Conference for Food Protection
2010 Issue Form

Internal Number: 002
Issue: 2010 I-012

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

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Title:
Employee Written Agreement for Employee Health Reporting

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

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

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

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

2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees.

Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. The person in charge is responsible for ensuring all food employees and conditional employees are knowledgeable and understand their responsibility to report listed symptoms, diagnosis with an illness from a

listed pathogen, or exposure to a listed pathogen to the person in charge. The person in charge is also responsible for reporting to the regulatory official if a food employee reports a diagnosis with a listed pathogen.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or has a history of exposure to a listed pathogen in this Code may transmit disease through the food being prepared. The person in charge must first be aware that a food employee or conditional employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

The person in charge may observe some of the symptoms that must be reported. However, food employees and conditional employees share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the listed symptoms, have a history of exposure to one of the listed pathogens, or have been diagnosed with an illness caused by a listed pathogen. Food employees must comply with restrictions or exclusions imposed upon them.

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

Recommended Solution: The Conference recommends...:

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

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

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

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Conference for Food Protection
2010 Issue Form

Internal Number: 003
Issue: 2010 I-008

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

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Title:
Wild Harvested Mushrooms

Issue you would like the Conference to consider:
There are currently no standards by which a Regulatory Authority can certify that individuals who collect, inspect and sell wild harvested mushrooms are competent in mushroom identification.
Section 3-201.16 Wild Mushrooms of the FDA Food Code does not provide adequate guidance to Regulatory Authorities for the regulation and enforcement of the collection and sale of wild harvested mushrooms.
While this certification program is still in draft form, we would request CFP's support to proceed with this project for future adoption in the FDA Food Code Annex 3.
Please see attachments (State of Maine):
Wild Mushroom Partnership Proposal
List of Wild Mushroom Species Approved for Sale
Maine Wild Harvested Mushroom Certification Manual

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

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting the following language be placed in Annex 3 of the FDA Food Code Section 3-201.16 to present as a model that states can adopt or modify to develop and implement a wild harvested mushroom certification program for their state.
3-201.16 Wild Mushrooms.*
(A) Except as specified in section B, mushroom species picked in the wild shall be identified and found to be safe by a certified mushroom identifier whose competence has been verified and approved by the regulatory authority through the successful completion of a wild mushroom identification course provided by either an accredited college,

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

~~(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an APPROVED mushroom identification expert.~~

(B) *This section does not apply to:*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Attachments:

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

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Conference for Food Protection
2010 Issue Form

Internal Number: 001
Issue: 2010 I-011

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

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Title:
Signage Requirement on Reporting of Employee Health Conditions

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

Public Health Significance:
According to the Centers for Disease Control and Prevention, approximately 25% of foodborne outbreaks caused by viruses or bacteria may be attributed to infected food workers. Eighty-five percent of front line workers have no paid sick leave prompting many employees to continue to work while ill (ACORN, 2007.)
In 2007, thousands of Harris County, Texas restaurant patrons were potentially exposed to food handled by an employee infected with hepatitis A. This food worker handled ready-to-eat foods without using gloves or utensils, and it could not be verified that the employee followed appropriate hand washing procedures. In order to prevent illness among those who were potentially exposed, health officials administered a preventive vaccine to over 2,000 restaurant customers. This effort cost taxpayers $70,000 in medication costs and required hundreds of staff hours.
The following paragraphs of Annex 3 of the 2009 FDA Food Code emphasize the importance of educating employees regarding their personal responsibility in reporting certain health conditions that have the potential of transmitting foodborne disease.
2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees.
Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. The person in charge is responsible for ensuring all food employees and conditional employees are knowledgeable and understand their responsibility to report listed symptoms, diagnosis with an illness from a listed pathogen, or exposure to a listed pathogen to the person in charge. The person in

charge is also responsible for reporting to the regulatory official if a food employee reports a diagnosis with a listed pathogen.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or has a history of exposure to a listed pathogen in this Code may transmit disease through the food being prepared. The person in charge must first be aware that a food employee or conditional employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

The person in charge may observe some of the symptoms that must be reported. However, food employees and conditional employees share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the listed symptoms, have a history of exposure to one of the listed pathogens, or have been diagnosed with an illness caused by a listed pathogen. Food employees must comply with restrictions or exclusions imposed upon them.

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

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

Recommended Solution: The Conference recommends...:

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

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

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

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Attachments:

- "Food Employee Reporting Sign"

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Conference for Food Protection
2010 Issue Form

Internal Number: 013
Issue: 2010 I-010

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

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Title:
USFDA Recall Policy Revision

Issue you would like the Conference to consider:
Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process.
Consider:
>FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR
>Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA
>Firms affected by the recall throughout the complex food system (distributers, sub-producers, brokers) have no official FDA guidance
>There is no time limit for executing a Class I Recall, or any other Class
>There are no minimum requirements for the information required in a recall notice
>There is no consideration of cost to benefit
>Current Classification system is ambiguous and confusing:
Current Classification System from FDA web site for Industry:
Recall Classifications

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

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

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

Public Health Significance:

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

Recommended Solution: The Conference recommends...:

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

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

Class I:

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

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

Class II:

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

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

Class III:

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

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

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Attachments:

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

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Conference for Food Protection
2010 Issue Form

Internal Number: 022
Issue: 2010 I-001

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

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Title:
Report - TCS Implementation Committee

Issue you would like the Conference to consider:
During the 2008 Conference for Food Protection Biennial Meeting, the TCS (Temperature Control for Safety) Implementation Committee was created and given the following charges as an outcome of Issue 2008 1-008:
1.) Send a letter to the FDA requesting that they monitor and subsequently post to the FDA website the following information:
a. Any new or additional information that will assist regulators and industry in the implementation of the new PHF/TCS definition
b. The finalized FAQ from the 2005 TCS survey
c. The response document from NACMCF (National Advisory Council for Microbiological Criteria for Foods) on inoculation studies
2.) Work with the Conference to provide a link on the CFP website to the FDA information noted above.
This Issue presents the TCS Implementation Committee's report with supporting documents (Committee Roster and Letter to FDA) and requests acknowledgement of the report.
The TCS Implementation Committee worked to complete their charges by crafting the required letter with the appropriate requests.

Public Health Significance:
Food establishments are required to maintain certain foods at required temperatures unless the food item meets parameters that would prevent pathogenic microorganism growth or toxin formation. By changing the term "PHF" and replacing with "PHF/TCS food" clarifies that "time" and "temperature" have a role in preventing growth and encourage the use of science based food safety principles and programs. Additionally, the new definition recognizes the "Hurdle Concept" which shows that the interaction of several factors at levels that alone would not prevent or control growth, can prevent or control growth when used together.
The posting of the documents as requested by the committee to both the CFP and FDA web sites will allow all interested parties to have access to the necessary information in order to accurately apply the "PHF/TCS food" criteria.

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

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Attachments:
- "TCS Implementation Letter to FDA"
- "TCS Implementation Committee Final Report 2010"
- "TCS Committee Roster"

Conference for Food Protection
2010 Issue Form

Internal Number: 023
Issue: 2010 I-014

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

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Title:
Report - Criticality Implementation and Education Committee

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

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

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

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

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

Recommended Solution: The Conference recommends...:

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

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Attachments:

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

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Conference for Food Protection
2010 Issue Form

Internal Number: 024
Issue: 2010 I-015

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

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Title:
Criticality Implementation&Education Committee- Criticality Training Slides

Issue you would like the Conference to consider:
The Criticality Implementation and Education Committee requests that the Conference for Food Protection (Conference) accept the PowerPoint presentation titled "Re-designation of Food Code Provisions" and place it in a downloadable format under the "Conference Developed Guidance and Documents" section of the Conference web site. Further, the committee recommends that the Conference send a letter to FDA requesting the same presentation be made available on the FDA web site.

Public Health Significance:
The Criticality Implementation and Education Committee acknowledges that extensive training will be necessary for successful implementation of the re-designation of the 2009 Food Code provisions from two to three risk-based priority designations. Therefore, a PowerPoint training tool, complete with speaker's notes, has been prepared by the committee. Providing workable and readily available training tools is a value for all public health stakeholders and should be shared in many venues. It is advantageous for trainers of any organization to be able to fully utilize training materials for a varied audience.

Recommended Solution: The Conference recommends...:
1. Acceptance of the PowerPoint presentation and speaker notes titled "Re-designation of Food Code Provisions" and place it in a downloadable format under the "Conference Developed Guidance and Documents" section of the Conference web site.
2. That a letter be sent to FDA requesting the same PowerPoint presentation and speaker notes be made available through its web site.

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Attachments:

- ""Re-designation of Food Code Provisions" PowerPoint Slides and Speaker Note"

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Conference for Food Protection
2010 Issue Form

Internal Number: 025
Issue: 2010 I-020

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

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Title:
American National Standards for Food Equipment - Clarification of Food Code

Issue you would like the Conference to consider:
Section 4-205.10 of the Food Code, titled *Food Equipment, Certification and Classification* currently references ANSI accredited certifications or classifications of food equipment, but the Food Code language is not clear or specific as to what the certification or classification programs should be based on. In the U.S., state and local regulatory agencies routinely require retail foodservice equipment to comply with the specific requirements of American National Standards, which in turn comply with the requirements of the Food Code. Expanding the Food Code to reflect the wide range and complexity of retail foodservice equipment technical requirements is not practical. This considerable level of technical detail has traditionally, and effectively, been dealt with by reference to American National Standards. As such, it is requested that the Conference for Food Protection clarify this section of the Food Code to reflect the original intent and current practice. This is efficiently accomplished by adding "...to the corresponding American National Standard listed in Annex 8," to *Section 4-205.10.*

Public Health Significance:
The rapid increase of imported foods and food equipment, and the many public health related issues associated with imported products, makes it vitally important to have products comply with American National Standards, where specific requirements for compliance are clearly spelled out. Manufacturers, exporters, importers, wholesalers, retailers, consultants and regulators at all levels understand the role and importance of American National Standards, and participate in their development and maintenance. Specification of the appropriate national standards in the Model Food Code clarifies the original intent, increases consistency of certifications, and results in increased public health protection. Having clearly defined equipment requirements is essential to increasing regulatory compliance.
Background
Equipment sanitation is a critical component of state and local regulatory food safety programs, and is an integral part of the Model Food Code. Food equipment materials, performance, design and cleanability are all critical components of the Model Food Code and are detailed in the American National Standards for Food Equipment. The purpose of

the current Section 4-205.10 of the Food Code is to reference ANSI-accredited third party certifications or classifications of Food Equipment. It is implied that the certifications or classifications are to the requirements of specific American National Standards. Given the widespread adoption of the Model Food Code at the State and Local levels, it is very important that the intent of the FDA and the CFP is without question.

The 2009 Model Food Code currently references "Acceptability" of foodservice equipment in Section 4-205.10, titled Food Equipment, Certification and Classification. This section of the Food Code currently reads:

Acceptability 4-205.10 Food Equipment, Certification and Classification.

- *FOOD EQUIPMENT that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.*

Section 4 of the 2009 Model FDA Food Code addresses foodservice equipment sanitation requirements for only limited types of commercial food equipment, whereas today, the scope of food equipment used in the foodservice industry is much broader. This wider scope of equipment is collectively covered by the combined American National Standards established for commercial foodservice equipment listed in the attached Annex 8. Referencing the ANSI standards simply reflects what manufacturers and regulators use today. Listing the ANSI Standards does not preclude other standards from being accepted by the state or local regulatory authorities.

Adoption of the proposed language recognizes that the technical requirements established in American National Standards for foodservice equipment meet the same minimum technical requirements of the 2009 Food Code, and more importantly, clarify that the American National Standards are the basis of ANSI-accredited certification programs, as currently cited in Section 4-205.10 of the Food Code.

Recommended Solution: The Conference recommends...:

sending a letter to the FDA requesting the addition of the language specified below to the Food Code, as well as Annex 8 that lists the relevant American National Standards.

Acceptability 4-205.10 Food Equipment, Certification and Classification.

- *FOOD EQUIPMENT that is certified or classified for sanitation <u>to the corresponding American National Standard listed in Annex 8,</u> by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.*

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Attachments:

- "Proposed ANNEX 8 of Food Code"
- "NEHA Letter of Support"

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Conference for Food Protection
2010 Issue Form

Internal Number: 026
Issue: 2010 I-016

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

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Title:
Criticality Implementation&Education Committee - Frequently Asked Questions

Issue you would like the Conference to consider:
The Criticality Implementation and Education Committee requests that FDA provide answers to a list of Frequently Asked Questions (FAQs) developed by the committee and have the FAQs and answers available for stakeholders on or before June 30, 2010.

Public Health Significance:
The re-designation of the Food Code provisions from two to three criticality ratings was accepted by the 2008 Biennial Meeting of the Conference Food Protection. The Criticality Implementation and Education Committee was charged with providing a variety of educational tools to explain the changes and the rationale of the new three risk-based priority designations. A list of Frequently Asked Questions (FAQs) was developed by the committee in anticipation of many of the questions that will be asked by stakeholders as they incorporate the use of the new designations into action plans, intervention strategies, and effectiveness measures. The FAQs will help stakeholders understand the use of the new designations in prioritizing violations and corrections in regards to risk factors.

Recommended Solution: The Conference recommends...:
That a letter be sent to FDA requesting that they:

1. provide answers to the list of FAQs included in the attached document.
2. have the FAQs and answers available for stakeholders on or before June 30, 2010 by posting on the FDA website.

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Attachments:

- ""Frequently Asked Questions" Document"

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Conference for Food Protection
2010 Issue Form

Internal Number: 027
Issue: 2010 I-021

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

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Title:
3-304.14 Wiping Cloths, Use Limitation

Issue you would like the Conference to consider:
Some state/county regulatory jurisdictions only allow the use of reusable wet wiping cloths to wipe counters/equipment and require they be stored in a chemical sanitizing solution. Many retail establishments across the United States use dry disposable towels with pre-mixed sanitizer supplied in spray bottles in lieu of the wet cloth and bucket method. Some health authorities require that a variance must be applied for to use dry disposable towels with a spray bottle of sanitizer instead of the wet wiping cloths. The Food Code needs to recognize the use of dry disposable towels and a spray bottle of chemical sanitizer solution in lieu of wet wiping cloths stored in a sanitizing solution is an acceptable and equivalent method for wiping down counters and equipment.

Public Health Significance:
As long as the disposable towels are disposed of after each use, and the chemical sanitizer solution in the spray bottle meets the concentration specified under 4-501.114, there are no adverse Public Health consequences. This process has been in use extensively throughout the retail food industry without consequence for years. In fact, it can further minimize risks by avoiding the potential build up of organic material associated with the re-usable cloth and bucket method for wipe downs. It also maintains the correct concentration of sanitizer since it is not exposed to dilution and organic buildup. Annex 3, 3-304.14 essentially supports this issue in that it states that dry wiping cloths do not require being stored in a sanitizer solution at all times and disposable wiping cloths avoid the issue of buildup of soil from organic material.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that section 3-304.14, section (B), be amended to add subsection 3 as follows:
3-304.14 Wiping Cloths, Use Limitation.

1. (A) Cloths in-use for wiping food spills from tableware and carry-out containers that occur as food is being served shall be:

(1) Maintained dry; and
(2) Used for no other purpose.

(B) Cloths in-use for wiping counters and other equipment surfaces shall be:
(1) Held between uses in a chemical sanitizer solution at a concentration specified under § 4-501.114; and
(2) Laundered daily as specified under ¶ 4-802.11(D); or
(3) Dry disposable towels used in conjunction with a spray bottle of chemical sanitizer solution at a concentration specified under § 4-501.114 are excluded from being maintained in a chemical sanitizer solution as long as the towels are disposed of after each use.

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Conference for Food Protection
2010 Issue Form

Internal Number: 028
Issue: 2010 I-024

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

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Title:
Management Responsibility Code Section 2-101.11

Issue you would like the Conference to consider:
Food Code Chapter 2, Management and Personnel, Part 2-1 Supervision, Section 2-101.11 Responsibility: The current language fails to clearly define permit holder responsibility for implementation and maintenance of operating procedures to control and prevent the occurrence of risk factors known to cause foodborne illness after a food establishment is permitted.
Clearly the intent of the Food Code is that applicants for a permit to operate a food establishment develop operating procedures as required by Section 8-201.12 to ensure compliance with requirements of the Code. The duties of the Person-In-Charge and other management requirements specified in Chapter 2 would presumably be addressed in these operating procedures; however, this is not stated.

Public Health Significance:
Current Food Code language fails to assign specific management responsibility for the implementation and continued maintenance of operational procedures after a food establishment is permitted. Operating procedures are an important management tool for the control of risk factors inherent in a food establishment. The absence of procedures for performing specific task, training employees and management verification may compromise consumer safety. Operating procedures should be implemented and sustained to control risk factors and prevent "behavior creep." For example, a cooling procedure is designed to use a specific-size shallow pan for cooling. However, one day, the designated pan is not readily available, so an employee uses a deeper pan. New employees are hired and they adopt the new practice and it becomes routine for employees to use a deeper pan out of convenience, although it results in much longer cooling times. Because of behavioral creep, the procedure is no longer safe and the risk factor is no longer under control. Operating procedures provide a constant against which day to day operations may be evaluated by management to prevent behavior creep and ensure day to day control of risk factors.
Also, because there is no specific requirement in Chapter 2 that operating procedures be maintained and updated after a permit is issued, regulatory inspectors do not consistently verify that operating procedures are current or even exist. This often results in a discussion

of operating procedures after code violations are noted during a regulatory inspection and corrective action is necessary. A more desirable approach would be for regulator inspections to review and reinforce the food establishment's operating procedures during routine inspections to prevent future code violations.
The development and implementation of operating procedures which address polices and procedures, employee training, and management oversight are proven management principles. Operating procedures designed to control the risk inherent to a specific food operation provide the management structure for a safe and successful food operation.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that the language in Food Code Section 2-101.11 (Responsibility and Assignment) be replaced with the following language and that additional changes to Chapter 2 be made as necessary to be consistent with this change.
Responsibility 2-101.11 Assignment*
The PERMIT HOLDER through the certified food manager or person in charge (PIC) is responsible for ensuring:
· That standard procedures that ensure compliance with the requirements of this Code are developed & implemented as specified under 8-201.12 (E) & (F);
· Procedures for the operation of the FOOD ESTABLISHMENT are kept current and address all risk factors which are inherent to the food operation.
· Employees are trained to ensure tasks are performed in accordance with the operating procedures and that there is at least one trained individual present at all times;
· Food preparation activities are directed & action taken, as needed, to protect the health of the consumer; and
· In-house self-inspections of operations are conducted on at least a daily basis to ensure that food safety policies & procedures for the control of risk factors inherent to the operation are followed.

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Conference for Food Protection
2010 Issue Form

Internal Number: 030
Issue: 2010 I-005

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

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Title:
Consumer Advisory for pinned/injected/tenderized meats: Food Code 3-603.11

Issue you would like the Conference to consider:
The current consumer advisory requirement in Section 3-603.11 do not clearly communicate to the consumer that consumption of raw or undercooked meats which have been tenderized may increase there risk of foodborne illness. This is particularly relevant for beef steaks. Consumers are not generally aware that mechanical tenderization steak should be cooked to a higher temperature than whole-muscle intact beef steak to achieve the same degree of safety.

Public Health Significance:
The increased use of mechanically tenderized meats by food establishments is a growing food safety concern. Undercooked meats and beef steak in particularly must be cooked to higher temperatures to achieve the same degree of safety as whole-muscle intact cuts of meat. Consumers who consume tenderized steaks cooked rare or medium rare are not generally aware of this increased risk. A recent foodborne illness has been traced to the consumption of tenderized steaks which were cooked rare or medium rare.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that additional language be added to 3-603.11 (B) [1] and 3-603.11 (C) [3] to read as follows:
· 3-603.11 (B) [1] A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)" " raw-EGG Caesar salad," "hamburger (can be cooked to order)" and "mechanically tenderized meats (pinned or injected);" or
· 3-603.11 (C) [2] Consuming raw or undercooked Meats, Poultry, seafood, shellfish, eggs or tenderized meats (pinned or injected) may increase your risk of foodborne illness; or

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Attachments:

- "Recall Notice Update"

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Conference for Food Protection
2010 Issue Form

Internal Number: 034
Issue: 2010 I-002

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

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Title:
Report - Plan Review Committee

Issue you would like the Conference to consider:
The Conference for Food Protection (CFP) Plan Review Committee seeks Council I's acknowledgement of its committee report and requests that the committee be reinstated to continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2012 CFP Biennial Meeting.

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

Recommended Solution: The Conference recommends...:
1. Acknowledgement of the CFP Plan Review Committee Report;
2. Re-creation of the committee to continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2012 CFP Biennial Meeting; and,
3. Thanking the Committee members.

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Attachments:
- "Plan Review Committee Final Report"

- "2008-2010 Plan Review Committee Member Roster"

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Conference for Food Protection
2010 Issue Form

Internal Number: 038
Issue: 2010 I-018

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

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Title:
Effective Risk Communication for Process HACCP

Issue you would like the Conference to consider:
The current FDA Food Code form of using "Priority, Priority foundation and Critical item" designations needs better clarification, categorization and communication within the code Annex.

Public Health Significance:
Use of the same terms but from different perspectives has led to confusion among food handlers, inspectors and the public relative to "critical limits" for critical control points.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting that the following language be placed in the Food Code Annex 3 section 1-201.10, after "Accredited Program" section and before "egg" section:
There are up to *three different critical limit concepts* or points of refence for every *pathogen* related critical control point:

1. The science based critical limit. Lets call is the "SCL". It is the same in Saigon as in St. Paul. If we identify all of the environmental and food characteristics that give rise to the given microbial hazard, then we can agree upon peer reviewed published data and given statistical analysis and the consensus standards process establish a single fixed "SCL". With that, we'd likely say that 127.5F is the SCL for hot food holding based upon peer reviewed, published scientific research (*F. Busta, et al*).
2. The compliance critical limit. Lets call it the "CCL". In Minnesota, since their administrative rule (MR4626) is based on the 1995 FDA Food Code, that minimum hot safe food holding temp is 140F. In Maryland where they modeled code after the 2008 FDA Food code and their Title 10, subtitle 15 Chapt 03.06 states: "(7) Except as provided in §B(8)-(14) of this regulation, the internal temperature of a potentially hazardous food is kept at 41°F or less or 135°F or greater". The downward revision to 135F was hotly debated for several CFPs with data presented in council 3 to support the scientific critical limit was at least 12 degress below 140. The revision finally passed at the '08 conference. (comment: some will say that the point at which the critical limit should be measured is a core temp. *This is not true*. Surface temps

are most likely to be abused when you are hot or cold holding....not core temps.) Note that the CCL's change based upon the local licensing authority, and the method and means for measuring the critical limit may vary by interpretation and inspector. Further confusion abounds do to differences in equipment performance test standards critical limits and the food codes criteria. For example, the NSF/ANSI standard 7 critical limit measurement point for cold holding is 1" below the surface of the food. The food code requires all of the food to be at the stated CL or better without exempting the top 1" layer of food. Then, where is the point of measurement for hot holding critical limit relative to the code vs. NSF/ANSI Std 4? These "gaps" reduce the effectiveness of the codes risk message.

3. The quality critical limit. Lets call this the "QCL". One of my global QSR clients sets a QCL for hot food holding at 160F. One of their franchisees sets a QCL for his stores at 165. QCL's change with each operator. In some cases it varies by franchisor. But in others it may vary from one franchisee to another. Multiunit operators food safety plans must have the flexibility to accommodate these differences without confusing its food handlers and risk managers at corporate and franchise levels.

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Attachments:

- "The Three Tiers for Microbial Critical Limits"

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Conference for Food Protection
2010 Issue Form

Internal Number: 039
Issue: 2010 I-009

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

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Title:
New Recall Notification Section of the Model Food Code, Section 3-603.12.

Issue you would like the Conference to consider:
The Model Food Code recognizes that consumers may not receive adequate, timely information in the event of a food safety recall, and that retailers play an important role in disseminating critical public health information. Grocery stores and vendors selling packaged food should make every reasonable effort to notify consumers in the event of a Class I Recall.

Public Health Significance:
Removal of contaminated foods is vital to minimizing the adverse impact on consumers and public health, including reducing the size of associated foodborne illness outbreaks. While retailers play an important role in removing recalled foods from the shelves, this does not address the products that have already been sold. The amendment proposes two approaches to better inform consumers about recalled products.

Posting of recall information in a prominent manner in grocery stores is an important part of protecting the public health from contaminated product. Consumers may purchase product that is later implicated in a recall, and grocery stores can play an integral role in warning consumers not to consume the product. Unfortunately, current warning systems are inadequate to reach consumers. Providing notice in grocery stores would remind consumers of ongoing recalls, so that they may better check their home kitchens for recalled products.

Further, where retailers routinely collect consumer purchase data, that information can be used to assist consumers in the event of a Class I recall. Retailers should be using purchase information and the coordinating consumer contact information to alert consumers to their previous purchases of products that are currently subject to a Class I recall. Such personalized notice will help consumers identify recalled product at home, and will establish the retailer as a source of important public health information.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA recommending the addition of the following Section 3-603.12 of the Model Food Code, *Recall Notification.*

<u>3-603.12 Recall Notification.</u>

(A) Every FOOD ESTABLISHMENT that offers PACKAGED FOOD for purchase by consumers shall, in the event of a Class I Recall of any FDA or USDA product sold by the FOOD ESTABLISHMENT, inform consumers of the recall by way of a DISCLOSURE and REMINDER as specified in sections (1) and (2) of this section.

(1) DISCLOSURE shall include:

1. A sign indicating that a Class I Recall is in effect for the relevant product, which shall be:
    - 1.1. at the location within the FOOD ESTABLISHMENT where a consumer would ordinarily find the product, such as a shelf, freezer case, or produce cart, and
    - 1.2. Within 3 feet of the cash register or point of purchase, and
    - 1.3. Within 3 feet of the entrance to the FOOD ESTABLISHMENT.

(2) REMINDER shall include contacting consumers for whom the store has purchasing information (through use of a consumer loyalty card or other data-collection methods) indicating the purchase of the recalled product within the previous 60 days, and for whom the FOOD ESTABLISHMENT has contact information.

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Conference for Food Protection
2010 Issue Form

Internal Number: 041
Issue: 2010 I-004

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

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Title:
Inclusion of Inspection Result Posting in the Model Food Code

Issue you would like the Conference to consider:
Rigorous health inspections are a critical component of an effective food safety system. The Model Food Code recognizes that the results of restaurant inspections are public documents and should be available for public review. However, complex rules regarding public access create difficulty for consumers who wish to consider inspection results.

Public Health Significance:
Consumer access to the results of these inspections plays an important role in maintaining the efficacy and credibility of the inspection system, and allows consumers to consider critical food safety information when making restaurant choices. Recent data show that nearly half of all foodborne illnesses are contracted from food prepared outside the home. Although food establishments are routinely inspected, the results of those inspections are not readily available to consumers-who thus have no way of minimizing their risk by knowing how an establishment performed on its most recent food safety assessment. For more information, visit
http://www.cspinet.org/dirtydining/index.html.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA recommending addition of the following language to Section 8-4 *Inspection and Correction of Violations*:

8-403.51 Public Posting.
The REGULATORY AUTHORITY shall make available the results of the inspection report by requiring the timely posting of the most recent inspection results in the entrance, front window, or similarly prominent consumer-accessible area of the FOOD ESTABLISHMENT. Results may be posted in the form of a letter grade, numerical score, or other form as determined by the REGULATORY AUTHORITY.

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Conference for Food Protection
2010 Issue Form

Internal Number: 042
Issue: 2010 I-003

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

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Title:
Addition to Section 8-4 Inspection and Correction of Violations

Issue you would like the Conference to consider:
The Model Food Code recognizes that the results of restaurant inspections are public documents and should be available for public review. However, complex rules regarding public access create difficulty for consumers who wish to consider inspection results.

Public Health Significance:
Consumer access to the results of these inspections plays an important role in maintaining the efficacy and credibility of the inspection system, and allows consumers to consider critical food safety information when making restaurant choices. Recent data show that nearly half of all foodborne illnesses are contracted from food prepared outside the home. Although food establishments are routinely inspected, the results of those inspections are not readily available to consumers-who thus have no way of minimizing their risk by knowing how an establishment performed on its most recent food safety assessment. In some jurisdictions, consumers must submit a formal Freedom of Information Act request to the regulatory authority to access an inspection report. The addition of the following language to the Model Food Code will ensure public access to inspection results at the food establishment, improving consumer access and decision-making, without placing any additional or undue burden on food establishments. For more information, see http://www.cspinet.org/dirtydining/index.html.

Recommended Solution: The Conference recommends...:
that a letter be sent to the FDA recommending the addition of the following language to Section 8-4 *Inspection and Correction of Violations*:

8-403.50 Public Information.

Except as specified in § 8-202.10, the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it at the FOOD ESTABLISHMENT and otherwise as provided in law.

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Conference for Food Protection
2010 Issue Form

Internal Number: 043
Issue: 2010 I-022

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

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Title:
Key Drop

Issue you would like the Conference to consider:
"Key drop" delivery is a common practice in the food industry, including the retail and restaurant segments. The practice allows for the safe delivery of food and other products during hours when the establishment is closed, usually between midnight and 6 am. Delivery personnel store items appropriately as refrigerated, frozen or dry goods and establishment personnel inspect and officially confirm receipt of the goods upon their arrival the day of the delivery.

Public Health Significance:
The current FDA Food Code (¶ 2.103.11 (E)) identifies the importance of having a Person in Charge or "employee" duty include the receipt and inspection of foods and other goods delivered to an establishment. Food Code ¶ 1.201.10 (B) defines an employee to mean "the permit holder, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in the food service establishment." This definition allows for the lawful delivery of goods by a distribution company provided that the distribution personnel are performing their duties under contract with the food establishment.
It is important to clarify this role in ¶ 2-103.11 (E) to include distribution personnel and affirm that the key drop practice, already in accordance with FDA Food Code, is specifically identified for all to understand. It is with this further clarity that all States may confidently adopt this segment of the FDA Food Code and consistently enable the key drop practice.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA requesting the following changes to the Food Code:
that § 2.103.11 of the FDA Food Code be amended by adding a new ¶ 2.103.11 (F), and renumbering subsequent paragraphs in this Section appropriately, to specifically allow for the practice of key drop deliveries by including the following language:
(F) Distribution EMPLOYEES for key drop deliveries are delivering goods at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the delivered goods at time of delivery Pf;

Further, that ¶ 1-201.10 (B) be amended to define key drop as follows:
"Key Drop" means a delivery of food and goods to an establishment that occurs when it is closed. Distributors deliver and place products in coolers, freezers and dry goods storage areas for LATER confirmation of receipt and inspection by representatives of the establishment.

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Conference for Food Protection
2010 Issue Form

Internal Number: 044
Issue: 2010 I-017

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

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Title:
Criticality Implementation&Education Comm. -Timely Correction of Violations

Issue you would like the Conference to consider:
The FDA Criticality Work Group re-designated each Food Code provision into one of three terms. The three terms were used to rank the provisions in the Food Code according to how direct their relationship was to preventing, eliminating or reducing to an acceptable level, hazards that cause foodborne illness or injury. Out of compliance risk factors and Food Code interventions have a direct relationship and good retail practices have an indirect relationship. The timely correction sections in Chapter 8 that specify how long an operator has to correct a violation still has only two categories and does not adequately reflect the three separate terms now being used.
Sequentially, a need exists to combine existing Code sections 8-405.11 (Timely Corrections of Priority or Priority Foundation items) with 8-406.11 (Time Frame for Correction for Core Item violation), and add a third section to correspond with the new three tier structure in the Food Code. The new sections will be numbered 8-405.11, 8-405.12, and 8-405.13.

Public Health Significance:
The three terms defining criticality will enable both regulators and industry to prioritize their time and efforts. These three terms are distinct with Priority Items directly controlling hazards associated with food borne illness or injury. Priority Foundation Items support, facilitate or enable other Priority Items; and Core Items are general sanitation, maintenance, operations control, and facility and equipment design.
These three categories are based on risk ranking, with Priority violations being the highest risk and Core the lowest risk. There are currently only two categories defining the timely corrections of these violations, based on the previous critical and non-critical terms. Priority and Priority Foundation are currently lumped together even though the risk ranking for the two is not the same. For the purpose of training and compliance, the time for correction should also be a new three- tier system to be consistent with the level of risk clearly identified.
There can be punitive penalties associated with the highest risk category. These penalties can include fines, re-inspections, and suspended or revoked license with what used to be critical violations. Placing all Priority and Priority Foundation violations together in Chapter

8 will result in confusion with both regulatory and industry thinking all of the violations carry the same risk and legal weight.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting revision and/or addition to the following three sections in Chapter 8, Compliance and Enforcement in the FDA Food Code: 8-405.11, 8-405.12 and 8-405.13 (new language is in underline format; deleted language in strike through).

Violation of Priority Item ~~or Priority Foundation Item~~ 8-405.11 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a permit holder shall at the time of inspection immediately initiate and correct ~~a violation of a~~ priority item violations ~~or priority foundation item~~ of this Code and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit. [Pf]

(B) *Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame for corrective actions that have been initiated but not yet completed, not to exceed 72 hours ~~10 calendar days~~ after the inspection, for the permit holder to correct ~~violations of a~~* priority item ~~or priority foundation~~ *~~item or HACCP plan deviations~~ violations*.

Violation of Priority Foundation Item 8-405.12 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a permit holder shall at the time of inspection immediately initiate and correct priority item violations of this Code.

(B) *Considering the nature of the violation involved or the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame, not to exceed 10 calendar days after the inspection, for the permit holder to correct violations of a* priority item *violations.*

Core Item Violation ~~8-406.11~~ 8.405.13 Time Frame for Correction.

(A) Except as specified in ¶ (B) of this section, the permit holder shall correct core item~~s~~ violations by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.

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Conference for Food Protection
2010 Issue Form

Internal Number: 050
Issue: 2010 I-019

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

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Title:
4-501.114-Manual and Mechanical Warewashing Equipment Chemical Sanitation

Issue you would like the Conference to consider:
Every sub-section (A-E) in Section 4-501.114 currently has an individual criticality rating although complying with the first part automatically covers all subsequent items. Having the sub-sections individually rated may result in the food establishment incurring multiple Priority ^{P} violations when in fact they should only have one.

Public Health Significance:
Section 4-501.114 begins with a requirement that a chemical sanitizer used in a sanitizing solution for manual or mechanical warewashing at contact times specified elsewhere in the FDA Food Code meet additional criteria specified in 7-204.11, be used in accordance with EPA registered label use instructions and be used as set forth in sub-paragraphs (A) through (E). This entire paragraph is classified as a Priority ^{P} item as is each individual sub-section (A) - (E). The result is that instead of one Priority ^{P} item assessed for 4-501.114, the food establishments are now subject to 9 additional Priority ^{P} items that all essentially are covered in the first paragraph of this section. If anyone of the variables listed under (A) through (E) was not in compliance, the food establishment would not be in compliance with the first section of 4.501.114. Having the extra 9 Priority ^{P} items only adds to the Food Establishment being subjected to additional violations for the same reason. Removing the Priority ^{P} item classifications from the sub-sections in (A) through (E) would not affect Public Health since any one not in compliance would be assessed a violation under the first paragraph.

Recommended Solution: The Conference recommends...:
That a letter be sent to FDA requesting that Section 4-501-114(A) through (E) have a single Priority ^{P} item classification for the entire section, and that the subsequent 9 Priority ^{P} item classifications contained within sections (A) through (E) be removed. The initial paragraph and Priority ^{P} item classifications (as indicated below in italics) would cover any and all of the requirements under Section 4-501.114.
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows [P]:

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Conference for Food Protection
2010 Issue Form

Internal Number: 052
Issue: 2010 I-013

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

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Title:
Jewelry Prohibition

Issue you would like the Conference to consider:
Add earrings and facial jewelry to the types of jewelry that are prohibited from being worn by Food Service Employees during food preparation (Section 2-303.11 of the Food Code).

Public Health Significance:
Eliminating facial/ear jewelry while performing food service would prevent Physical Contamination of food and prevent medical problems for consumers such as chipped and/or broken teeth and internal cuts and lesions. The same hazards associated with rings, bracelets and watches also apply to earrings and facial jewlery.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA advising that changes be made to Food Code section 2-303.11 to state:
Except for a plain ring such as a wedding band, while preparing FOOD, FOOD EMPLOYEES may not wear jewelry including medical information jewelry on their arms ~~and~~, hands, ears and face.

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Conference for Food Protection
2010 Issue Form

Internal Number: 070
Issue: 2010 I-007

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

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Title:
Addition to Section 3-603.11 of the Model Food Code, Consumer Advisory.

Issue you would like the Conference to consider:
The Model Food Code recognizes that consumers should have notice regarding the risk of foodborne illness from raw or undercooked meats, poultry, seafood, shellfish, or eggs. However, the model consumer advisory fails to provide adequate notice for persons to accurately assess the risk of severe illness and death from *Vibrio vulnificus* in raw oysters harvested from the Gulf of Mexico. An adequate advisory is modeled in title 17 of the California Code of Regulations § 13675 which provides a basis for the proposed addition to Section 3-603.11.

Public Health Significance:
Vibrio vulnificus in raw oysters harvested from the Gulf of Mexico poses a well-defined risk of severe illness and death to consumers with compromised immune systems, liver damage, diabetes, the genetic disorder hemochromatosis, and certain gastric disorders. Although it is mainly associated with mild gastroenteritis in persons with healthy immune systems, cases, while rare, also exist that document life threatening infections in persons without known pre-existing medical conditions. Each year 30 or more people are diagnosed with *V. vulnificus* induced septicemia from raw oysters sourced to Gulf waters and approximately half die from the infection. Even with aggressive treatment the case fatality rate is 30 to 40 percent and mortality is 100 percent if a patient is not treated within 72 hours of symptom onset. Because *V. vulnificus* presents as primary septicemia, a common disease with many causes, misdiagnosis almost certainly results in underreporting of the disease. It is critical that persons have adequate notice of the risk so that they will seek early medical care and inform their doctor they have eaten raw oysters. While the strongest prevention would be a ban on Gulf oysters unless they have been treated post-harvest to eliminate the pathogen, the industry has resisted such requirements. The proposed warning is, therefore, consistent with industry preferences for consumer education in lieu of other controls. It is a critical requirement because other than self-identification, food establishments have no way of recognizing at-risk patrons. To the extent that patrons have adequate information about their own health status, the warnings may reduce the number of illnesses and deaths (with the attendant bad publicity associated with news reports and lawsuits). Additionally, since consumer perceptions can alter choices thus reducing demand, industry interests and public health walk hand-in-hand with providing adequate

notice that allows at-risk populations to understand and assess the danger of consuming raw oysters.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA recommending the addition of the following language to Section 3-603.11 of the Model Food Code, *Consumer Advisory.*
3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.*
(D) Every FOOD ESTABLISHMENT that offers raw oysters harvested from the Gulf of Mexico (any oyster harvested from the Gulf waters bordering the states of Alabama, Florida, Louisiana, Mississippi, or Texas) shall provide a written warning to any person who orders raw oysters, stating:
WARNING
THIS FACILITY OFFERS RAW OYSTERS FROM THE GULF OF MEXICO. EATING THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS WHO HAVE LIVER DISEASE, CANCER, DIABETES, OR OTHER CHRONIC ILLNESSES THAT WEAKEN THE IMMUNE SYSTEM. If you eat raw oysters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician.
(E) Warnings under subsection (D) are not required whenever the FOOD ESTABLISHMENT has received a copy of a current verification letter from the dealer and tags or labels are as required by Section 3-202.18 of this Code demonstrating that the oysters have been subjected to an oyster treatment process sufficient to reduce *Vibrio vulnificus* to an undetectable level, as defined in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 2004 Edition.

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Attachments:
- "Journal Article re Gulf Coast oysters"
- "Vibrio Vulnificus Infection: Diagnosis and Treatment"

Conference for Food Protection
2010 Issue Form

Internal Number: 073
Issue: 2010 I-025

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

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Title:
Addition to S. 2-103.11 of the Model Food Code, Duties: Person in Charge

Issue you would like the Conference to consider:
The Model Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some food establishments-retailers as well as restaurants-may grind intact beef to produce ground beef "in house". While this practice is lawful, it may present an increased risk of foodborne illness to consumers, because intact beef may not be subject to the same rigorous pathogen control as ground beef.

Public Health Significance:
Grinding intact beef "in house" may spread pathogenic contamination from the exterior of an intact product throughout the resulting ground beef, or, may serve as a source of cross-contamination of grinding equipment. Further, consumers may mistakenly believe that ground beef produced "in house" in this way is fresher or safer, and thus may order such products undercooked (i.e. rare or medium rare), which is insufficient to kill pathogens.
It is thus imperative that those employees tasked with handling and grinding such meats (and those employees responsible for cleaning the grinding equipment, if different) are specially trained in both the logistics of cleaning and the importance of rigorous cleaning for the prevention of foodborne illness.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA recommending the addition of the underlined language to Section 2-103.11 of the Model Food Code, *Duties: Person in Charge*:
2-103.11 Person in Charge.
(L) EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties; <u>specifically and especially those employees who may be responsible for production and handling of "in house" ground beef, such as the grinding of PRIMAL CUTS and WHOLE MUSCLE, INTACT BEEF;</u> and

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Conference for Food Protection
2010 Issue Form

Internal Number: 077
Issue: 2010 I-026

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

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Title:
Mandatory Food Protection Manager Certification for Persons in Charge

Issue you would like the Conference to consider:
The FDA is considering modifying the FDA Food Code so as to require that the designated "Person in Charge" of a Food Establishment be a Food Protection Manager that is certified by a recognized Food Protection Manager Certification program.
Recent studies seem to confirm that the presence of a Certified Food Protection Manager can help to improve food safety practices in a food establishment. FDA supports the efforts made by State, local and tribal agencies toward requiring such certification of the Person In Charge (as defined in the Food Code). FDA also believes it is important that the Food Code continue to identify the types of knowledge that the Person in Charge must possess as they relate to the specific food establishment. Further, FDA believes code compliance during a specific inspection should be considered one of the desired outcomes of, rather than an alternative to, the possession of food safety knowledge and a Food Protection Manager Certification for the Person in Charge.
Since the 1995 edition of the Food Code, certification as a food protection manager has simply been an option for the Person in Charge as a means of demonstrating the basic food safety knowledge that is required of that position. FDA is seeking the Conference's recommendations on how mandatory Food Protection Manager Certification can best be incorporated into the Food Code so as to achieve its effective adoption and implementation at the State, local and tribal level.

Public Health Significance:
The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks and other economic, staffing, cultural and behavioral challenges make it imperative that food protection managers know and control the factors that impact the safety of the food they sell or serve.
Food handling procedures and behaviors that may contribute to foodborne illness are well documented in FDA's retail risk factor studies (9, 10) See Attachment B, and in the CDC Environmental Health Specialists Network (EHS-Net) survey of food service workers' self-reported food preparation practices (4). Frank Bryan identified significant activities that make food safer including knowledge of the *Food Code* and training of industry food workers and managers (1). Certified food protection managers can have an important role

in formulating policies and communicating information to food employees about recommended practices to reduce the risk of foodborne illness and verifying they do so (2).
The results of a number of studies that have shown the prospective benefits associated with the certification of food protection managers. Published studies (See Attachment B, References) that show some of the benefits include:
· A CDC EHS-Net study suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak for an establishment and was a distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had not. (5).
· Kneller found a statistically significant decrease in critical violations and increase in restaurant inspection scores after managers completed a 15-hour food safety training and certification program (6).
· Cotterchio showed a significant increase in inspection scores and decrease in critical violations which was maintained after two years in facilities with a certified food protection manager (3).
· FDA's 2004 retail risk factor study suggests that the presence of a certified manager has a positive correlation with more effective control of certain risk factors, such as poor personal hygiene, especially in different facility types (9). FDA's 2009 risk factor study also indicates that the presence of certified food managers is positively correlated to improved compliance in certain facility types (10)
· Cates found the presence of certified food managers is protective for most types of critical violations including a lower likelihood of violations for personnel, food source and handling, facilities and equipment and warewashing. They were also more likely to be more knowledgeable about relationships between foodborne illness risk factors and safe food handling practices (2).
FDA is aware that there are a number state and local agencies that currently mandate food protection manager certification for certain food establishment personnel. For example, in 2002, Schilling found there were 16 states that mandated food protection manager certification and 34 states with some form of voluntary program (8). By 2009, National Restaurant Association's ServSafe website showed 23 states with a mandatory statewide food protection manager certification (7).
Attachment A contains an example of revisions to the Food Code that would recognize the importance of having a person in charge during all hours of operation that is knowledgeable in food safety and certified as a food protection manager. The suggested edits also recognize that the enhanced level of food protection afforded by having a knowledgeable and certified food protection manager present is not made unnecessary simply because no violations of the Code were observed during a single inspection.
FDA is interested in learning if the Conference believes there are certain types of food establishments or other conditions for which exceptions to the recommended solution are appropriate.

Recommended Solution: The Conference recommends...:
that a letter be sent to FDA recommending modification to the next edition of the FDA Food Code, so as to

1) Require that the Person in Charge, as currently defined in the 2009 Food Code, possess certification by a food protection manager certification program that is recognized under 2009 Food Code section 2-102.20.
2) Require that the Person in Charge also possess and be capable of demonstrating knowledge of the key food safety principles that are identified in 2009 Food Code Paragraph 2-102.11(C))
3) Eliminate the recognition of the achievement of full compliance with the Food Code during a single inspection as a suitable alternative to the requirements recommended in items 1) and 2), above.

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Attachments:

- "Attachment A-Manager Certification-Suggested Changes for the PIC"
- "Attachment B - Manager Certification - References"

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Conference for Food Protection
2010 Issue Form

Internal Number: 089
Issue: 2010 I-023

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

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Title:
Proper Identification of Seafood Species

Issue you would like the Conference to consider:
The Food Code requires that food offered for human consumption be honestly presented in a manner that does not mislead or misinform the consumer (3-601.12). There are hundreds of different species of FISH that are marketed in the United States. Identifying species of FISH with incorrect names (often referred to as "species substitution") 1) misleads the consumer by representing a less expensive or valued species as a more expensive or valued species or 2) negatively impacts the ability of the consumer, FOOD ESTABLISHMENT and REGULATORY AUTHORITY to accurately assess the potential inherent food safety hazards associated with specific species.
The Food Code currently does not emphasize the importance of properly identifying FISH names.

Public Health Significance:
While species substitution is often viewed as an economic fraud or misbranding issue, the practice can also have public health implications. Proper identification of species of FISH is essential for the correct identification and control of food safety hazards pertinent to specific species and for accurate traceback during foodborne disease outbreak investigations.
CDC analyses of foodborne disease outbreak surveillance data consistently indicate that the primary cause of foodborne disease outbreaks associated with finfish are chemical agents - specifically ciguatoxin and scombrotoxin. Ciguatoxin and scombrotoxin are food safety hazards each associated with specific species. Correct identification of the species that are associated with either ciguatoxin or scombrotoxin formation is essential for proper hazard control as well as proper traceback during foodborne disease outbreak investigations.
Some species of fish may cause illness due to naturally occurring toxins in the fish. Escolar or oilfish naturally contains a strong purgative oil, called gempylotoxin, which may cause intestinal cramping and diarrhea. Print media stories investigating species substitution at restaurants frequently find escolar being represented as tuna. Puffer fish or fugu may contain tetrodotoxin, a potent, sometimes lethal neurotoxin. In 2007 two individuals were sickened by the tetrodotoxin from Puffer fish that was misidentified as monkfish.

Paragraph B of section 3-402.11 of the Food Code identifies specific species of FISH that do not require parasite destruction when the READY-TO-EAT form is raw, raw-marinated, partially cooked, or marinated-partially cooked. Misidentification of a species (for example, escolar being labeled as albacore tuna (Thunnus alalunga)) would give the PERSON IN CHARGE at the FOOD ESTABLISHEMENT and REGULATORY AUTHORITY the false impression that the parasite destruction controls outlined in the Food Code do not apply.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending the following additions to the Food Code:

1. That section 3-601.12 be amended as follows:

3-601.12 Honestly Presented.

(A) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

(1) FISH shall be identified by the appropriate FDA-acceptable market name or scientific common name.

(B) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food.

2. That section 3-601.12 of Annex 2 - References be amended as follows:

3-601.12 Honestly Presented.

1. Food and Drug Administration, 2009. Guidance for Industry: The Seafood List - FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce.

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Conference for Food Protection
2010 Issue Form

Internal Number: 090
Issue: 2010 I-006

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

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Title:
Grocery Seafood Advisory for Women of Childbearing Age and Children

Issue you would like the Conference to consider:
This proposal asks the Conference to require grocery stores to post fish advisory information aimed at Women of Childbearing Age and Children (the "TARGET GROUP"). This "FISH ADVISORY" will apply only to retail seafood purchases in grocery stores, excluding "ready to eat" food, and would not apply to ready to eat food provided by other non-grocery FOOD ESTABLISHMENTS. The purpose of the proposal is to communicate to the TARGET GROUP federal Food and Drug Administration and Environmental Protection Agency consumption advice regarding the benefits of fish and the relative presence of methlymercury in seafood species. This information is primarily only available online through these agencies and should be communicated to the TARGET GROUP at grocery stores.

Public Health Significance:
This issue represents a public health matter of the highest order: protecting children's' developing brains and cognitive health. Women of childbearing age need this information posted at grocery stores rather than online. First, this will reduce the problem of concerned women avoiding otherwise-healthy seafood that is important for fetal development when they are unsure about which seafood is safe to eat. Second, it will address the problem of ill-informed consumers in the TARGET GROUP unknowingly exposing developing fetuses and children to seafood that contains high amounts of methylmercury.

Though most people do not have elevated mercury levels, developing fetuses are particularly susceptible to mercury exposure and consumption of contaminated fish is the main source of exposure to methylmercury. As the EPA explains on its website, studies in other countries have shown that "mothers with no symptoms of nervous system damage [have given] birth to infants with severe disabilities, [from which] it became clear that the developing nervous system of the fetus may be more vulnerable to methylmercury than is the adult nervous system" (Attachment 3, EPA Health Effects). Most children do not exhibit such disabilities but instead may suffer from subtle, sub-clinical neurological deficits that can lower their IQ and educational attainment.

Studies analyzing data from the Centers for Disease Control's National Health and Nutrition Examination Survey ("NHANES") have shown that perhaps 400,000 children each year

may have mercury levels at or above the Reference Dose level set by the EPA (Mahaffey et al. 2005, Transande et al. 2005). Further, these figures are significantly higher if the recent studies on the higher ratio of fetal cord blood to maternal blood are taken into account.[1] Recent studies from the more comprehensive 1999-2004 NHANES results show that overall, 4.7% of women of childbearing age exceed the EPA's 5.8ug/L standard and 10.4% exceed the suggested, more sensitive 3.5ug/L level (Mahaffey et al. 2009)(See also Attachment 5, CDC NHANES Data on Levels Exceeding EPA RfD).

This burden on the population can have long-range health and economic implications for states and the nation as a whole. Seafood has nutritional benefits which can enhance cognitive function in children, however, so it is important from a public health perspective that women of childbearing age and children not eliminate seafood from their diets. To ensure this, consumers need better information on the relative mercury contents of fish so they can enjoy fish consumption while lowering their mercury exposure by consuming lower-mercury seafood. For this reason it is imperative that the TARGET GROUP have access at grocery stores to the federal fish consumption advice that the FDA and EPA jointly publish online (Attachment 1, Online Advisory).

The proposed changes first reflect the recommendations of the FDA-EPA's 2004 Online Advisory in an easy-to-understand format. The FISH ADVISORY also facilitates these recommendations by containing a chart that categorizes seafood by relative mercury content, the majority of this seafood being low in mercury. These proposed changes are intended to better protect the public health of fetal and child cognitive development by disseminating to the TARGET GROUP the federal Online Advisory. This proposal will thereby also restore consumer confidence in the safety of the commercial seafood supply by expanding awareness among the TARGET GROUP of healthy, lower mercury seafood products.

Currently, the online FDA-EPA Advisory does not effectively reach consumers. Indeed, most women of childbearing age either do not know of the risks of mercury or, if they do, they are confused about the extent of their exposure and which fish species represent safe, healthy choices. While the Online Advisory lists four "DO NOT EAT" fish and a handful of lower-mercury choices, it leaves consumers in the dark about the vast majority of other fish, most of which are low in mercury. This limits consumer choice and undermines confidence in the seafood industry, which in turn may jeopardize public health.

<u>Background</u>

Since 2004, the FDA and EPA have jointly published an Online Advisory to communicate recommended guidelines for the consumption of seafood by women of childbearing age (ages 45 or under) and children (the TARGET GROUP)(Attachment 1, Online Advisory). The Online Advisory states that the TARGET GROUP should not eat certain high-mercury species (shark, swordfish, tilefish, and king mackerel), and should limit albacore tuna to six ounces per week, to reduce fetal and childhood exposure to methylmercury. Methylmercury is present in most seafood in varying amounts and is a neurotoxin that can impair child neurodevelopment when consumed at certain levels.

The FDA-EPA's Online Advisory is designed to reduce methylmercury exposure within the TARGET GROUP, to generally keep levels generally at or below the EPA's Reference Level of 5.8 ug of mercury per liter of blood, which corresponds to a Reference Dose of 0.1 ug Hg/kg-bw/day (the "RfD"). The EPA established this RfD for methylmercury in 1999, based on the best evidence then available, using data from a long-term epidemiological study in the Faeroe Islands carried out by researchers at Harvard University and elsewhere.

Research since then confirms that public health concern over methylmercury exposure is justified, and that efforts to guide women to pick low-mercury fish must be expanded and improved (Attachment 6, Review of Recent Scientific Studies). Since women are advised to consume fish while pregnant, for nutritional benefits, it is vitally important that women have information to help them identify low-mercury fish, so they (and their babies) can simultaneously enjoy these nutritional benefits while minimizing their exposure to methylmercury.

The federal commercial fish Online Advisory translates the EPA's Reference Dose into consumption recommendations based on the relative average mercury content of various seafood species. Based on this, for example, the federal Online Advisory (Attachment 1) makes the following three major recommendations to the TARGET GROUP:

- Do not eat very high-mercury species such as shark, swordfish, tilefish, and king mackerel;
- Limit canned albacore tuna to 6-ounces per week; and
- Eat two servings (up to 12-ounces) of lower mercury fish per week, including shrimp, salmon, and light canned tuna.

For example, as to the recommendation for lower-mercury fish, for an average-weight woman this consumption recommendation comports with the EPA's RfD guidelines for seafood that contain 0.12 ppm or less of methylmercury. This grouping includes light canned tuna, which contains an average of 0.118 ppm of methylmercury and thus can be consumed by the TARGET GROUP up to two times a week (Attachment 4, FDA Fish Data).

It is also key to note that the EPA's RfD is based on weight, whereas the consumption recommendations by the EPA and FDA are based on a hypothetical, average-weight woman. Therefore, lighter-weight individuals in the TARGET GROUP-such as children and smaller women-who follow the ounce recommendations would have mercury exposure above the EPA's RfD.[2] The federal Online Advisory addresses this by advising that children eat smaller-sized portions, though women with below-average weight also should eat smaller portion sizes to remain within the EPA's RfD.

The federal Online Advisory does not give any information on other fish, other than the very high-mercury fish and a handful of lower mercury species of seafood; it leaves out, for example, both other fish in the low mercury category and fish with moderate mercury. The proposed FISH ADVISORY will remedy this to give women the information they need to make informed health decisions. (Attachment 7, Proposed Fish Advisory)

<u>Proposed Changes</u>

The proposed changes to the Model Food Code solve this problem by giving consumers expanded species-specific information about the relative mercury levels in most seafood sold commercially in the U.S., based on FDA seafood data. It also gives the TARGET GROUP more comprehensive EPA consumption guidelines to allow for a broader range of seafood choices than does the Online Advisory. These changes seek to better promote public health not only by giving the TARGET GROUP this federal advice where they need it - *in grocery stores* - rather than online, but also by filling in the information gaps that the Online Advisory left unanswered.

Seafood contains important nutrients, which for many seafood species include high amounts of beneficial Omega-3 fatty acids. The majority of the nation's seafood market is in fact low in mercury, and consumers in the TARGET GROUP need greater awareness of the array of low-mercury seafood choices from which they can consume healthy seafood while

at the same time protecting fetal and childhood development. For these reasons it is vital to effectively communicate to the TARGET GROUP not only the recommended consumption limits but also which seafood species are low in mercury and thus meet the consumption limits.

In providing this information, the proposed FISH ADVISORY presents a simple, color-code chart displaying the relative mercury levels in the majority of commercial seafood, divided into high, moderate, and lower-mercury categories. These categories are based on EPA calculations of recommended fish consumption, based on the EPA's RfD for the average woman, which also serves as the foundation for the FDA-EPA joint advice in the 2004 Online Advisory. (Attachment 2, EPA Consumption Recommendations by PPM Level)

Specifically, the changes expand the range of seafood choices for the TARGET GROUP beyond the Online Advisory's current, limited list of low-mercury species. Further, these changes are based strictly on federal information available through the FDA and EPA, including FDA data on the mercury content in commercial fish species and EPA consumption guidelines for the TARGET GROUP (Attachment 2, EPA Consumption Recommendations). The EPA has six consumption categories, but for ease of understanding the proposed FISH ADVISORY uses a chart with only three "red-yellow-green" groupings:

1. The proposal eliminates the gap left by the FDA-EPA Online Advisory, by giving the complete list of low mercury seafood (defined as containing 0.12 ppm or less of methylmercury) that can be consumed twice a week by average-weight individuals in the TARGET GROUP;

2. It expands the list to include moderate-mercury seafood (containing 0.13 - 0.31 ppm of mercury), which are not mentioned on the Online Advisory despite the fact that under EPA guidelines the TARGET GROUP may safely consume fish from this category up to once a week;[3] and

3. It identifies higher-mercury species (above 0.31 ppm), which under EPA guidelines the TARGET GROUP should avoid. (The higher-mercury grouping in the current proposal does not contain albacore tuna, since the FDA-EPA Online Advisory issues specific consumption advice for albacore which the proposed FISH ADVISORY communicates elsewhere.)[4]

The EPA guidelines specify that fish in excess of 0.31 ppm of mercury should only be eaten once every two weeks, or once a month or less for fish with higher levels, with no other fish eaten during that period. Such infrequent seafood intake by the TARGET GROUP would deprive developing fetuses and children of the benefits of seafood, which the FDA recommends should ideally be consumed (from lower mercury species) twice a week, for up to a total of 12 ounces per week. Members of the TARGET GROUP who follow the proposed chart's "avoid" advice for these higher-mercury species will thus be able to more frequently consume seafood in the moderate- and lower-mercury categories. (Attachment 7, Proposed Fish Advisory Chart)

These figures were derived from the Online Advisory and/or the EPA's RfD consumption recommendations on which the Online Advisory is based. As the EPA stated in its 2004 Derivation of Safe Fish Consumption Rate (for noncommercial fish, which has the same RfD standard as commercial seafood), "one can safely consume 2 meals/week at concentrations ranging from >0.078 ppm to 0.12 ppm, and should consume no more than 1 meal/month at concentrations ranging from >.47 ppm to 0.94 ppm" (Attachment 2, EPA Consumption Recommendations by PPM Level). These breakdowns are also found in the

EPA's "Monthly Fish Consumption Limits for Noncarcinogenic Health Endpoint - Methylmercury." (Attachment __????____)

The EPA further sets forth that moderate-mercury fish with >0.12 -0.23 ppm be consumed once a week (four times a month) and fish with 0.23 - 0.31 ppm be consumed slightly less than once a week (three times a month) [4] (Attachment 2). The proposed FISH ADVISORY reflects this consumption limit on the "moderate"-mercury (or yellow-designated) portion of the chart, to be consumed only once a week.

Including the full range of seafood in this way, which THE REGULATORY AUTHORITY may expand by adding information about locally-caught noncommercial fish), will further enable members of the TARGET GROUP to accurately assess their overall mercury exposure to make better-informed decisions about which seafood to purchase at the grocery store. This expanded information will eliminate uncertainty among consumers in the TARGET GROUP and restore their confidence in the safety of seafood products. In the absence of this information, confusion might lead some consumers to otherwise avoid healthy seafood products.

Moreover, the proposed FISH ADVISORY communicates this information in the clear, easily-understood format of a color-coded chart. This method will quickly convey information to TARGET GROUP consumers and is supported by a study on the effectiveness of advisories, which showed that such red-yellow-green designations are a preferred format for communicating fish advisory information (Ujihara). Most importantly, the proposal gives consumers this information where they need it most, at the point of sale in the grocery store. With these changes, consumers within the TARGET GROUP can be confident that the seafood products they purchase are safe based on their individual consumption patterns.

Notes:

[1] Several studies have estimated would lower the EPA Reference Dose level from 5.8 ug of mercury per liter of blood to 3.5 ug/L[1] (Stern and Smith 2003) and that 15.7% of women of childbearing age were found in the 1999-2001 NHANES study to exceed this level (NRC 2006, Mahaffey et al.2004, Trasande et al. 2005).

[2] *Mercury Update: Impact on Fish Advisories* (EPA 2001), found at: www.epa.gov/ost/fishadvice/mercupd.

[3] This category is technically not as protective as the EPA guidelines, since the proposal for the moderate-mercury category includes fish with 0.23-0.31 ppm of mercury, which the EPA recommends that the target group consume only three times a month, rather than the current proposal's higher, once per week recommendation.

[4] The instant FISH ADVISORY is not designed to establish the most protective mercury consumption advice, but simply to convey the current federal advice.

[5] Table 4-3 from US EPA, 2000, cited in 2004 EPA Derivation of Safe Fish Consumption Rate, National Noncommercial Fish Advisory.

Recommended Solution: The Conference recommends...:

that the Conference Chair send a letter to the FDA Commissioner to urge the following addition to the 2009 Food Code to require grocery stores to post a FISH ADVISORY for

Women of Childbearing Age and Children (the "TARGET GROUP") to communicate to the TARGET GROUP:

1) the FDA-EPA 2004 Advisory recommendations ("Online Advisory", see Attachment 1);

2) EPA consumption recommendations for moderate and higher-mercury fish; and,

3) a chart displaying the relative mercury content of commercial seafood..

The specific proposed language to add NEW sections to the Model Food Code as follows:

3-603.12 Seafood Methylmercury Disclosure for Consumption of Seafood Products by Women of Childbearing Age and Children.

(A) GROCERY STORES shall post a commercial Fish Advisory to inform consumers of the recommended FDA-EPA consumption guidelines for Women of Childbearing Age (Under Age 45) and Children (collectively the "TARGET GROUP") and the relative amounts of methylmercury in various seafood species using written advisories and/or placards posted at the point of sale (the "FISH ADVISORY") as specified in paragraphs (B) - (F) of this section.

(B) CONTENT OF DISCLOSURE. The FISH ADVISORY shall contain the following primary components, conform to the format set forth below, and shall essentially follow the sample sign presented below in section (F).

(1) Title. The sign shall be entitled "FISH ADVISORY", depicted in bold 48-point font size and be immediately followed by the underlined heading "Women Under Age 45 and Children" in bold 36-point font size.

(2) Explanatory Information. Immediately below this title, the FISH ADVISORY must contain the following prefatory statement to explain the purpose and the intended TARGET GROUP. This statement, in large type (at least 20-point font size) for ease of visibility, shall state: "Seafood contains important nutrients, including Omega-3 fatty acids, but also contains mercury, which can be harmful to women and children."

(3) Key Consumption Limits. The sign shall then post the following key consumption recommendations by the FDA-EPA Joint Fish Advisory for the TARGET GROUP:

(a) The first statement, boxed and in at least 28-point font size, shall state the "DO NOT EAT" list of fish which includes the following high-mercury species: swordfish, shark, tilefish, and king mackerel.

(b) A second statement, boxed and in at least 17-point font size, shall state to the TARGET GROUP: "Limit albacore tuna to one, 6-ounce serving per week, and eat no other fish that week. Light canned tuna, however, may be eaten twice per week."

(4) Seafood Chart. Second, the FISH ADVISORY shall contain a simple, color-coded chart that groups seafood species by methylmercury content into three, easily-understood high, medium, and low categories. These three categories, separated into three columns, shall be correspondingly delineated by red, yellow and green color designations and by the accompanying consumption recommendations, as set forth below in paragraphs (a)-(c).

(a) Lower-Mercury Seafood:

(i) The first column on the chart shall list those species which contain 0.12 parts per million ("ppm") or less of methylmercury, according to FDA monitoring data or more recent data obtained by the REGULATORY AUTHORITY;

(ii) These species shall include, in ascending value of mercury content, fish that contain above 0.05% of market share and are listed on Table 2 of the FDA's information on Mercury Levels in Commercial Fish and Shellfish as "Fish and Shellfish With Lower Levels of Mercury" (at or below 0.12 ppm of methylmercury): shrimp, sardines, tilapia,

clams/oysters, scallops/mussels, salmon, crayfish, freshwater trout, ocean perch/mullet, pollock, Atlantic mackerel, anchovy/herring, sole/flounder, crab, pike, butterfish, catfish, squid, Atlantic croaker, whitefish, Pacific mackerel/chub, smelt, cod, canned light tuna and spiny lobster;

(iii) The chart shall entitle this group "lower" mercury seafood, designate this category by a green color coding, and state that these fish should be eaten by the TARGET GROUP no more than 12-ounces per week.

(b) Moderate-Mercury Seafood:

(i) The second column on the chart shall list those species which contain 0.13 - 0.31 ppm of methylmercury, according to FDA monitoring data or more recent data obtained by the REGULATORY AUTHORITY;

(ii) These species shall include, in ascending value of mercury content: snapper, skate, freshwater perch, monkfish, halibut, sablefish, sea bass, sea trout, and American lobster;

(iii) The chart shall entitle this group "Moderate" mercury seafood, designate this category by a yellow color coding, and state the EPA Reference Dose advice that these fish should be eaten by the TARGET GROUP no more than one serving per week, with no other fish eaten that week.

(c) High-Mercury Seafood:

(i) The third column shall list those commercial seafood species which contain above 0.31 ppm of methylmercury, according to FDA monitoring data or more recent data obtained by the REGULATORY AUTHORITY, subject to section (iv) below.

(ii) These species shall include, in ascending value of mercury content: fresh/frozen tuna, Spanish mackerel (South Atlantic), Chilean bass, grouper, marlin, and orange roughy;

(iii) The chart shall entitle this group "High" mercury seafood, delineate this category by a red color coding, and label on the chart that the TARGET GROUP should "Avoid" these fish.

(iv) This "High" category shall exclude canned albacore tuna, given that the FISH ADVISORY set forth in this section specifies per paragraph (B)(3)(b) above that the TARGET GROUP may consume up to 6-ounces of albacore tuna. It shall also exclude the "DO NOT EAT" fish that are highlighted at the top of the FISH ADVISORY per paragraph (B)(3)(a) above.

(5) In addition to the provisions of paragraphs (B)(1)-(B)(3) above, the FISH ADVISORY shall generally follow the content and format set forth in section (F).

(C) LOCATION OF FISH ADVISORY. The FISH ADVISORY shall be posted in GROCERY STORES as follows:

(1) The FISH ADVISORY shall be displayed on a laminated, 8.5-inch by 11-inch sign or placard; and

(2) The FISH ADVISORY shall be displayed prominently at the point-of-sale, at or immediately adjacent to the specific location where the seafood is being sold, as close as reasonably possible to the seafood product.

(a) Disclosure for frozen SEAFOOD PRODUCTS shall be centrally affixed to the glass display case that contains the SEAFOOD PRODUCTS or, if there is no glass display case, otherwise in a prominent location within the display case that is clearly visible to consumers.

(b) Disclosure for SEAFOOD PRODUCTS sold at the fresh seafood counter in GROCERY STORES shall be displayed on the display case and also posted atop the seafood counter at the point-of-sale.
(c) Disclosure for canned or nonperishable, packaged SEAFOOD PRODUCTS shall be affixed prominently to the shelving or, if none, otherwise at or within two feet of the display area where they are located.
(D) DEFINITIONS.
(1) Under this section "SEAFOOD PRODUCT" shall be defined to include any food product offered for sale in a GROCERY STORE that contains two or more ounces of seafood per serving size.
(2) Under this section "GROCERY STORE" shall be defined in the normal sense of the word, to exclude retail FOOD ESTABLISHMENTS other than restaurants and other entities that sell "ready to eat" products.
(E) MODIFICATIONS. The REGULATORY AUTHORITY may modify the FISH ADVISORY in any of the following ways:
(1) To designate by an asterisk the seafood species that contain high Omega-3s;
(2) To add to the lists of high-, moderate-, or lower-mercury categories locally-caught fish from local lakes, streams, or coastal areas, so that consumers may more accurately assess their total mercury exposure when buying commercial seafood products;
(3) To add information on serving or portion sizes for children;
(4) To add a state contact phone number or state governmental website address for consumers to contact for more information concerning seafood consumption.
(5) To add other information that the REGULATORY AUTHORITY may reasonably deem important for the health of or seafood purchasing decisions of members of the TARGET GROUP.
(F) SAMPLE CHART. [See Attachment 7, Proposed Fish Advisory Chart]

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Attachments:

- "ONLINE ADVISORY, JOINT EPA-FDA FISH ADVISORY"
- "ATTACHMENT 2: EPA CONSUMPTION RECOMMENDATION BY PPM LEVEL"
- "ATTACHMENT 3: EPA, HEALTH EFFECTS"
- "ATTACHMENT 4: FDA FISH DATA"
- "ATTACHMENT 5: CDC, NHANES DATA ON MERCURY LEVELS EXCEEDING EPA RfD"
- "ATTACHMENT 6: REVIEW OF RECENT SCIENTIFIC STUDIES"
- "ATTACHMENT 7: PROPOSED FISH ADVISORY CHART"

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