as being exempt from the Food Code's date marking provisions as specified in Section 3-501.17. They note that specific RTE cheese, "in addition to refrigeration, there are several factors in certain cheeses that may further control growth of pathogenic organisms. These factors may include the presence of organic acids, preservatives, or competing flora; pH; water activity; or salt concentration. When two or more of these are combined, the resultant effect is an additional hurdle to the outgrowth of pathogens of concern." The FDA issued this guidance on December 15, 1999, to provide state/local regulatory agencies and the industry clear and concise guidance on specific cheeses exempt from date marking (available at Website <http://www.cfsan.fda.gov/~ear/ret-chdt.html>).

Issue 02-III-37 was presented during the 2002 Conference for Food Protection and was accepted as submitted. In a response letter to the recommendations for the 2002 recommendations related to the FDA Food Code (dated August 5, 2001), Janice Oliver responded that FDA categorized the recommendation of Issue 02-III-37 under Category I. For Category 1 recommendations, FDA acknowledged that "we [they] plan to incorporate the intent of the recommendation in the next edition of the Food Code. The exact language recommended by CFP may be modified before being incorporated into the Food Code to clarify or to maintain the Code's internal consistency."

Since then, FDA has issued an errata sheet (August 23, 2002) and supplement to the Food Code (August 29, 2003) to reflect many of the recommendations from the 2002 CFP. However, neither of these documents includes language or intent of the recommendation for Issue 02-III-37.

#### REFERENCES:

1. Code of Federal Regulation, Part 21, Title 133.
2. FDA Food Code, 2001.
3. FDA 2001 Food Code Errata Sheet, August 23, 2002.
4. FDA Supplement to the 2001 Food Code, August 2003.
5. FDA Retail Food Safety Program Manual: Date Marking of Cheese, December 15, 1999.
6. Conference for Food Protection, Issue 02-III-37.

### 3. Public Health Significance:

The inclusion of exempt cheese identification within Section 3-501.17 has no adverse public health risk associated with it and provides clear and concise clarification of properly identified cheeses as being exempt from date marking guidelines. The omission of incorporating previous accepted CFP recommendations will continue to result in food establishment requirements to dedicate unwarranted resources on date marking foods where no public health concerns exist and may cause greater confusion by regulatory agencies focusing on identified low risk foods.

### 4. Recommended Solution: The Conference recommends.....

The Conference Chair send a letter to the FDA Commissioner to urge the revision of Section 3-501.17 of the of the 2001 FDA Food Code previously accepted by the 2002 CFP, by adding an additional paragraph after 3-507.17(C) stating:

"Paragraphs (A) and (B) of this section do not apply to specific cheeses containing certain moisture content meeting the aging standards of 21 CFR Part 133 and maintained under refrigeration as specified in § 3-501.16."

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
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Issue # 2004 III-015  
Internal # 015

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Section 3-501.17 date marking violation to be identified as a non-critical violation.

### 2. Issue you would like the Conference to consider:

The 2001 FDA Food Code defines "Critical Item" as meaning "if in non compliance, is more likely than other violations to contribute to food contamination, illness or environmental hazard." Based on best available science and the current definition of critical item, date marking violations under Sections 3-501.17 are not "more likely" than other violations to cause illness or food contamination and therefore should be changed to non-critical through removal of the asterisk. The date marking provisions are recognized as one of many good retail practices (GRPs) and interventions provided in the 2001 FDA Food Code to potentially reduce the opportunities for Listeria to grow in certain high risk foods. Some of these interventions are classified as non-critical violations.

The Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993 – 1997, entitled, "Surveillance for Foodborne-Disease Outbreaks – United States," identified five broad categories of risk factors that most often contribute to foodborne illness:

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

Missing from the CDC surveillance report is any inference or data for time limitations (date marking) under the category of "Improper Holding Temperatures." The "Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors" (referred to as Baseline Report) serves as a management tool for regulators to use to focus greater attention and increased resources on control of risk factors. The Baseline Report defines "Risk Factor" as meaning "one of the factors identified by the Centers for Disease Control and Prevention (CDC) as a major contributor to the foodborne outbreaks that have been investigated and confirmed. These factors include: Unsafe Sources, Inadequate Cooking, Improper Holding, Contaminated Equipment and Poor Personal Hygiene." The non-compliance to date marking has not been shown by any published scientific study or the Baseline Report to contribute to a critical violation that "if in non compliance, is more likely than other violations to contribute to food contamination, illness or environmental hazard."

References:

1. Food and Drug Administration (FDA) 2001 Food Code
2. FDA Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (available at <http://vm.cfsan.fda.gov/~dms/retrskfl.html>)
3. FDA Recommended National Retail Food Regulatory Program Standards
4. FDA 2001 Food Code Errata Sheet, August 23, 2002.
5. FDA Supplement to the 2001 Food Code, August 2003.
6. FDA/USDA/CDC Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods
7. FDA/CDC Reducing the Risk of *Listeria monocytogenes* - 2003 Update of the *Listeria* Action Plan
8. Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993 – 1997, Surveillance for Foodborne-Disease Outbreaks – United States
9. USDA FSIS Backgrounder on Date Marking (available at <http://www.fsis.usda.gov/OA/pubs/dating.htm>)

### **3. Public Health Significance:**

Listeriosis is the result of persons consuming sufficient numbers of pathogenic *Listeria* organisms. The non-compliance to date marking has not been shown by any published scientific study to be categorized as a "critical" as defined in the 2001 FDA Food Code. The practice of date marking by itself will not reduce the likelihood of Listeriosis as a result of contaminated food being introduced anywhere from manufacturing through retail preparation, to post-retail handling.

The 2001 FDA Food Code provides risk intervention guidance specific for active managerial control, such as prevention of initial contamination, cleaning and sanitizing of food contact surfaces, cross contamination and temperature control, which are more likely than the date marking to cause Listeriosis if not achieved. The date marking provisions of Section 3-501.17 of the 2001 Food Code provide good retail practices (GRPs) for food establishments to reduce the opportunities for *Listeria* growth in certain high risk foods, but not in all ready-to-eat (RTE) potentially hazardous foods (PHFs).

In September 2003, the FDA/USDA/CDC released the "Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods" (referred to as Quantitative Assessment). This Quantitative Assessment focuses on reduction of risk to an acceptable level without defining the acceptable level or the risk management plan. Section V and Appendix 8 of the Quantitative Assessment provides data on the growth of *L.m.* in foods, but does not provide sound science or sufficient data to demonstrate that date marking is a critical item. The captured data does illustrate that time/temperature parameters may allow for 1 log growth of *L.m.* within the 7-day/41F or 4-day/45F parameters specified under Section 3-501.17; growth may not occur until well beyond these time parameters; or that levels may actually decline resulting in a negative mean exponential growth rate. These findings reflect that date marking RTE PHFs cannot be accomplished in a "one size fits all" approach.

The CFP should recognize the continuing tasks of the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) to evaluate the scientific parameters of establishing safety-based "use-by" date labels for refrigerated RTE foods; determining what modeling approaches are best suited to the development of these dates; evaluating

influences of multiple factors that influence the growth and survival of L.m.; and impact that safety-based “use by” date labels will have on the control of foodborne pathogens in RTE foods. The NACMCF findings may complement the Quantitative Assessment and FDA/CDC’s Action Plan, however, they do not define if date marking guidelines under Section 3-501.17 should be deemed as “Critical Items.”

**4. Recommended Solution: The Conference recommends.....**

the Conference Chair send a letter to the FDA Commissioner recommending that FDA change Section 3-501.17 from a “critical” to a “non-critical” by removal of the asterisk (\*) at the end of the tagline because guidelines provided in this section do not meet the qualification of “critical item” as defined in paragraph 1-201.10(B)(19) of the 2001 FDA Food Code.

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
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Internal # 027

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Section 3-501.17 and 18 - Date marking violation to be identified as a non-critical violation.

### 2. Issue you would like the Conference to consider:

Based on best available science and the current definition of critical violation, date marking violations under Sections 3-501.17 and 3-501.18 are not "more likely" than other violations to cause illness or food contamination and therefore should be changed to non-critical through removal of the asterisk.

### 3. Public Health Significance:

The FDA Food Code defines critical item as "if in non compliance, is more likely than other violations to contribute to food contamination, illness or environmental hazard." Listeriosis is the result of persons consuming sufficient numbers of pathogenic Listeria organisms. The non-compliance to date marking has not been shown by any published scientific study to contribute to "food contamination, illness or environmental hazard." The practice of date marking by itself will not reduce the likelihood of Listeriosis as a result of contaminated food being introduced anywhere from manufacturing through retail preparation. There are other risk factors, such as prevention of initial contamination, cleaning and sanitizing of food contact surfaces, cross contamination and temperature control that are more likely than date marking to cause Listeriosis and are sufficiently addressed in the code. The date marking provisions of the Food Code provide a good "best practices" for retailers to adhere to in reducing the opportunities for Listeria to grow in certain high risk foods. This committee is supporting the date marking of high risk foods along with recommendations to address other interventions that target the reduction of Listeria. The scientific studies conducted by NFPA, entitled, "Listeria monocytogenes: Low Levels Equals Low Risk" (J.Food Protection, Vol 66, No. 4, 2003 pages 570-577 and "Survey of Listeria monocytogenes in Ready-to-Eat Foods, (pages 559-569) implied that, "consumers are exposed to detectable levels of L.monocytogenes billions of time each year" but that fact is inconsistent with the relatively low level of listeriosis cases reported by CDC. It is further shown that the studies overall prevalence data of 1.82% was much less than previously reported and that controlling the level to < 100 CFU/g would reduce cases approximately 99%. The committee sees this as more than meeting the goals of the Healthy People 2010 initiative (i.e. reduce illnesses caused by L.m. by 50%) and requiring a critical finding on these paragraphs does nothing to support this. Retail focusing on date marking high risk foods has a much greater chance of compliance than the one size fits all currently in the code and will support protection of consumer's health. Further, 3-501.18 addresses date marking disposition as a critical item.

Specifically, (A)(2) would have one discard a package "that does not bear a date or day or... ." This is very unusual, in that food that is improperly cooked or cooled, two of the top controls for food safety, do NOT have specific "critical" disposition instructions in the code. In most cases, the code states specific food safety requirements and the disposition is "implied" based on that requirement. This is not the case for the administrative requirement to date a product opened in a retail environment and lends to perception issues when it becomes a matter of public record.

**4. Recommended Solution: The Conference recommends.....**

that FDA change the date marking violation in the Food Code , paragraphs 3-501.17 and .18 from critical to non-critical by removal of the asterisks. We would further recommend that if disposition is still felt to be warranted for "date marking" than the revised 3-501.18 portions be combined under 3-701.11 as paragraph (E) with appropriate language of why the food is "unsafe" because a date marking is missing or inappropriately applied.

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Addition of exempt food to Section 3-501.17

### 2. Issue you would like the Conference to consider:

The FDA/USDA/CDC has published the "Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat (RTE) Foods (hereafter referred to as LMRA). The LMRA recognizes two (2) risk designation groups of food as unlikely significant sources for foodborne listeriosis; and one (1) risk designation group where the use of bactericidal treatments in the food manufacture/preparation, or commonly employed conditions and compounds inhibit the growth of *Listeria monocytogenes* (Lm). Products within these three groups should be exempt from date marking provisions of Section 3-501.17 of the FDA 2001 Food Code.

#### References:

- FDA/United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS)/CDC, Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, September 2003. <http://www.foodsafety.gov/~dms/lmr2-toc.html>
- Institute of Food Technologist (IFT), 2003. Evaluation and Definition of Potentially Hazardous Foods. IFT/FDA Contract No. 223-98-2333, Task Order No. 4.

### 3. Public Health Significance:

The scientific foundation and support for the LMRA is summarized in the LMRA's Interpretive Summary and Conclusion. This document explains that food identified as risk designation "Low" is generally consumed in small quantities by a small portion of the population on an infrequent basis. This results in low predicted per annum relative risks. Exposure data for these products are limited so there is substantial uncertainty in the findings. However, the current results predict that these products, when manufactured consistent with current good manufacturing practices, are not likely to be a major source of foodborne listeriosis. Products within this risk designation include preserved fish and raw seafood. Based on the best available data these food items should be exempt from Section 3-501.17.

The LMRA provides similar data and a summary for food identified as risk designation "Very Low." Food within this risk designation group have in common the characteristics of being subjected to a bactericidal treatment, having very low contamination rates, and possessing as an inherent characteristic that either inactivates Lm or prevents growth. Foods under this risk designation include cultured milk products, hard cheese, ice cream

and other frozen dairy products, and processed cheese. As with products included in the "Low" designation group, the current and best available science recognized by the federal agencies demonstrates that these food items pose very little public health threat to the consumer as related to growth of Lm and should be exempt from Section 3-501.17.

Lastly, the LMRA provides a summary of data for food identified as risk designation "Moderate." This group includes nine food categories (Cooked Ready-to-Eat Crustaceans, Deli Salads, Dry/Semi-Dry Fermented Sausages, Frankfurters-Reheated, Fresh Soft Cheese, Fruits, Semi-soft Cheese, Soft Ripened Cheese, and Vegetables). The "Moderate" risk designation group encompasses a range of contamination rates and consumption profiles. Based on best available science, the LMRA recognizes that food within this group "include effective bactericidal treatments in their manufacture or preparation (e.g., Cooked Ready-to-Eat Crustaceans, Frankfurters-Reheated, Semi-soft Cheese) or commonly employ conditions or compounds that inhibit the growth of *Listeria monocytogenes* (e.g., Deli Salads, Dry/Semi-dry Fermented Sausages)." The risks associated with these products appear to be primarily associated with product recontamination, which in turn, is dependent on continuous, vigilant application of proven control measures as already defined in the FDA 2001 Food Code.

The three risk designation groups above emphasize that a "one size fits all" approach to date marking all RTE PHFs should be re-evaluated due to recognized intrinsic factors associated with individual foods (see IFT Report) and associated risks of RTE PHFs and non-PHF.

#### **4. Recommended Solution: The Conference recommends.....**

The Conference Chair send a letter to the FDA Commissioner to urge the revision of Section 3-501.17 of the of the 2001 FDA Food Code by listing foods or providing an easy to use table identifying foods that are unlikely to be a significant source of foodborne listeriosis and are exempt from date marking as identified in the LMRA as "Moderate," "Low" or "Very Low" risk designation groups.

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

The Date Marking Provisions Should Be Limited to High-Risk Foods, as Identified in the FDA's Listeria monocytogenes Risk Assessment.

### 2. Issue you would like the Conference to consider:

The Date Marking Committee was formed to address the date marking issue. The Committee reviewed numerous research studies, illness data, scientific references, and risk assessment documents issued by the U. S. Department of Agriculture and the U.S. Food and Drug Administration. Much of the evidence indicates the risk of listeriosis is much greater when the levels of Lm are high in a consumed food. The evidence also indicates that there are some foods that are far more likely to contribute to food-borne listeriosis because higher levels of Lm are more frequently found in those foods because they support growth of the organism and may be held refrigerated for extended periods of time. The FDA/FSIS Lm Risk Assessment, released in September 2003, categorized the relative risk of ready-to-eat foods attributing to food-borne listeriosis. The National Food Processors Association's "Survey of Listeria monocytogenes in Ready-to-Eat Foods" (J. Food Protect. 66: 559-569. 2003) also found the prevalence of Lm to be higher in some categories of food, making these foods a higher risk for contributing to food-borne listeriosis. Date marking is a method that monitors and limits the amount of time that a food is stored under refrigeration, which results in minimizing the growth of Lm that may be present in food. Date marking is a managerial tool that can help ensure that the levels of Lm can be kept low before consumption of a ready-to-eat food that supports growth. Inspectional resources and managerial control should be focused on the categories of foods that are listed as high-risk. Only foods that have been categorized as high-risk need to be date marked.

### 3. Public Health Significance:

Listeria monocytogenes is known to cause listeriosis when high levels of the pathogenic bacteria are ingested, especially when ingested by a highly susceptible population. A risk assessment conducted by NFPA (J. Food Protect. 66: 570-577. 2003) showed that low levels of Lm pose minimal risk, even to the susceptible population. The FDA's Lm Risk Assessment has identified some categories of ready-to-eat foods that are more likely to support the growth of Lm and can have high levels of Lm. These foods are designated as high-risk and minimizing the levels of Lm in these foods should reduce the incidence of listeriosis. Focusing on the high-risk foods is a science-based approach that will allow food service operators to focus on foods in which date marking can potentially have an impact on public health. It will be easier to date mark a few categories of food, rather than all ready-to-eat, potentially hazardous foods. The date marking provisions will not apply to

those retail food establishments that do not serve or store the high-risk foods.

**4. Recommended Solution: The Conference recommends.....**

that the Food Code, Section 3-501.17, be changed to require only the high-risk foods be date marked. "Potentially hazardous foods" should be replaced with "high-risk foods, including deli meats, frankfurters, soft unripened cheeses, high fat and other dairy products, pasteurized fluid milk, pâté and meat spreads, unpasteurized fluid milk, and smoked seafood". Section 3-501.17(E) should be deleted in its entirety. FDA should provide a table listing all the high risk and very high risk food items. Annex 3, under Section 3-501-17, should also state that the list of high-risk foods may change or be increased as continued surveillance sampling and research is conducted, as part of the FDA's 2003 Updated Listeria Action Plan. The Date Marking Committee recommends that the FDA continually review and reclassify foods based on new science, industry practices, and product formulation.

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Guidance to control the growth of *Listeria monocytogenes* in post-lethality exposed (ready-to-eat) RTE meat and poultry products at retail

### 2. Issue you would like the Conference to consider:

When RTE meat and poultry products are sliced intermittently in restaurant and deli service establishments, the uncut portion of the product in its original packaging could remain in refrigerated storage for days, or weeks. This practice potentially exposes the meat and poultry products to environmental contamination with *L. monocytogenes*. The probability of cross-contamination increases with practices like the following: 1) use of the same slicing machine for all the deli meat and cheese and other products, 2) slicing machines being used intermittently without cleaning in-between slicing deli, cheese, and other products, or 3) using the same slicing machine for deli meat, cheese, and other products that are date-marked differently (i.e., with the date in which the package was opened for each product).

FSIS recently issued an interim final rule on the control of *L. monocytogenes* in RTE meat and poultry products (68 Federal Register 34208, June 6, 2003). The rule requires Federally-inspected establishments to select one of three control measures to address *L. monocytogenes* in post-lethality exposed RTE meat and poultry products. Establishments can use a post-lethality treatment, and/or an antimicrobial agent or process, or a sanitation program to control the pathogen in post-lethality exposed processed meat and poultry products. The label of products that received a post-lethality treatment or antimicrobial agent or process validated to eliminate, reduce or inhibit *L. monocytogenes* may bear a claim on their label stating that the product has been treated or contains an agent or process to control the presence of *L. monocytogenes*. For retail operations, although they may not have the ability to apply a treatment to kill or suppress the growth of *L. monocytogenes*, such operations could enhance their sanitation practices in deli operations to reduce the potential for cross-contamination of RTE product with this pathogen, and could seek to sell products that were specifically treated to kill or suppress growth of this pathogen.

### 3. Public Health Significance:

There are two documents that show the risk of *L. monocytogenes* contamination of deli products at retail. The FDA-FSIS "Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods" indicated that deli meats posed the greatest per serving risk and per annum risk of illness or death from *L. monocytogenes* ([www.foodsafety.gov/~dms/lmr2-su.html](http://www.foodsafety.gov/~dms/lmr2-su.html) )

. A study was conducted by the National Food Processors Association (NFPA) to determine the presence and levels of *L. monocytogenes* in eight categories of RTE meat and poultry products from retail markets at the Maryland and northern California FoodNet sites. The NFPA study identified *L. monocytogenes* prevalence of 0.4 % in case-ready (manufacturer-packaged) versus 2.7 % in in-store packaged RTE product at retail in these two FoodNet sites (Gombas et al., 2003). The survey, which was conducted in two state sites, showed a much higher prevalence of the pathogen at retail. The requirements of the USDA FSIS interim rule on *L. monocytogenes* would control the pathogen in all Federally- inspected establishments producing RTE meat and poultry during post-lethality exposure. Since some of these RTE products are processed and handled at restaurant and deli service establishments, these establishments should re-evaluate, develop and apply methods to extend the control of *L. monocytogenes* to the retail sector.

Reference:

Gombas, D.E., Y. Chen, R.S. Clavero, and V. N. Scott. 2003. Survey of *Listeria monocytogenes* in Ready-to-Eat Foods. J. Food Protection vol. 66, No. 4 pp. 559-569.

**4. Recommended Solution: The Conference recommends.....**

USDA develop, and FDA include as an Annex to the Food Code, guidance for retail establishments that incorporates information on the risk of *L. monocytogenes* in RTE meat and poultry products and the action that both FDA and USDA are implementing to reduce these risks. The guidance will also include control practices that the retail establishments can include, such as: 1) the use of post-lethality treatments and antimicrobial agents and processes in the processing of deli products; 2) the use of more rigorously performed and documented sanitation procedures to ensure separation of RTE and not RTE products, and of different categories of RTE products, and prevent cross-contamination; and 3) the selection of processed RTE meat and poultry products that receive intervention treatments to control *L. monocytogenes* and prolong the refrigerated shelf life for deli or retail sale. [Attachment]

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Identification of sanitation practices, standard operating procedures, and good retail practices to limit post-processing contamination with and growth of *Listeria monocytogenes* in food establishments.

### 2. Issue you would like the Conference to consider:

Based upon the Date Marking Committee's review of research studies, illness data, scientific references, and other materials related to the growth of Lm within food establishments, there are no specific guidelines in the Food Code for the prevention of Lm contamination within food establishments as defined in the FDA Food Code. A review of the Food Code is necessary to assure that sanitation control chapters and references in the Food Code identify methods to reduce Lm harborage areas and eliminate the potential for Lm contamination.

### 3. Public Health Significance:

*Listeria monocytogenes* is a pathogen that must be controlled with strategies other than strict control of refrigeration temperatures. Food establishments must eliminate post processing contamination of ready-to-eat foods. Food establishments can control refrigeration temperatures, sources of Lm within their facilities (approved sources of food, floor drain maintenance, etc.), and behaviors of food workers (cleaning and sanitizing surfaces, preventing cross contamination, proper cleaning and sanitization of food contact surfaces, monitoring refrigeration temperatures, etc.) in an effort to reduce the potential for Lm illness. Food establishments cannot control contamination that occurs in food processing facilities. Operators and regulators should be provided with guidance to understand Lm and its controls.

One of the primary objectives of the "2003 FDA/CDC Update of the *Listeria* Action Plan" is to develop and revise guidance for processors that manufacture or prepare ready-to-eat foods and develop or revise guidance for retail and food service and institutional establishments. Controlling Lm exposures in all food establishments along with those in food manufacturing facilities will ultimately control illness related to Lm.

### 4. Recommended Solution: The Conference recommends.....

that a committee be formed to address the specific cleaning, maintenance, and cross contamination interventions that can be used to control Lm in food establishments. The committee should review the Food Code and all existing materials to identify strengths and gaps in cleaning guidelines in relation to Lm harborage areas within food establishments and, if necessary, should develop a new guidance document for industry

and regulators. The committee should include representatives of the FDA, state and local health jurisdictions, and the retail and food service industries.

In addition, this committee should be charged to work with FDA and respond to Objective 1 of the FDA "Reducing the Risk of Listeria monocytogenes FDA/CDC 2003 Update of the Listeria Action Plan". Input from the CFP will ensure a continuation of broad considerations that the food service and retail food industries and state/local regulatory agencies require when considering the use of control interventions for Listeria monocytogenes at food establishments.

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Exception to 14 day shelf life limit

### 2. Issue you would like the Conference to consider:

Food Code 2003 Supplement Section 3-502.12(5) prohibits shelf life in excess of 14 days. An exception is needed to allow for extended low temperature refrigerated storage at -3.0 to -1.6C (26-29F) of food prepared by formal cook chill systems that provide electronic documentation of pasteurization, rapid chilling, and extended low temperature refrigerated storage processes. Once removed from extended low temperature refrigeration and placed in a standard walk in refrigerator that holds food below 5C (41F), the food items are consumed within 72 hours.

### 3. Public Health Significance:

While section 3-502.12(5) may be appropriate in routine restaurant settings, it is inappropriate for highly technical cook chill systems with extensive documentation of pasteurization, rapid chilling that exceeds the Gompertz model, and long term storage at documented temperatures of -3.0C to -1.6C (26-29F). These foods are not frozen but are rapidly chilled and stored at temperatures below the low growth threshold for *Clostridium botulinum*. American companies are the world-wide leaders of this technology. Adoption of this section will inhibit an industry that manufactures food systems already in place and safely used to produce food by hospitals, government, military, universities, industrial feeders, and large volume restaurants in the United States. In addition, it may remove good paying jobs without scientific justification.

Food items produced by cook chill systems have documented pasteurization with electronic temperature logs that verify thorough cooking. Tumble chiller units that chill products from 180F to below 60F within 1 hour and to below 37F within 2 hours. Products are then immediately stored at low temperature -3.0 to -1.6C (26-29F). The temperatures are electronically monitored. These products are safely below the low temperature threshold for *Clostridium botulinum* growth. Millions of meals are produced everyday by these systems. There has been no reported incident in more than 30 years.

Food Code 2003 Supplement footnotes 26 and 29, are not related to this technology. We agree with FDA that food held in walk in refrigerators at temperatures above 38F presents a botulism hazard when held longer than 14 days. Public Health Reasons for 3-502.12 state *Clostridium* may not be a significant hazard in ROP packaged products that are properly cooled and "frozen immediately". *Clostridium botulinum* is inhibited when stored at temperatures above "frozen" as implied in the Public Health Reasons of the

supplement.

#### 4. Recommended Solution: The Conference recommends.....

(1) The Council that receives this document be authorized to create a subcommittee to develop recommendations for regulations for cook chill systems exceeding the Gompertz model for inclusion in the next version of Food Code. (2) The Conference Chair be authorized to write a letter to FDA recommending Section 3-502.12 (5) be modified to include section (5) (a) that reads as follows:

"(a) Except that retail food establishments using specified equipment that can reliably document pasteurization, rapid chill that exceeds the Gompertz model, followed by immediate extended low temperature refrigerated storage at -3.0 to -1.6C (26-29F), that is verifiable by untamperable electronic monitoring of time and temperature during extended low temperature storage, may exceed 14 days shelf life, as authorized by the regulatory authority."

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## CONFERENCE FOR FOOD PROTECTION

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Issue # 2004 III-022  
Internal # 080

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Regulatory for Cook Chill

### 2. Issue you would like the Conference to consider:

Cook Chill Systems are technical food processing systems specifically designed and used by food establishments to cook, rapidly chill, and hold food over prolonged periods safely. Wording of Section 3-502.12(5) of Food Code Supplement inappropriately limits their application by an overbroad limitation for ROP processing to less than 14 days unless the food is frozen, without scientific justification. In cook chill systems food is pasteurized, rapidly chilled, and held at -3.0 to -1.9 C (26-29F) for prolonged periods safely.

### 3. Public Health Significance:

Manufacturers agree with FDA in its application of shelf limitation to 14 days of products stored in walk in refrigerators at 5C (41F). However the broad application of this section as written limits the development of cook chill systems with cooking rotation longer than 14 days that take advantage of prolonged low temperature refrigeration at -3.0 to -1.9C (26-29F).

Most food technologists agree that Clostridium botulinum is not a hazard when the food is held below 38F. Designed systems employ rapid chilling and prolonged low temperature refrigeration at -3.0 to 1.9C (26-29F). This has not been an issue at retail until the wording in the 2003 Supplement. There is a science gap between 38 F and "frozen". Technology developed by cook chill systems is specifically tailored to store food in this "gap zone" that has now been created. These systems should be properly regulated through Food Code as they have been in use for 30 years and their applications are broadening in accordance with technological advancements.

### 4. Recommended Solution: The Conference recommends.....

(1) The Chair of the Council handling this issue be authorized to appoint a subcommittee to develop recommended regulations for cook chill systems employing extended low temperature refrigeration to appear in the next version of Food Code. (2) The Conference Chair send a letter to the FDA Commissioner to urge that Section 3-502.12(5) in the current Supplement be amended to read as follows:

"(a) Except that retail food establishments using approved equipment designed specifically for cook chill systems that can reliably document pasteurization, rapid chilling, and prolonged low temperature storage at -3.0 to -1.9C (26-29F) may exceed 14 days, as authorized by the regulatory authority."

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Revise Reduced Oxygen Packaging, Criteria.\*

### 2. Issue you would like the Conference to consider:

To Revise Reduced Oxygen Packaging, Criteria.\*, to allow licensed operators with cook-chill systems envisioned in the 1980 patent (attached) to not be limited to 14 days storage from date of packaging to consumption.

Many thousands of pounds of food have been safely produced every month in cook-chill systems manufactured and sold by U.S. manufacturers domestically and abroad for over thirty years. Though the original 1980 patent (#4218486) makes reference to smaller casings and faster cooling than is done in practice, these systems and process have been in place for over 30 years and their safety is a matter of record. The 1980 patent makes reference to prior art dating back to 1953. Users of such systems include medical centers, public and private, the U.S. military, VA's, long and short term care facilities, public schools, colleges and universities, retailers, contract feeders and gaming operators. There is no data to show that persons have been injured by the pasteurized foods that are hot filled in laminated pouches and casings, whether solid muscle meats cooked in cook tanks, or pumpable foods prepared in open steam jacketed kettles whilst being agitated which are subsequently chilled in tumble chillers powered by ice builders. The manufacturers of complete cook-chill systems have many hundreds of these systems installed in food service, retail and USDA inspected operations. Each one of these cook-chill systems has had a cost of at least 3/4 million dollars (with the mean cost being substantially higher) for equipment alone, not including facilities and mechanical systems.

### 3. Public Health Significance:

Cook-Chill systems by the major equipment manufacturers have control, monitoring and validation criteria that has empirically proven itself by safe processing and packaging of PHF foods whilst preventing toxin formation by *C. Botulinum*, *C. Perfringens* or *B. Cereus*. The actual refrigerated storage time (at mean temperatures above 28F and below 36F) for various cook-chill packaged foods depends on its individual HACCP plan which in turn is a function of the individual foods acidity, salinity, the package size, the foods thermal diffusivity,  $a_w$  and other food chemistry criteria known to affect replication, and to be within the operational goals of the system. Where operators do not have such equipment or controls and validation systems and due to concerns for toxin formation by anaerobic *C. Botulinum*, *C. Perfringens* and *B. Cereus*, the 14 day limitation is reasonable and in the interest of public health. But where certain operators have made the investment in these mostly turn-key systems and have provided the required facilities,

training, and a higher caliber of staff certified in its operation, they ought not be constrained by a 14 day rule as to do so places a significant financial hardship upon them and punishes those that have already demonstrated (in some cases for over (30) years) their diligence in safe food production. Note that a 14 day limitation on foods produced in these systems presents a conundrum in that it is less likely sampled foods that return presumptive positive could be recalled as it takes at least half of that time to culture a sample.

**4. Recommended Solution: The Conference recommends.....**

that a letter be written to the FDA recommending that Section 3-502.125 Reduced Oxygen Packaging, Criteria.\* be revised to provide exception for variance by HACCP plan when a complete cook-chill system comparable to that envisaged in the 1980 patent (attached) is used and those responsible for its operations have been certified by the manufacturer as competent in its operation within the frame of its intended use.

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Latex Gloves Prohibited

### 2. Issue you would like the Conference to consider:

FDA Food Code 3-304.15 Gloves, Use Limitation

A number of studies have shown that individuals can and do develop allergic reactions to the proteins found in latex, so much so that the following statement was developed by a joint subcommittee of the American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy, Asthma and Immunology (AAAAI). It was approved by the ACAAI Board of Regents on the recommendation of the Executive Committee on July 21, 1997:

"Latex gloves should be used only as mandated by accepted Universal Precautions standards. The routine use of latex gloves by food handlers, housekeeping, transport and medical personnel in low risk situations (e.g. food handling, bed transport, routine physical examination) should be discouraged."

Additionally, Annex 3 of the 1999 FDA Food Code points out that:

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves. This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Occasionally, the allergies developed by individuals can be extremely severe, even life-threatening. It has been reported that highly sensitized individuals can go into anaphylactic shock simply from eating a sandwich prepared by someone wearing latex gloves.

### 3. Public Health Significance:

There are numerous alternatives to the use of latex gloves in the food preparation process, including having in place a proper hand-washing program. Thus, there will be no increased risk to any member of the public if latex gloves are forbidden. On the other hand, consumers with allergies will be safer, and food service workers will not be confronted with the possibilities of allergy development from long-term exposure.

**4. Recommended Solution: The Conference recommends.....**

Add to the following to FDA Food Code section: 3-304.15(A) Gloves, Use Limitation.

(A) If used, SINGLE-USE gloves shall be used for only one task such as working with READY-TO-EAT FOOD or with raw animal FOOD, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation. [SINGLE-USE gloves intended for food handling or preparation shall not consist of or contain any form of natural rubber latex.]

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Short Task Food Gloves

### 2. Issue you would like the Conference to consider:

In an effort to continue to reduce fingertip contamination, an additional definition for the use of gloves needs to be added to chapter 3 /section 3.304.15 -- Gloves -Use Limitation. The recommendation is to add a definition for a "short task food glove" in addition to the existing "single-use glove." The short task (ST) food glove is used similar to a utensil, for one specific food type (raw or ready-to-eat) requiring greater dexterity than a utensil to dispense or place the food. The gloves are immediately discarded. ST gloves are uniquely dispensed for one hand donning that takes less than 3 seconds. Currently, the 2001 Food Code requires handwashing before starting a new task and between each glove change. In this case, the risk of contamination doing the same task is very low. Handwashing between changes of the short task food glove should not be necessary, as long as the food worker does not change the specific food task, and follows their existing handwashing policy if hands or gloves become cross-contaminated.

### 3. Public Health Significance:

This addition to the Food Code will provide a practical solution to helping reduce fingertip contamination during quick food service tasks. Like a utensil, disposable gloves provide a physical barrier to contamination from fingertips to food or vice versa. For tasks requiring some dexterity for food placement and speed, new products such as polyethylene gloves and mitts have been designed for one quick food handling task. The short task (ST) food gloves would have additional restrictions over single-use gloves such as:

- 1) ST gloves can only be used by a designated, trained worker to handle one food type, i.e. ready-to-eat food types that cannot cross-contaminate each other OR single species raw foods such as raw beef burger patties, raw chicken breasts, etc.;
- 2) ST food gloves are removed when the specific handling step is complete--usually a few seconds to less than 2-3 minutes and new ST gloves are donned during the next repetitive task i.e. a raw food task like loading the grill with raw beef patties or ready-to-eat task like building a sandwich;
- 3) The handwashing interval for workers using the ST food glove is the same as the operation's existing handwashing policy. If incidental contamination from any source occurs, or the food handling task changes, hands must be washed prior to re-gloving;
- 4) ST food gloves are removed by grasping the top of each cuff, peeling the glove inside out and immediately discarding the glove(s);
- 5) ST food gloves are made of polyethylene, the ingredients are listed in the CFR for

food contact, and are 3<sup>rd</sup> party quality certified for safety, cleanliness, and durability.

**4. Recommended Solution: The Conference recommends.....**

Modify 3-304.15 as follows: Add: (E) Short task food gloves can be used if the five criteria (listed above) are met.

**5. Submitter:**

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

All information above the line is for conference use only.

### 1. Title:

Qualification of Gloves for Food Preparation to Prevent Contamination

### 2. Issue you would like the Conference to consider:

Section 3.3-301.11 states that "...food employees may not contact exposed, ready-to-eat food with their bare hands..." Several options to bare hand contact are available to food operators which include utensils, bakery/deli papers and gloves. The information presented in the FDA Food Code Annex 3 (3-304.15 Gloves: Use Limitations) clearly states that all gloves used in direct contact with food must meet FDA criteria for indirect food additives.

Relevant Codes:

3-304.15 Gloves: Use Limitations

3-202.12 Additives

3-302.14 Protection from Unapproved Additives

3-301.11 Preventing Contamination from Hands

3-304.15 Annex 3 and Annex 2: Gloves, Use Limitation

There are a number of issues to be considered when gloves are utilized. Resistance to a more universal use of gloves has been due to glove irritant and allergen properties, poor fit or excessive sweating and glove failure or damage during use (London et al. 1992; Michaels 2001). There are hundreds of types of thin-walled gloves available to the food industry today consisting of 7 or 8 different main material types having varying thicknesses and internal and external coatings or powders (Tillotson 2000). The extreme variability as to effectiveness of gloves in reducing risk is a result of the extreme quality differences in these glove materials and types. Some glove types are unsuitable for food applications for which they are currently employed. When gloves are used properly and glove material is capable of maintaining integrity, risk of pathogen transmission can be reduced considerably, but use must be monitored carefully to ensure that the gloves are task appropriate (Montville et al. 2001; Gill & Jones 2002).

It has been noted that gloves are increasingly being used in hospital food service facilities operated under HACCP systems, reflecting measures to protect susceptible populations (2001 Food Code). Glove use cannot reduce one kind of risk, by preventing bare hand contact, while at the same time increasing risk of chemical contamination of food as has been noted with; (1.) latex allergens (Beezhold et al. 1994; Beezhold 2000; Franklin & Pandolfo 1999; Schwartz 1995; Nixon & Lee 2000; Lee et al. 2001), (2.) vinyl glove plasticizer phthalate contamination and allergic reactions (Tsumura et al. 2001; Tsumura et al. 2001b; Tsumura et al 2003; Kawamura et al. 2002; Frosch et al. 1987 ) and (3.) chemical contaminants and contact urticaria caused by nitrile gloves (Mutsuga et al.

2002; Wakui et al 2001; Aalto-korte et al. 1996; Horn & Aldridge 2003; Mutsuga et al 2003; Brehler 1996) . Glove powders or donning agents have also been found to be a source of irritation and allergic reactions to wearers and, if glove punctures occur, can contaminate food (Tomazic et al 1994, FDA 1997).

Vinyl gloves have a very high defect rate as manufactured and have been described as having an extremely high leakage rate during use (Kotilainen et al 1989; Cervera et al. 1990; DeGroot-Kosolcharoen et al. 1989; Douglas et al. 1997). The Canadian Food Inspection Agency reports that among the common complaints associated with certain types of processed foods are the presences of glove pieces mixed in with food product (CFIA 1997). Negative consequences result when inferior gloves are used that are not up to the food handling requirements or current FDA regulations resulting in increased food safety risks. Gloves used in food environments should be chosen based on their dermal compatibility, barrier performance, durability, comfort of fit, and most importantly on their chemical purity and lack of unapproved chemical transfer to food.

### **3. Public Health Significance:**

It is estimated 2.3 million people in the US are affected by latex allergy. Latex allergy is an IgE-mediated reaction to certain proteins retained in products manufactured from natural rubber latex. Many other irritant and allergic reactions have been identified with other glove types including vinyl and nitrile. Allergic reactions range from mild symptoms, such as hives and itching, to life-threatening anaphylactic reactions while irritation reactions result in reduced hygiene and missed days from work. In the Healthy People 2010 report it is estimated that the cost of occupational skin disease each year is between \$ 200 million and \$ 2 Billion annually (Healthy People 2010). When a person with latex allergy comes into contacts or ingests food that has been handled by latex gloves, that an allergic reaction can result (Beezhold et al. 1994; Beezhold 2000; Franklin & Pandolfo 1999; Schwartz 1995; Nixon & Lee 2000) Research demonstrates that latex, vinyl and nitrile gloves used by food handlers can be a direct source of food adulteration caused by the migration of allergenic proteins or potentially toxic compounds from the glove surface to food products. This type of transfer from glove surfaces to food products has been scientifically documented. It has previously been noted that latex allergy is comparable to serious food allergies such as peanut and seafood allergies where the ingestion of trace amounts can cause systemic allergic reactions. Similarly, trace amounts of other potentially toxic compounds may represent an unknown hazard of increasing proportion as glove use continues to become more widespread. Non-latex, non-vinyl and non-nitrile food processing/service gloves are available that do not contain potentially toxic compounds and are chemically pure.

### **4. Recommended Solution: The Conference recommends.....**

The code does not require glove use, nor does it specify the type of gloves that may be used, except they should be “single-use” (3-301.11).” This section should ban the use of gloves linked to release of compounds having known human toxicity to protect both food workers and the consuming public. The Conference Chair should send a letter to the FDA urging the Commissioner to implement rulemaking process to amend or modify the current food additive regulation, 21CFR 177.2600, concerning natural rubber latex as it pertains the use of latex gloves in food operations, based on food safety considerations. The Conference Chair should further request the FDA set minimum physical and chemical specification standards for gloves that would be acceptable for food handling

activities adhering to the guidelines set forth in the Food Drug and Cosmetic Act.

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## CONFERENCE FOR FOOD PROTECTION

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**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

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### 1. Title:

Third Party Certification of Disposable Single Use Food Contact Gloves

### 2. Issue you would like the Conference to consider:

In an effort to provide clean, sanitary and safe disposable single use gloves for the food industry we ask that Council III require third party certification of disposable single use food contact gloves.

### 3. Public Health Significance:

Due to fact that there are limited manufacturing standards for food contact gloves in the United States, food preparers run the risk of compromising food safety with an unknown quality of disposable single use food contact gloves (e.g. pinholes, weak seams, high bacteria counts, etc.), including no sanitary requirements for factories. The only standard that has been used until recently for the production of single use disposable gloves was for medical exam gloves, these standards only include the manufacturing of dipped gloves, (ex. vinyl, synthetic, or latex). Also there were no standards for heat seamed POLY gloves other than 21 CFR Indirect Food Additives - Polymers (Federal Food & Drug Cosmetics Act). Medical glove standards include: (1) Acceptable Quality Level (AQL) of 4.0 to 1.5, (2) FDA Premarket Notification to sell medical gloves and (3) labeling for traceability. The American Society for Testing & Materials (ASTM) does set standards for latex, vinyl and nitrile ingredients and physical standards. However, there are no requirements for medical exam gloves to be used in the food industry. Third party certification would guarantee: (1) Safety, including toxicology – making sure all ingredients are approved for food contact; Biocompatibility – approved ingredients for each glove type, ingredients must be safe for skin contact, and sets allowable protein levels for the production of latex gloves. (2) Durability, including barrier integrity – water testing, tensile strength and elongation (ability to stretch before breaking); visual inspection, including checking for visible defects, rips, tears, imbedded materials, and discoloration; labeling – packaging includes proper glove usage and the latex warning. Glove powder – sets allowable powder levels; (3) Cleanliness, Bioburden - sets the maximum bacteria levels in disposable single use gloves; ISO 9000 compliance for factories, plants following good manufacturing practices, HACCP plans in place, and unannounced annual audits to insure ongoing compliance.

The 2001 FDA Model Food Code - Section 4 -105.10 Food Equipment, Certification and Classification (this is not a requirement, but for operators information only) states that if equipment is certified or classified for sanitation by the American National Standards Institute (ANSI) – the accredited certification program will be deemed to comply with Parts

4 - 1 and 4 - 2 of this chapter. Section 4 -1 reads (4 - 102.11) Single - Service and Single Use Characteristics.\* Materials that are used to make single - service and single - use articles: (A) May not: (1) Allow the migration of deleterious substances, or (2) Impart colors, odors, or tastes to food; and (B) shall be: (1) Safe, and (2) Clean. Section 4 - 2 reads (4 - 201.11) Durability and Strength: Equipment and Utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions. Because this section of the code is not mandatory this allows for food industry operators to use gloves manufactured with unknown standards including questionable quality and poor durability and unacceptable plant sanitation.

**4. Recommended Solution: The Conference recommends.....**

that a letter be written to FDA to recommend the following change: In order to protect the public health, disposable single use food contact gloves shall be required to be manufactured under a third party certification, this can be accomplished by modifying Section 4 -105.10 Food Equipment and Utensils to state that disposable single use food contact gloves be third party certified.

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Preventing Contamination from Hands, Section 3-301.11

### 2. Issue you would like the Conference to consider:

Section 3-301.11 This section states that "...food employees may not contact exposed, ready-to-eat food with their bare hands..." and prohibits bare-hand contact by food employees. While Food Code Annex 3 goes on to give some guidance on possible exceptions to the absolute prohibition, Annex 3 is not part of the mandatory code. Therefore, the annex has proven difficult to comply with and has been widely interpreted. Furthermore, it is generally lost during state adoption. This section, in some localities has been enforced as a mandatory glove law or a complete bare-hand prohibition without allowing reasonable alternatives. The FDA has publicly stated that this is not the Agency's intent, but the Food Code in Section 3-301.11 and in Annex 3 states that "bare-hand contact with ready-to-eat food...is prohibited...."

### 3. Public Health Significance:

Evaluations of actual ready-to-eat (RTE) food handling tasks in restaurants found a significant number that were not likely to be accomplished with the current alternatives to bare hand contact. Regulatory officials in certain municipalities that have mandated no bare hand contact with RTE foods have observed such examples and "exempted" them on a case-by-case basis, while other regulatory officials have not – leading to growing non-uniformity. Tasks like the garnishing of a plate, peeling shrimp and picking steamed crabs have elicited a "don't ask – don't tell" policy with certain inspectors that is counter to the openness sought for HACCP discussions.

The use of gloves is in itself not a cure all and still requires a good handwashing program to ensure food safety. FDA highlighted this in their report (Evaluation of Risks Related to Microbiological Contamination of Ready-to-eat Food by Food Preparation Workers and the Effectiveness of Interventions to Minimize those Risks, 1999) that "it has been demonstrated that both the interior and exterior of gloves can become contaminated with surface hand microorganisms if the hands are not washed prior to gloving. Hands themselves can also be contaminated with organisms found on the glove surface."

On September 22, 1999, NACMCF met and was charged by the FDA to evaluate if bare hand contact with food contributes to foodborne illnesses. The NACMCF discussion noted that science supports policies to remove ill food handlers from food handling tasks and that proper hand washing procedures reduce microbial loads on the skin. However, the NACMCF recommended that insufficient scientific data exists to support a complete



ban on bare hand or arm contact of ready-to-eat food or whether physical barriers are needed at all times.

The NACMCF recommendation to FDA involved the following elements that are already part of the food code:

- Effective hand washing practices and management (Subpart 2-301)
- Food-safety training promoting the importance of healthy food handlers and hand washing practices (Subpart 2-102-103)
- Use of utensils/tongs/deli tissues or single-use gloves in high-risk food preparation situations. (Subpart 3-304)

While the public health significance of this issue is provided by FDA in Annex 3; the vast majority of government agencies who have adopted the FDA Food Code (in whole, part, or by reference) have not adopted the Annexes, and this scientific reasoning is not recognized or communicated to the user level.

Furthermore, the Conference deliberated this issue in 2002 and came to a consensus recommendation in Council III that was supported by the FDA.

#### **4. Recommended Solution: The Conference recommends.....**

The Conference recommends a letter should be sent to the FDA Commissioner to urge the following changes to Section 3-301.11, page 48 of the 2001 Food Code:

Section 3-301.11 of the 2001 FDA Model Food Code should be modified to accommodate a more practical approach to limiting bare hand contact. The model Food Code should read as follows:

(C ) Except when washing fruits and vegetables as specified under § 3-302.15 or as specified in (D) and (E) of this section, FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT.

(D) FOOD EMPLOYEES may contact exposed, READY-TO-EAT FOOD with their bare hands  
if:

- (1) The PERMIT HOLDER complies with § 2-201.11;
- (2) The PERSON IN CHARGE complies with Subparagraphs 2-102.11(C)(1)-(3) and (8), 2-103.11 (D), and §§ 2-201.12 and 2-201.13;
- (3) The PERSON IN CHARGE maintains a documented plan in the FOOD ESTABLISHMENT that is readily available at all times for use by EMPLOYEES and for REGULATORY AUTHORITY review upon request, and that specifies:
  - (a) Why it is necessary for FOOD EMPLOYEES to contact READY-TO-EAT FOOD in specified situations,
  - (b) The FOODS that will be contacted by bare hands,
  - (c) The HAZARD presented by bare-hand contact is the possible transfer of bacterial, viral, or parasitic pathogens from FOOD EMPLOYEES' hands to the FOOD,
  - (d) The procedures and practices that require EMPLOYEES to wash their hands before returning to their work stations,

- (e) A training program for the FOOD EMPLOYEES that specifies:
  - (i) Who is responsible for the training,
  - (ii) The program content, including instructions to FOOD EMPLOYEES about the HAZARD as specified in Subparagraph (D)(3)(c) of this section, not to work when they are ill with any of the symptoms or diagnoses specified under § 2-201.11, good hygienic practices, proper handwashing, the principles of safe FOOD preparation procedures, and precluding cross contamination, and
  - (iii) The frequency of the training including periodic refresher sessions,
  - (f) How FOOD EMPLOYEE compliance with the plan will be monitored, documented, and verified, and
  - (g) Corrective actions to be taken when the plan is not followed, such as when an ill FOOD EMPLOYEE is found preparing FOOD;
- (4) The PERSON IN CHARGE ensures compliance with the plan specified in Subparagraph (D)(3) of this section and amends it as required by the REGULATORY AUTHORITY; and
- (5) FOOD EMPLOYEES comply with the plan specified in Subparagraph (D)(3) of this section, § 2-301.14, and Part 2-4.

(E) A PERMIT HOLDER or PERSON IN CHARGE electing to comply with (D) of this section, may also implement one or more of the following:

- (1) Vaccination against hepatitis A for FOOD EMPLOYEES, including initial and booster shots or medical evidence that a FOOD EMPLOYEE has had a previous illness from hepatitis A virus;
- (2) Double handwashing;
- (3) Use of nailbrushes; or
- (4) Use, after proper handwashing, of a hand sanitizer as specified under § 2-301.16.

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Reducing Norovirus: Prevention of Bare Hand Contact with Ready-to-Eat Foods

### 2. Issue you would like the Conference to consider:

Scientific evidence supports the need for prohibiting bare hand contact (BHC) with ready-to-eat (RTE) foods at the retail level (See attachment #3). However, there are some practices in food service and the retail food industry where BHC must occur. The current exception for "BHC with RTE food", as specified under paragraph 3-301.11(B) of the 2001 Food Code does not provide guidance on how to minimize the risks of BHC with RTE food, and can lead to increased risk of NoV and other fecal oral route pathogen transmission if improperly addressed.

### 3. Public Health Significance:

CDC estimates that norovirus (NoV) is the leading cause of foodborne illness in the United States. NoV impacts all ages from infants to the elderly, with the highest incidence occurring in young children, and the greatest mortality risk occurring in the elderly (See attachment #4).

When the Food Code was first developed in 1993, little scientific information was available on NoV. However, NoV is now recognized as the single most common cause of gastroenteritis in all age groups, and one of the most important foodborne pathogens in the western world.

Several feeding studies using stool filtrate from symptomatic individuals to infect volunteers, have established NoV infectivity via the fecal oral route. The CDC has also reported that hands are the most important means by which enteric viruses are transmitted. BHC by an infected food worker with RTE food items is a significant cause of NoV foodborne illness outbreaks.

Viral foodborne illnesses provide a potential high microbial contamination level on the hands of infected food workers. NoV is shed in the feces up to 1,000,000 viral particles per gram of feces during peak infectivity. The level of contamination in a food item is completely dependent on the food worker that is handling the food item. Bidawid et al (2000), has shown that more than 1000 virus particles can easily be transferred from fecally contaminated fingers to foods and surfaces. NoV is highly infectious, with the infectious dose believed to be as low as 10-100 virus particles. NoV is also resistant to heat and chemical disinfectants and easily spread from fecally contaminated hands to food products and environmental surfaces.

Asymptomatic infections are common, with as much as 30% of the NoV infections occurring as asymptomatic infections. Asymptomatic shedders make the control of NoV foodborne outbreaks more difficult, since symptoms can not be relied upon as an

indicator of the risk of NoV. In this case, prevention of foodborne illness outbreaks is dependent on a combination of effective handwashing and preventing direct hand contact with RTE foods.

**4. Recommended Solution: The Conference recommends.....**

based on discussion and deliberation, that FDA amend the Food Code to reduce the risk of fecal-oral route transmission of Norovirus and all other fecal oral route microbial foodborne pathogens from the hands of infected food workers, through prevention of BHC with RTE foods. For those instances where BHC must occur, focused control measures must be in place that have been mutually accepted by the industry and the regulator.

FDA is asked to amend the Food Code to delete "except when otherwise approved" from paragraph 3-301.11 (B) and replace with a new paragraph (3-301.11(D)), requiring a variance with specific written procedures describing focused control measures that are necessary to reduce the risk of microbial transmission (See attachment #1). The written procedures are based on the latest science available on fecal oral route pathogen transmission, and have been designed to focus emphasis on reducing the risk of viral, protozoan, and bacterial transmission from infected food workers to consumers, through RTE foods. The written procedures provide enough focus on reducing the risk of microbial transmission, so a HACCP PLAN is not needed for this variance. A model application form for this variance process is provided in attachment #2.

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-030  
Internal # 086

**Council Recommendation:**      **Accepted as Submitted** \_\_\_\_\_ **Accepted as Amended** \_\_\_\_\_ **No Action** \_\_\_\_\_

**Delegate Action:**      **Accepted** \_\_\_\_\_ **Rejected** \_\_\_\_\_

*All information above the line is for conference use only.*

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### 1. Title:

Reducing Norovirus: Implementing Effective Employee Health Interventions

### 2. Issue you would like the Conference to consider:

When the Food Code was first developed in 1993, little scientific information was available on norovirus (NoV), known previously as "Norwalk-like virus" (NLV). However, NoV is now recognized as the single most common cause of gastroenteritis in all age groups, and one of the most important foodborne pathogens in the western world. Several recent scientific publications recognize consuming food that has been contaminated by infected food workers as a leading risk of NoV foodborne illness, and emphasize that more must be done to control the incidence of Norovirus foodborne illness. New information on NoV provides a better understanding of the transmissibility and extreme infectivity of NoV and allow us to develop improved guidance in the Food Code to further reduce the risk of transmitting NoV at the retail level (see attachment #1: CDC Background paper on Norovirus).

Focusing on excluding food workers exhibiting vomiting and/or diarrhea does not mean that we can ignore infected food workers that are asymptomatic or diagnosed with highly infectious and virulent fecal oral route pathogens. The Employee Health section of the Food Code should retain guidance on controlling the transmission of all fecal oral route pathogens through exclusion and restriction of infected food workers with highly infectious and virulent fecal oral route pathogens.

### 3. Public Health Significance:

CDC estimates that NoV is the leading cause of foodborne illness in the United States. The CDC has also reported that hands are the most important means by which enteric viruses are transmitted. Transmission of NoV has been shown to occur most commonly through the fecal oral route, with contaminated food identified as the most common vehicle of transmission. More must be done to remove infected food workers from the food facility when diarrhea symptoms are present, to reduce the potential transmission of all highly infectious fecal oral route foodborne pathogens.

NoV has also been reported to cause infection by airborne transmission when individuals are in close physical proximity to an infected individual vomiting in the facility. Therefore an infected individual vomiting in a food facility increases the risk of infecting employees and consumers. Foodborne illness outbreaks have occurred from consumers vomiting in the dining room, or employees vomiting on the premises. Removing food workers from a food facility that is exhibiting vomiting symptoms protects consumers and fellow workers from infection with NoV.

Since NoV is shed in the stool at extremely high concentrations in infected individuals,

and through airborne particles in vomit, and infected food worker with diarrhea or vomiting symptoms should not be allowed in the facility until the individual is no longer a threat to fellow workers and consumers (see attachment #1: CDC Background paper on Norovirus).

**4. Recommended Solution: The Conference recommends.....**

based on discussion and deliberation, that FDA upgrade Employee Health, Section 2-2, Subpart 2-201, of the Food Code (see attachment #2: Proposed Draft of Section 2-2, Subpart 2-201) to include guidance on preventing the transmission of NoV and all other CDC identified frequently transmitted fecal oral route foodborne pathogens, through the exclusion of symptomatic food workers with vomiting and/ or diarrhea until the employee has been asymptomatic for at least 24 hours, and maintaining the requirement to exclude food workers diagnosed with any of the fecal oral route pathogens identified by CDC, in List I. "Pathogens Often transmitted by Food Contaminated by Infected Persons Who Handle Food, as published in the Federal Register, November 6, 2003, Volume 68, Number 215.

The upgrade to section 2-2 will clarify provisions for exclusion and restriction, based on science, and focus on removing infected food workers exhibiting vomiting and/or diarrhea from the food facility, until symptoms have subsided (see attachment #2) (Note that the attachment has not been finalized through the Agency review process).

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## CONFERENCE FOR FOOD PROTECTION

2004 ISSUE FORM  
Deadline Feb 2, 2004

Issue # 2004 III-031  
Internal # 046

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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### 1. Title:

Allow vacuum packaging of hard and semi-soft cheese at retail food establishments

### 2. Issue you would like the Conference to consider:

The 2001 Food Code Sec 3-502.12 Reduced Oxygen Packaging Criteria states that food for which *Clostridium botulinum* has been identified as a microbiological hazard in the final packaged form shall ensure that there are at least two barriers in place to control the growth and toxin formation of *C. botulinum*. Some state and local health jurisdictions have interpreted this section to prohibit the vacuum packaging of hard and semi-soft cheese (<40% moisture) at the retail level. FDA personnel who have been consulted have suggested that this issue be submitted to CFP. There is a reluctance for a policy decision to be made by any individual, although no one has stated that they know the practice to be dangerous.

### 3. Public Health Significance:

Allowing hard and semi-soft cheese to be vacuum packaged at retail establishments will allow for fresher product, more flexibility in package sizing and labor efficiencies. While researching this topic, I received a letter written in response to my inquiry. The entire letter is attached to this Issue, but it states that :

"The packaging of cheese in oxygen impermeable packaging will not introduce a condition that is not already present in the cheese as its interior is already anaerobic."

"No reports are in the literature that suggest that properly manufactured cheese can cause botulism. Many data suggest that properly manufactured hard cheese will not support the growth of *Clostridium botulinum* at any temperature."

"Where botulism was associated with cheese, there had been errors in manufacturing and none of the outbreaks were the result of reduced oxygen packaging."

"The growth of *Clostridium botulinum* can be controlled by proper control of pH and Aw. Properly manufactured cheese will not allow the growth of *Clostridium botulinum*."

"If properly manufactured cheese is obtained from an FDA inspected facility, the cutting and vacuum packaging of such cheese in oxygen impermeable film at a retail store that follows normal sanitation practices will not compromise its safety. To the contrary, such packaging will enhance the safety, quality and shelf life of the cheese."

It is my conclusion that if food handlers follow the other requirements of the Food Code including temperature controls, sanitation and personal hygiene practices and the cheese as defined is procured from an FDA inspected facility, there is no danger to health and likely a benefit to safety and quality of the product.

**4. Recommended Solution: The Conference recommends.....**

that paragraph (D) be added to section 3-502.12 stating, "Hard and semi-soft cheese (varieties including but not limited to cheddar (mild, medium, sharp), Colby (not more than 40% moisture), Monterey Jack, Colby-Jack, Muenster, Swiss, Parmesan, Asiago, Romano, Blue, Brick, Edam, Gorgonzola, Gouda, Pasteurized process cheese, and Provolone. This does not include Brie, Camembert, Cottage, Ricotta and Teleme.) are allowed to be vacuum packaged in oxygen impermeable film at a retail food establishment, as long as the sell by date does not exceed the original date placed on the bulk cheese package by the manufacturer; and such cheese is exempt from the provisions of paragraph (B) of this section.

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## CONFERENCE FOR FOOD PROTECTION

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Deadline Feb 2, 2004

Issue # 2004 III-032  
Internal # 054

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Provide guidance to retail establishments and restaurants on the handling of steaks that have been blade tenderized.

### 2. Issue you would like the Conference to consider:

Restaurants and retail operations receive steaks or similar cuts of meat that have been blade tenderized but typically are not labeled to signify that the products have been tenderized. In the blade tenderization process, multiple blades or needles, in single or multiple passes, penetrate the surface of the meat typically for the purpose of tenderizing the product. Intact meat (i.e., non-tenderized product) is generally considered sterile on the interior portion but may be contaminated with pathogens on the exterior surface. The blade or needle carries contamination on the surface of the product to the product interior. A study on blade tenderized beef steaks showed that 3-4% of the surface bacterial load is transferred to the interior of the product (Spring, 1999). Using the oven broiler, no difference in microbial numbers was observed between intact and non-intact steaks cooked to end point temperatures. The reduction of *E. coli* O157:H7 was less when using the gas grill than the broiler oven. Of the three methods of preparation – oven, commercial grill, and skillet, skillet cooking provided the least effective and most variable reduction in *E. coli* O157:H7.

Pan searing, or skillet cooking, is a typical method for preparation of rare or medium steaks. Blade tenderization in combination with marination (generally referred to as needle injected product with a marinade for flavoring and tenderization) is a common practice for marketing case-ready steaks and roasts. It is unknown as to whether the injection of the marinade enhances the distribution of surface contamination throughout the product. However, a recent *Escherichia coli* O157:H7 outbreak was associated with needle-injected, marinated blade tenderized beef steaks (FSIS, 2003). These products were not labeled to indicate that the products were blade tenderized. The products did bear an ingredient statement that identified the marinade components.

Section 3-401.11(C)(3) of the Food Code states that a raw or undercooked whole-muscle, intact beef steak may be served or offered for sale provided that it is cooked to a surface temperature of 63°C (145°F) or above and a cooked color change is observed on all exterior surface. This section should not be applicable to blade tenderized beef steaks or other non-intact beef steaks. However, blade tenderized steaks are not labeled in a manner to reflect that the product is blade tenderized. In addition, generally, it is not possible to visually discern a blade tenderized beef steak from an intact beef steak. Consequently, neither the food service preparer nor the consumer would know that the

cooking requirements of 3-401.11(C)(3) may not be sufficient to result in a safe product, in case of blade tenderized products and particularly if skillet cooking is used.

### 3. Public Health Significance:

*E. coli* O157:H7 foodborne illnesses associated with blade tenderized steaks have been reported in Canada and Michigan. Although the level of surface contamination of steaks is expected to be very low, the number of *E. coli* O157:H7 necessary to cause illness also is very small – estimated to be approximately 4 CFU/gm. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), in evaluating the risk of *E. coli* O157:H7 in blade tenderized steaks concluded that: 1) non-intact blade-tenderized steaks served very rare with cold spots (less than 120° F internal temperature) present a concern/risk, particularly to immunocompromised individuals; 2) there was insufficient data to address the need for labeling of blade tenderized steaks at this time. However, NACMCF recommended that non-intact blade tenderized steaks do not present a greater risk to consumers if the meat is oven broiled and cooked to an internal temperature of 140° F and above.

#### References:

Sporing, Sarah. 1999. *Escherichia coli* O157:H7 risk assessment for production and cooking of blade tenderized beef steaks. M.S. thesis, Kansas State University, Manhattan, Kansas.

Rodrigue, D.C., E.E. Mast, K.D. Green, J.P. Davis, M.A. Hutchison, J. Wells, T.J. Barrett, and P.M. Griffin. 1995. A university outbreak of *Escherichia coli* O157:H7 infections associated with roast beef and an unusually benign clinical course. *J. Infect. Dis.* 172 (4): 1122-1125

Foodborne Illness Investigation: *E. coli* 0157, August 2000. Michigan Department of Community Health, Communicable Disease and Immunization Division.

### 4. Recommended Solution: The Conference recommends.....

1) USDA, in consultation with FDA, develop guidance for retail establishments to be included in the Annex of the Food Code, which includes the recommendations from NACMCF addressing the safe cooking of blade tenderized steaks and other non-intact steaks to reduce or eliminate the risk of *E. coli* O157:H7; and 2) FDA, in consultation with USDA, incorporate the AMI Best Practices document that provides enhanced sanitation considerations for the blade tenderization process (final draft expected to be completed by first quarter of 2004) into Annex 3: Public Health Reasons/Administrative Guidelines.

### 5. Submitter:

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

All information above the line is for conference use only.

### 1. Title:

Chemical Sanitization Using Quaternary Ammonium Compound Solutions

### 2. Issue you would like the Conference to consider:

The FDA Food Code, Section 4-501.114 (C)(1) specifies a single minimum temperature of 24°C (75°F) for a quaternary ammonium compound solution, therefore not allowing for applications requiring lower temperatures.

### 3. Public Health Significance:

The FDA Food Code sets a limit on the amount of time potentially hazardous food (PHF) can remain out of proper temperature control or in the “danger zone”. In addition to enhancing food safety, cold temperatures extend the shelf life of many foods, including meat, fish and poultry, by slowing the growth of spoilage bacteria. Thus, “cold rooms” such as the meat departments in supermarkets are typically maintained at temperatures much lower than 75°F. Many such meat departments wish to use a quaternary ammonium compound solution to sanitize food contact surfaces of equipment. As currently written, the minimum temperature requirement does not provide for the use of a “quat” in a “cold room”.

### 4. Recommended Solution: The Conference recommends.....

the Conference Chair send a letter to the FDA Commissioner to urge the following changes to the Food Code:

- (1) Develop and publish in the FDA Food Code a chart showing appropriate alternative concentration and temperature combinations for quaternary ammonium compound solutions (and iodine solutions if necessary) to allow use of sanitizer spray bottles at cold temperatures (40°F), assuring that the same level of public health protection is afforded for all concentration/temperature combinations; and
- (2) Provide the chart in lieu of current language in 4-501.114(C) (1) and (2).

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## CONFERENCE FOR FOOD PROTECTION

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Issue # 2004 III-034  
Internal # 089

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Modify cold food holding surface temperatures on open top prep tables and salad bars.

### 2. Issue you would like the Conference to consider:

3-501.16 Potentially Hazardous Food, Hot and Cold Holding.\* Open top prep tables and salad bars are not intended to hold food, but rather are intended to display or merchandise foods that are for immediate sale, preparation and/or nearly immediate consumption.

### 3. Public Health Significance:

Cold food holding temperatures as listed in the code are understood to apply to storage of foods typically in units designed to keep food that is already cold. Preparation tables and salad bars are used as process refrigeration where the foods in the rail or on display are intended for nearly immediate consumption. RTE PHF foods that have been held at 41F or below for less than (7) days remain safe when placed into a salad bar or open top prep tables for up to (6) hours with a mean surface temperature of 48F (never exceeding 50F) since there is not sufficient time to get to the log phase for listeria monocytogenes which actually begins to grow at temperatures slightly above zero degrees F. These temperatures are in fact more realistic given thermal diffusivity of foods and the state of the art in refrigeration design when foods are openly exposed to ambient room air temperature conditions. Note that cold temperatures do nothing to prevent cross contamination or growth of viruses which are responsible for 67.4% of all illness in the U.S. according to CDC data. This recommendation will help operators by stopping written orders for threshold violations that otherwise do not compromise public health.

### 4. Recommended Solution: The Conference recommends.....

that a letter be written to FDA recommending the addition of section 3-501.165. This section should be added to allow foods in open top prep tables and salad bars to have surface temperatures (as measured by low mass thin wire thermocouples) of up to 50F provided temperature data logging profiling for those items shows that the standard deviation mean surface temperature does not exceed 48F.

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## CONFERENCE FOR FOOD PROTECTION

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Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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### 1. Title:

Ready to Eat Fruits and Vegetables Committee

### 2. Issue you would like the Conference to consider:

The 2002 CFP Conference through Issue 02-03-33 charged "That a committee be formed to develop guidance for minimizing the potential of contamination and growth of pathogens in ready-to-eat fruits and vegetables in retail food operations. It is further recommended that the committee seek out ongoing guidance that may be available through government, industry, or academic sources to avoid duplication of effort." Since no Issue or report was received from this committee, the Conference needs to determine if this Committee should be recreated to complete the original charge from 2002.

### 3. Public Health Significance:

To provide guidance to minimize potential of contamination and growth of pathogens in ready-to-eat fruits and vegetables in retail food operations.

### 4. Recommended Solution: The Conference recommends.....

That the Council determine if the committee should be re-created to discuss the charges from the 2002 CFP Conference. If the recommendation is to re-create the committee, then the Council should make recommendations on committee members and procedures to help complete this charge.

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## CONFERENCE FOR FOOD PROTECTION

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Issue # 2004 III-036  
Internal # 094

Council Recommendation: Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

Delegate Action: Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

### 1. Title:

Potentially Hazardous Foods Definition Committee

### 2. Issue you would like the Conference to consider:

The 2002 CFP Conference, through Issue 02-III-17, recommended that the Potentially Hazardous Foods Definition Committee be re-created beyond the April 2002 meeting for the purposes of reviewing and commenting on the IFT report. The charge to the committee included addressing the following 6 Issues, identified in the "public health significance" section of 02-III-17, by making recommendations for actions by the CFP Executive Board and / or the 2004 CFP. The issues included "1) Using "Hazard" in a manner that is different than it is used in HACCP, 2) Addressing growth vs. zero tolerance, 3) Defining "rapid and progressive," 4) Clarifying adulterated or contaminated vs. supporting growth, 5) Stating that "non-PHF" can be infectious/"hazardous", and 6) Using a performance standard or listing of commodities."

No issue or report was submitted by the Committee but FDA reported that the FDA Center for Food Safety and Applied Nutrition consulted with the Committee Co-Chairs to request that they include a recommendation in their final committee report to recreate the committee to work with FDA.

FDA has convened an internal work group to evaluate the recommendations of IFT's Task Order 4 Report, Evaluation and Definition of Potentially Hazardous Foods and has submitted an issue to the 2004 CFP revising the definition of PHF based on part of the IFT Report's recommendations. FDA has stated that a phased in change to the definition is necessary and a PHF Definition Committee could provide a valuable help to state and local food safety agencies in the transition.

### 3. Public Health Significance:

If FDA intends to change the definition of potentially hazardous foods or implement any other recommendation or policy changes based on IFT's Report on potentially hazardous foods, an effective implementation and training strategy will be necessary for state and local regulatory agencies as well as for the food service, retail food store and vending industries. The balanced perspective of a CFP committee would provide useful input to FDA.

### 4. Recommended Solution:

That the Council determine if the Potentially Hazardous Food Definition Committee should be recreated to work with FDA to implement recommendations in the IFT Report,

Evaluation and Definition of Potentially Hazardous Foods. They should also determine if any of the six issues charged to the 2002 committee should continue as charges for a 2004 committee, if recreated. The Council should also make recommendations for committee members and committee Chairs to make sure the charges are addressed.

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