Title: Report - TCS Implementation Committee

Issue you would like the Conference to consider:

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

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

   a. Any new or additional information that will assist regulators and industry in the implementation of the new PHF/TCS definition

   b. The finalized FAQ from the 2005 TCS survey

   c. The response document from NACMCF (National Advisory Council for Microbiological Criteria for Foods) on inoculation studies

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

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

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

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

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

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

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

**Submitter Information:**
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Fax:  
E-mail: adam.johnson@supervalu.com

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

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*
December 4, 2009

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

Dear, Mr. Smith

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

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

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

CFP is aware that FDA has already published information on its website related to the items mentioned above. These include “Evaluation and Definition of Potentially Hazardous Foods”, and “Potentially Hazardous Food: The Evolving Definition of Temperature Control for Safety”. Links to these FDA webpages can now be found on the CFP website. In addition, a link to the 2009 report published by NACMCF on inoculation studies has also been placed on the CFP website. CFP applauds your efforts to clarify and standardize the information available to industry and regulators pertaining to the implementation of PHF/TCS requirements. We respectfully request that you continue these efforts, including the possible compiling and publishing of a list of FAQ’s based on the 2005 CFP survey related to PHF/TCS and the placement of a link to the NACMCF report on inoculation studies on the FDA website.
This letter is being sent on behalf of the CFP TCS Implementation committee with the full knowledge and approval of CFP Conference Chair, David Gifford. FDA’s support of and cooperation with the Conference through the years has resulted in an improved regulatory process and increased efforts toward food safety. The CFP Executive Board looks forward to continuing this same collaboration and partnership with the FDA in the coming years. With such a liaison, we expect to continue the great progress of the past.

Sincerely,

Adam Johnson
Chair, TCS Implementation Committee
CONFERENCE FOR FOOD PROTECTION  
COMMITTEE NAME: TCS IMPLEMENTATION

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

DATE OF REPORT: DECEMBER 4, 2009

SUBMITTED BY: Adam Johnson

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

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

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

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

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

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

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

Based on a review of the committee charge it was recognized that there were significant web postings related to charges #1 and #2 that had already been posted. These included “Evaluation and Definition of Potentially Hazardous Foods”, and “Potentially Hazardous Food: The Evolving Definition of Temperature Control for Safety”. Links to these FDA web pages could also now be found on the CFP website. In addition, a link to the 2009 report published by NACMCF on inoculation studies had also been placed on the CFP website.
A letter was drafted and sent to the FDA requesting that they continue their efforts, including the possible compiling and publishing of a list of FAQ’s based on the 2005 CFP survey related to PHF/TCS and the placement of a link to the NACMCF report on inoculation studies on the FDA website.

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

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

**Issue:** Report – TCS Implementation Committee

The issue will request that the Committee Report be acknowledged.

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

<table>
<thead>
<tr>
<th>Casmir Tryba</th>
<th>Patrick Brown</th>
<th>Larry Kohl</th>
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<tbody>
<tr>
<td>Big Y Food Stores</td>
<td>Atlantic &amp; Pacific Tea Co.</td>
<td>Food Marketing Institute</td>
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<tr>
<td>Alan Tart</td>
<td>Susan M. Wallace</td>
<td>Richard Parker</td>
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<td>USFDA/CFSAN</td>
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<td>Marcel Elizondo</td>
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<td>Austin/Travis County HHS</td>
<td>Penn State University</td>
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<td>Austin, TX</td>
<td>State College, PA</td>
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**COMMITTEE MEMBER ROSTER:**
The member roster is presented as an attachment to this report.
<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Title</th>
<th>Position/Chair/Member</th>
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<th>Employer</th>
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Report - Plan Review Committee

Issue you would like the Conference to consider:

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

Public Health Significance:

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

Recommended Solution: The Conference recommends:

1. Acknowledgement of the CFP Plan Review Committee Report;

2. Re-creation of the committee to continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2012 CFP Biennial Meeting; and,

3. Thanking the Committee members.

Submitter Information:
Name: Liza Frias, Chair
Organization: 2008-2010 Plan Review Committee
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Telephone: 714-300-6813  Fax: 714-300-6931
E-mail: liza.frias@supervalu.com

Attachments:
• "Plan Review Committee Final Report"
• "2008-2010 Plan Review Committee Member Roster"

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

COUNCIL (I, II, OR III): I

DATE OF REPORT: December 4, 2009

SUBMITTED BY: Liza Frias, Chair

COMMITTEE CHARGE(s):

The Conference recommends that the Plan Review Committee continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2010 CFP Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Due to the resignation of the prior committee chair and lack of prior history, no committee work was completed until the first conference call which was held on August 18, 2009.

During the initial conference the following was discussed:

Review the progress of the past Plan Review Committee and to determine next steps.

- The final document as approved at the 2008 CFP Biennial Meeting was not formatted. The committee will complete formatting and send to the FDA Plan Review Working Group for final review. No additional charge is needed since the document was approved pending the final formatting.

Discuss how to approach the CFP charge with limited time.

- The committee decided to work on changes to the Pre-Operational Temporary Food Establishment document.

The committee has held monthly conference calls since August 2009 and has initiated discussions and recommended changes to the Pre-Operational Temporary Food Establishment document. Unfortunately, there is not a final draft that can be presented at the 2010 CFP Biennial Meeting.

Recommendations for future charge:

The committee recommends that the following charges be made to a re-created Plan Review committee following the CFP 2010 Biennial Meeting:

- Continue its review of the Mobile Food Establishment, Permanent Outdoor Cooking Operations, Temporary Food Establishment and Plan Review documents and present their findings at the 2012 CFP Biennial Meeting.

REQUESTED ACTION:

The Plan Review committee will submit one issue at the 2010 Biennial Meeting based on the recommendations of the committee.

Acknowledgement of Plan Review Committee’s report with continuation charges.
COMMITTEE MEMBER ROSTER: See attached
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<th>First Name</th>
<th>Position</th>
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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


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.

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


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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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.
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"

*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.*
Update #1 to National Steak and Poultry E. coli O157:H7 outbreak in blade tenderized steaks - CDC is collaborating with public health officials in several states and USDA FSIS to investigate a multistate outbreak of human infections due to E. coli O157:H7, in which as of January 4, 2010, 21 persons infected with the outbreak strain of E. coli O157:H7 have been reported from 16 states.

**Organization:** Centers for Disease Control and Prevention (CDC)

**Source:** CDC update from January 6, 2010

**Date Released:** 01/06/2010


The National Steak and Poultry web site is at [http://www.nationalsteak.com](http://www.nationalsteak.com) but as of this writing contained no information on the recall.


**Contact:** None provided.

**Summary:** From the Jan. 6, 2010 CDC update:

As of Monday, January 4, 2010, 21 persons infected with the outbreak strain of E. coli O157:H7 had been reported from 16 states. The number of ill persons who were identified resides in each state as follows: CA (1), CO (1), FL (1), HI (1), IA (1), IN (1), KS (1), MI (1), MN (3), NV (1), OH (2), OK (1), SD (2), TN (1), UT (2), and WA (1).

Known illness onset dates range from October 3, 2009 through December 14, 2009. Most patients became ill between mid-October and late November. Patients range in age from 14 to 87 years and the median age of patients is 34 years, which means half are younger than 34 years. Forty-three percent of patients are females. There have been 9 reported hospitalizations, 1 case of hemolytic uremic syndrome (HUS), and no deaths.
In early December 2009, CDC's PulseNet staff identified a multistate cluster of 14 E. coli O157:H7 isolates with a particular DNA fingerprint or pulsed-field gel electrophoresis (PFGE) pattern reported from 13 states. CDC's OutbreakNet team began working with state and local partners to gather epidemiologic information about persons in the cluster to determine if any of the ill individuals had been exposed to the same food source(s). Health officials in several states who were investigating reports of E. coli O157:H7 illnesses in this cluster found that most ill persons had consumed beef, many in restaurants. CDC is continuing to collaborate with state and local health departments in an attempt to gather additional epidemiologic information and share this information with FSIS. At this time, at least some of the illnesses appear to be associated with products subject to a recent FSIS recall.

On December 24, 2009, FSIS issued a notice about a recall of 248,000 pounds of beef products from National Steak and Poultry that may be contaminated with E. coli O157:H7. The recall was issued after FSIS determined there was an association between non-intact steaks (blade tenderized prior to further processing) and illnesses in Colorado, Iowa, Kansas, Michigan, South Dakota and Washington.

Prepared by: This message was distributed by Cindy Roberts, who may be reached at e-mail: car@fien.com or 202-669-6951

This article (#11964) was distributed by e-mail on January 7, 2010 to those whose names are on the FIEN, LLC Subject Matter Distribution Lists for Food Safety; Meat, Poultry and Eggs

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Food Industry Environmental Network, LLC (FIEN, LLC) - see http://www.fien.com - FIEN, LLC is a regulatory and policy e-mail update service for the agriculture and food industry which is operated as a partnership by Jack Cooper and Cindy Roberts
Title:

Grocery Seafood Advisory for Women of Childbearing Age and Children

Issue you would like the Conference to consider:

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

Public Health Significance:

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

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

Studies analyzing data from the Centers for Disease Control's National Health and Nutrition Examination Survey ("NHANES") have shown that perhaps 400,000 children each year may have mercury levels at or above the Reference Dose level set by the EPA (Mahaffey et al. 2005, Transande et al. 2005). Further, these figures are significantly higher if the recent studies on the higher ratio of fetal cord blood to maternal blood are taken into account.[1] Recent studies from the more comprehensive 1999-2004 NHANES results show that overall, 4.7% of women of childbearing age exceed the EPA's 5.8ug/L standard and 10.4% exceed the suggested, more sensitive 3.5ug/L level (Mahaffey et al. 2009)(See also Attachment 5, CDC NHANES Data on Levels Exceeding EPA RfD).

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

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

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

Background

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

The FDA-EPA's Online Advisory is designed to reduce methylmercury exposure within the TARGET GROUP, to generally keep levels generally at or below the EPA's Reference Level of 5.8 ug of mercury per liter of blood, which corresponds to a Reference Dose of 0.1 ug Hg/kg-bw/day (the "RfD"). The EPA established this RfD for methylmercury in 1999, based on the best evidence then available, using data from a long-term epidemiological study in the Faeroe Islands carried out by researchers at Harvard University and elsewhere. Research since then confirms that public health concern over methylmercury exposure is justified, and that efforts to guide women to pick low-mercury fish must be expanded and improved (Attachment 6, Review of Recent Scientific Studies). Since women are advised to consume fish while pregnant, for nutritional benefits, it is vitally important that women have information to help them identify low-mercury fish, so they (and their babies) can simultaneously enjoy these nutritional benefits while minimizing their exposure to methylmercury.

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

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

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

It is also key to note that the EPA's RfD is based on weight, whereas the consumption recommendations by the EPA and FDA are based on a hypothetical, average-weight woman. Therefore, lighter-weight individuals in the TARGET GROUP-such as children and smaller women who follow the ounce recommendations would have mercury exposure above the EPA's RfD.[2] The federal Online Advisory addresses this by advising that children eat smaller-sized portions, though women with below-average weight also should eat smaller portion sizes to remain within the EPA's RfD.
The federal Online Advisory does not give any information on other fish, other than the very high-mercury fish and a handful of lower mercury species of seafood; it leaves out, for example, both other fish in the low mercury category and fish with moderate mercury. The proposed FISH ADVISORY will remedy this to give women the information they need to make informed health decisions. (Attachment 7, Proposed Fish Advisory)

Proposed Changes

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

Seafood contains important nutrients, which for many seafood species include high amounts of beneficial Omega-3 fatty acids. The majority of the nation’s seafood market is in fact low in mercury, and consumers in the TARGET GROUP need greater awareness of the array of low-mercury seafood choices from which they can consume healthy seafood while at the same time protecting fetal and childhood development. For these reasons it is vital to effectively communicate to the TARGET GROUP not only the recommended consumption limits but also which seafood species are low in mercury and thus meet the consumption limits.

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

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

1. The proposal eliminates the gap left by the FDA-EPA Online Advisory, by giving the complete list of low mercury seafood (defined as containing 0.12 ppm or less of methylmercury) that can be consumed twice a week by average-weight individuals in the TARGET GROUP;
2. It expands the list to include moderate-mercury seafood (containing 0.13 - 0.31 ppm of mercury), which are not mentioned on the Online Advisory despite the fact that under EPA guidelines the TARGET GROUP may safely consume fish from this category up to once a week;[3] and

3. It identifies higher-mercury species (above 0.31 ppm), which under EPA guidelines the TARGET GROUP should avoid. (The higher-mercury grouping in the current proposal does not contain albacore tuna, since the FDA-EPA Online Advisory issues specific consumption advice for albacore which the proposed FISH ADVISORY communicates elsewhere.)[4] The EPA guidelines specify that fish in excess of 0.31 ppm of mercury should only be eaten once every two weeks, or once a month or less for fish with higher levels, with no other fish eaten during that period. Such infrequent seafood intake by the TARGET GROUP would deprive developing fetuses and children of the benefits of seafood, which the FDA recommends should ideally be consumed (from lower mercury species) twice a week, for up to a total of 12 ounces per week. Members of the TARGET GROUP who follow the proposed chart's "avoid" advice for these higher-mercury species will thus be able to more frequently consume seafood in the moderate- and lower-mercury categories. (Attachment 7, Proposed Fish Advisory Chart)

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

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

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

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

Notes:

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


[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.
What You Need to Know About Mercury in Fish and Shellfish (Brochure)

March 2004

Advice for
Women Who Might Become Pregnant
Women Who are Pregnant
Nursing Mothers
Young Children

from the
U.S. Food and Drug Administration
U.S. Environmental Protection Agency

The Facts

Fish and shellfish are an important part of a healthy diet. Fish and shellfish contain high-quality protein and other essential nutrients, are low in saturated fat, and contain omega-3 fatty acids. A well-balanced diet that includes a variety of fish and shellfish can contribute to heart health and children's proper growth and development. So, women and young children in particular should include fish or shellfish in their diets due to the many nutritional benefits.
However, nearly all fish and shellfish contain traces of mercury. For most people, the risk from mercury by eating fish and shellfish is not a health concern. Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. The risks from mercury in fish and shellfish depend on the amount of fish and shellfish eaten and the levels of mercury in the fish and shellfish. Therefore, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) are advising women who may become pregnant, pregnant women, nursing mothers, and young children to avoid some types of fish and eat fish and shellfish that are lower in mercury.

### 3 Safety Tips

By following these 3 recommendations for selecting and eating fish or shellfish, women and young children will receive the benefits of eating fish and shellfish and be confident that they have reduced their exposure to the harmful effects of mercury.

1. **Do not eat**
   - Shark
   - Swordfish
   - King Mackerel
   - Tilefish

   They contain high levels of mercury.

2. **Eat up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury.**
   - Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon, pollock, and catfish.
   - Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to 6 ounces (one average meal) of albacore tuna per week.

3. **Check local advisories about the safety of fish caught by family and friends in your local lakes, rivers, and coastal areas.**

   If no advice is available, eat up to 6 ounces (one average meal) per week of fish you catch from local waters, but don't consume any other fish during that week.

Follow these same recommendations when feeding fish and shellfish to your young child, but serve smaller portions.

### Frequently Asked Questions about Mercury in Fish and Shellfish:

Note:
If you have questions or think you've been exposed to large amounts of methylmercury, see your doctor or health care provider immediately.

1. **What is mercury and methylmercury?**
   Mercury occurs naturally in the environment and can also be released into the air through industrial pollution. Mercury falls from the air and can accumulate in streams and oceans and is turned into methylmercury in the water. It is this type of mercury that can be harmful to your unborn baby and young child. Fish absorb the methylmercury as they feed in these waters and so it builds up in them. It builds up more in some types of fish and shellfish than others, depending on what the fish eat, which is why the levels vary.

2. **I'm a woman who could have children but I'm not pregnant - so why should I be concerned about methylmercury?**
   If you regularly eat types of fish that are high in methylmercury, it can accumulate in your bloodstream over time. Methylmercury is removed from the body naturally, but it may take over a year for the levels to drop significantly. Thus, it may be present in a woman even before she becomes pregnant. This is the reason why women who are trying to become pregnant should also avoid eating certain types of fish.

3. **Is there methylmercury in all fish and shellfish?**
   Nearly all fish and shellfish contain traces of methylmercury. However, larger fish that have lived longer have the highest levels of methylmercury because they've had more time to accumulate it. These large fish (swordfish, shark, king mackerel and tilefish) pose the greatest risk. Other types of fish and shellfish may be eaten in the amounts recommended by FDA and EPA.

4. **I don't see the fish I eat in the advisory. What should I do?**
   If you want more information about the levels in the various types of fish you eat, see the FDA food safety website or the EPA website at www.epa.gov/ost/fish.

5. **What about fish sticks and fast food sandwiches?**
   Fish sticks and "fast-food" sandwiches are commonly made from fish that are low in mercury.
6. **The advice about canned tuna is in the advisory, but what's the advice about tuna steaks?**
   Because tuna steak generally contains higher levels of mercury than canned light tuna, when choosing your two meals of fish and shellfish, you may eat up to 6 ounces (one average meal) of tuna steak per week.

7. **What if I eat more than the recommended amount of fish and shellfish in a week?**
   One week’s consumption of fish does not change the level of methylmercury in the body much at all. If you eat a lot of fish one week, you can cut back for the next week or two. Just make sure you average the recommended amount per week.

8. **Where do I get information about the safety of fish caught recreationally by family or friends?**
   Before you go fishing, check your Fishing Regulations Booklet for information about recreationally caught fish. You can also contact your local health department for information about local advisories. You need to check local advisories because some kinds of fish and shellfish caught in your local waters may have higher or much lower than average levels of mercury. This depends on the levels of mercury in the water in which the fish are caught. Those fish with much lower levels may be eaten more frequently and in larger amounts.

For further information about the risks of mercury in fish and shellfish call the U.S. Food and Drug Administration's food information line toll-free at 1-888-SAFEFOOD or visit [FDA's Food Safety website](#).

For further information about the safety of locally caught fish and shellfish, visit the [Environmental Protection Agency's Fish Advisory website](#) or contact your State or Local Health Department. A [list of state or local health department contacts](#) is available. Click on Federal, State, and Tribal Contacts. For information on EPA's actions to control mercury, visit [EPA's mercury website](#).
DATE: March 11, 2004
RE: Origin of 1 Meal/Week Noncommercial Fish Consumption Rate in National Advisory for Mercury

Background
The national advisory states that, for noncommercial fish, consumers should first consult any local advisories that may pertain to their catch. In case of no local advisory, consumers are advised to restrict consumption to 1 meal/week. Because states and tribes have not monitored nor posted advisories on all waters in the U.S., the noncommercial fish consumption advice is provided as a baseline of protection. This technical memorandum provides the methodology from which the default safe consumption rate is derived.

Introduction
Statistics on mercury concentrations in noncommercial fish were calculated from a national database. Mean fish tissue concentrations were compared against default fish consumption limits for mercury, as presented in EPA guidance. Noncommercial fish can be consumed at a rate of one 6-oz. meal of fish per week for the vast majority of species.

Fish Tissue Database
Date range: All dates covering a range of years from 1987 to 2003.  
Species selected: All species with data from at least 100 sampling stations in the database.  
Sample type: Fillet only. Whole fish samples not included, as these are relevant for ecological risk.  
Additional Notes: The NLFWA fish tissue database is data voluntarily provided to EPA, representing sampling and analysis performed by States and Tribes for the purpose of fish consumption advisory assessments. Thus the data collection is targeted to those areas of concern for increased fish contaminant levels. All fish data are from adult fish. Juveniles and fish organs are not included in the database as such data are relevant for ecological risk assessments, rather than human health risk assessments.

Fish Tissue Statistics
Statistics for each species are provided in Table 1. All of the statistics calculated for Table 1 are based on sampling station averages (means). That is, the mean value was calculated at each sampling station for each species. The statistics shown in Table 1 (count, mean, median, minimum, and maximum), then are calculated based on the station level averages. While some stations had as few as a single sample per species, others might have hundreds of samples. Thus, using station-level averages eliminates biasing toward stations with a large number of samples, and produces statistics that are more representative of the
entire population of sampling stations. From Table 1, one can see that species means range from 0.06 ppm to 0.96 ppm, but that the bulk of the species (27 out of 34) have average mercury concentrations between 0.13 ppm and 0.43 ppm.

**Risk Based Fish Consumption Limits**

US EPA, 2000, Table 4-3 (see attachment) presents risk-based fish consumption limits which relate the number of fish meals that can be eaten per month to fish tissue concentrations of methylmercury. The inputs used in the development of Table 4-3, are described in Section 3.3 of the same document (US EPA, 2000). These include:

- **Reference Dose (RfD):** $1 \times 10^{-4}$ mg/kg-d.
- **Meal Size:** 8 oz., uncooked corresponding with 6 oz. cooked as used in the national advisory.
- **Body Weight:** 70 kg, average body weight of adult males and females combined, in the U.S. population.

**Derivation of Safe Fish Consumption Rate**

US EPA, 2000, Table 4-3 (see attachment) presents safe fish consumption rates corresponding to various ranges of mercury contaminant concentrations. While Table 4-3 is quite detailed, most states have issued fish consumption advisories according to a more coarse consumption rate categorization, i.e.: no consumption, 1 meal/month, 1 meal/week, and 2 meals/week. At this categorization, states typically collapse the 2-4 meals/month consumption rates to a single 1 meal/week category. That is, by Table 4-3 (US EPA, 2000), one can safely consume 2 meals/week at concentrations ranging from $>0.078$ ppm to 0.12 ppm, and should consume no more than 1 meal/month at concentrations ranging from $>0.47$ ppm to 0.94 ppm. As can been seen from Table 1, below, the vast majority of fish species with contamination data (27 out of 34 species) have concentrations within the coarse 1 meal/week range (i.e. 2-4 meals/month range or $>0.12$ ppm - 0.47 ppm). Thus, the general consumer should be advised to eat no more than 1 meal/week of noncommercial fish in the U.S. Note: Collapsing the 2-4 meal/month consumption rate to a 1 meal/week consumption rate strikes a balance between a too detailed advisory that would overwhelm or confuse most consumers, and simplified advice that balances risks from mercury with the benefits of fish. Consumers are encouraged to use more detailed information where available for the waterbodies on which they fish, and the fish species they choose to consume. Also, as can be seen from the minimum and maximum values in Table 1, mercury concentrations in fish vary considerably from waterbody to waterbody and region to region. Consumers should, first and foremost, consider any local advisories.

**Note:** Collapsing the 2-4 meal/month consumption rate to a 1 meal/week consumption rate strikes a balance between a too detailed advisory that would overwhelm or confuse most consumers, and simplified advice that balances risks from mercury with the benefits of fish. Consumers are encouraged to use more detailed information where available for the waterbodies on which they fish, and the fish species they choose to consume. Also, as can be seen from the minimum and maximum values in Table 1, mercury concentrations in fish vary considerably from waterbody to waterbody and region to region. Consumers should, first and foremost, consider any local advisories.
Table 1. Mercury Contamination Statistics by Species* [NONCOMMERCIAL]

<table>
<thead>
<tr>
<th>Species</th>
<th># Stations</th>
<th>Mean</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowfin</td>
<td>358</td>
<td>0.96</td>
<td>0.82</td>
<td>0.02</td>
<td>4.80</td>
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<tr>
<td>Chain pickerel</td>
<td>250</td>
<td>0.61</td>
<td>0.54</td>
<td>0.05</td>
<td>2.25</td>
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<tr>
<td>Largemouth bass</td>
<td>2,425</td>
<td>0.43</td>
<td>0.34</td>
<td>0.00</td>
<td>4.47</td>
</tr>
<tr>
<td>Walleye</td>
<td>1,520</td>
<td>0.40</td>
<td>0.34</td>
<td>0.02</td>
<td>3.30</td>
</tr>
<tr>
<td>Warmouth sunfish</td>
<td>147</td>
<td>0.39</td>
<td>0.34</td>
<td>0.02</td>
<td>1.36</td>
</tr>
<tr>
<td>Flathead catfish</td>
<td>158</td>
<td>0.37</td>
<td>0.34</td>
<td>0.02</td>
<td>2.31</td>
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<tr>
<td>Spotted bass</td>
<td>163</td>
<td>0.36</td>
<td>0.28</td>
<td>0.02</td>
<td>1.72</td>
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<tr>
<td>Northern pike</td>
<td>1,322</td>
<td>0.35</td>
<td>0.30</td>
<td>0.01</td>
<td>1.78</td>
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<tr>
<td>Lake trout</td>
<td>160</td>
<td>0.30</td>
<td>0.25</td>
<td>0.05</td>
<td>1.70</td>
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<td>Sauger</td>
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<td>0.28</td>
<td>0.18</td>
<td>0.03</td>
<td>1.40</td>
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<td>Smallmouth bass</td>
<td>738</td>
<td>0.27</td>
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<td>2.50</td>
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<td>Yellow bullhead</td>
<td>185</td>
<td>0.27</td>
<td>0.18</td>
<td>0.00</td>
<td>1.38</td>
</tr>
<tr>
<td>Striped bass</td>
<td>146</td>
<td>0.27</td>
<td>0.25</td>
<td>0.01</td>
<td>1.05</td>
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<td>Redear sunfish</td>
<td>215</td>
<td>0.26</td>
<td>0.21</td>
<td>0.01</td>
<td>1.58</td>
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<td>Yellow perch</td>
<td>604</td>
<td>0.22</td>
<td>0.17</td>
<td>0.01</td>
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<td>White perch</td>
<td>133</td>
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<td>0.15</td>
<td>0.01</td>
<td>1.05</td>
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<td>Freshwater drum</td>
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<td>0.16</td>
<td>0.01</td>
<td>1.91</td>
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<td>White bass</td>
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<td>0.21</td>
<td>0.14</td>
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<td>1.30</td>
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<td>White crappie</td>
<td>352</td>
<td>0.19</td>
<td>0.11</td>
<td>0.01</td>
<td>1.70</td>
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<td>Black crappie</td>
<td>652</td>
<td>0.19</td>
<td>0.14</td>
<td>0.00</td>
<td>1.50</td>
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<td>Rock bass</td>
<td>376</td>
<td>0.19</td>
<td>0.17</td>
<td>0.01</td>
<td>0.69</td>
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<td>Channel catfish</td>
<td>1,213</td>
<td>0.18</td>
<td>0.12</td>
<td>0.00</td>
<td>7.00</td>
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<td>Rainbow smelt</td>
<td>116</td>
<td>0.18</td>
<td>0.14</td>
<td>0.02</td>
<td>0.67</td>
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<td>Brown trout</td>
<td>131</td>
<td>0.16</td>
<td>0.12</td>
<td>0.01</td>
<td>1.25</td>
</tr>
<tr>
<td>Bluegill sunfish</td>
<td>1,062</td>
<td>0.15</td>
<td>0.10</td>
<td>0.01</td>
<td>4.49</td>
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<tr>
<td>Carp</td>
<td>426</td>
<td>0.14</td>
<td>0.10</td>
<td>0.01</td>
<td>1.84</td>
</tr>
<tr>
<td>Common carp</td>
<td>737</td>
<td>0.14</td>
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<td>0.00</td>
<td>1.80</td>
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<tr>
<td>Pumpkinseed sunfish</td>
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<td>0.13</td>
<td>0.09</td>
<td>0.01</td>
<td>1.02</td>
</tr>
<tr>
<td>Brown bullhead</td>
<td>214</td>
<td>0.13</td>
<td>0.08</td>
<td>0.01</td>
<td>2.46</td>
</tr>
<tr>
<td>White sucker</td>
<td>714</td>
<td>0.11</td>
<td>0.09</td>
<td>0.01</td>
<td>0.68</td>
</tr>
<tr>
<td>Rainbow trout</td>
<td>119</td>
<td>0.11</td>
<td>0.10</td>
<td>0.01</td>
<td>0.51</td>
</tr>
<tr>
<td>Black bullhead</td>
<td>130</td>
<td>0.10</td>
<td>0.07</td>
<td>0.01</td>
<td>0.68</td>
</tr>
<tr>
<td>Gizzard shad</td>
<td>151</td>
<td>0.09</td>
<td>0.10</td>
<td>0.01</td>
<td>0.40</td>
</tr>
<tr>
<td>English sole</td>
<td>241</td>
<td>0.06</td>
<td>0.06</td>
<td>0.02</td>
<td>0.13</td>
</tr>
</tbody>
</table>

Concentration statistics based on sampling station averages.
Shading indicates safe consumption rate associated with mean conc.:
1 meal/mo. 2 meal/mo. 3 meal/mo. 4 meal/mo. 8 meal/mo. 12 meal/mo.

References

Table 4.3. Monthly Fish Consumption Limits for Noncarcinogenic Health Endpoint - Methylmercury

<table>
<thead>
<tr>
<th>Risk Based Consumption Limit&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Noncancer Health Endpoints&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish Meals/Month</td>
<td>Fish Tissue Concentrations (ppm, wet weight)</td>
</tr>
<tr>
<td>unrestricted (&gt;16)</td>
<td>0 - 0.029</td>
</tr>
<tr>
<td>16</td>
<td>&gt;0.029 - 0.059</td>
</tr>
<tr>
<td>12</td>
<td>&gt;0.059 - 0.078</td>
</tr>
<tr>
<td>8</td>
<td>&gt;0.078 - 0.12</td>
</tr>
<tr>
<td>4</td>
<td>&gt;0.12 - 0.23</td>
</tr>
<tr>
<td>3</td>
<td>&gt;0.23 - 0.31</td>
</tr>
<tr>
<td>2</td>
<td>&gt;0.31 - 0.47</td>
</tr>
<tr>
<td>1</td>
<td>&gt;0.47 - 0.94</td>
</tr>
<tr>
<td>0.5</td>
<td>&gt;0.94 - 1.9</td>
</tr>
<tr>
<td>none (&lt;0.5)</td>
<td>&gt;1.9</td>
</tr>
</tbody>
</table>

<sup>a</sup> The assumed meal size is 8 oz (0.227 kg). The ranges of chemical concentrations presented are conservative, e.g., the 12 meal-per-month levels represent the concentrations associated with 12 to 15.0 meals.

<sup>b</sup> Chronic, systemic effects.

Notes:
1. Consumption limits are based on an adult body weight of 70 kg and an interim RfD of 1 x 10<sup>-4</sup> mg/kg-d.
2. None = No consumption recommended.
3. In cases where >10 meals per month are consumed, refer to Equations 3-1 and 3-2, Section 3.2.1.2, for methods to determine safe consumption limits.
4. The detection limit for methylmercury is 1 x 10<sup>-3</sup> mg/kg.
5. Instructions for modifying the variables in this table are found in Section 3.3.
6. Monthly limits are based on the total dose allowable over a 1-month period (based on the RfD). When the monthly limit is consumed in less than 1 month (e.g., in a few large meals), the daily dose may exceed the RfD (see Section 2.3).
Mercury

Health Effects

People in the U.S. are mainly exposed to methylmercury, an organic compound, when they eat fish and shellfish that contain methylmercury. Whether an exposure to the various forms of mercury will harm a person’s health depends on a number of factors (below). Almost all people have at least trace amounts of methylmercury in their tissues, reflecting methylmercury’s widespread presence in the environment and people’s exposure through the consumption of fish and shellfish. People may be exposed to mercury in any of its forms under different circumstances. The factors that determine how severe the health effects are from mercury exposure include these:

- the chemical form of mercury;
- the dose;
- the age of the person exposed (the fetus is the most susceptible);
- the duration of exposure;
- the route of exposure -- inhalation, ingestion, dermal contact, etc.; and
- the health of the person exposed.

Mercury exists in three chemical forms. They each have specific effects on human health.

- Methylmercury
- Elemental mercury
- Other mercury compounds (inorganic and organic)

Methylmercury effects

For fetuses, infants, and children, the primary health effect of methylmercury is impaired neurological development. Methylmercury exposure in the womb, which can result from a mother's consumption of fish and shellfish that contain methylmercury, can adversely affect a baby's growing brain and nervous system. Impacts on cognitive thinking, memory, attention, language, and fine motor and visual spatial skills have been seen in children exposed to methylmercury in the womb. Recent human biological monitoring by the Centers for Disease Control and Prevention in 1999 and 2000 (PDF) (3 pp., 42 KB,
About PDF) shows that most people have blood mercury levels below a level associated with possible health effects. More recent data from the CDC support this general finding.

Outbreaks of methylmercury poisonings have made it clear that adults, children, and developing fetuses are at risk from ingestion exposure to methylmercury. During these poisoning outbreaks some mothers with no symptoms of nervous system damage gave birth to infants with severe disabilities, it became clear that the developing nervous system of the fetus may be more vulnerable to methylmercury than is the adult nervous system.

For more information on fish consumption advisories across the country, visit EPA’s fish consumption web pages.

In addition to the subtle impairments noted above, symptoms of methylmercury poisoning may include; impairment of the peripheral vision; disturbances in sensations ("pins and needles" feelings, usually in the hands, feet, and around the mouth); lack of coordination of movements; impairment of speech, hearing, walking; and muscle weakness. People concerned about their exposure to methylmercury should consult their physician.

**Mercury and Cancer.** No human data indicate that exposure to any form of mercury causes cancer, but the human data currently available are very limited. Mercuric chloride has caused increases in several types of tumors in rats and mice, and methylmercury has caused kidney tumors in male mice. Scientists only observed these health effects at extremely high doses, above levels that produced other effects. When EPA revised its Cancer Guidelines in 2005, the Agency concluded that neither inorganic mercury nor methylmercury from environmental exposures are likely to cause cancer in humans. More technical information is available in volume V of the 1997 Mercury Study Report to Congress (PDF) (349 pp., 1.2 MB, about PDF) (see especially pages 47, 80, 107, and 161 of the file).

**Additional Information:**

Additional information on the health effects of methylmercury is available from the IRIS database at [http://www.epa.gov/iris/subst/0073.htm](http://www.epa.gov/iris/subst/0073.htm) and EPA’s Methylmercury Water Quality Criterion Web site at [http://www.epa.gov/waterscience/criteria/methylmercury/index.html](http://www.epa.gov/waterscience/criteria/methylmercury/index.html). You can also visit the Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profile for mercury.
 Mercury Levels in Commercial Fish and Shellfish

Return to Advisory on Mercury in Seafood

See also Mercury Concentrations in Fish: FDA Monitoring Program

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<tr>
<td></td>
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<td>STDEV</td>
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<td>WEAKFISH (SEA TROUT)</td>
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### Table 3. Mercury Levels of Other Fish and Shellfish†

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Mercury was measured as Total Mercury except for species (*) when only Methylmercury was analyzed.

ND - mercury concentration below detection level (Level of Detection (LOD)=0.01ppm)
N/A - data not available

†The following species have been removed from the tables:
- Bass (freshwater) – not commercial
- Pickerel – not commercial

‡ Standard deviation data generated for new data 2004 or later only.

1Includes: Blue, King, Snow
2Includes: Flounder, Plaice, Sole
3Includes: Sea bass/ Striped Bass/ Rockfish

**NOTE:** On February 8, 2006, technical changes were made to the data that was posted on January 19, 2006. The changes corrected data or more properly characterized the species of fish or shellfish sampled.
Blood Mercury Levels in Young Children and Childbearing-Aged Women ---

United States, 1999--2002

Exposure to high levels of mercury (Hg) can cause neurologic and kidney disorders (1--3). Because methylated Hg (methyl-Hg) in the aquatic environment accumulates in animal tissues up the food chain, persons in the United States can be exposed by eating freshwater fish, seafood, and shellfish. Exposure of childbearing-aged women is of particular concern because of the potential adverse neurologic effects of Hg in fetuses. To determine levels of total blood Hg in childbearing-aged women and in children aged 1--5 years in the United States, CDC's National Health and Nutrition Examination Survey (NHANES) began measuring blood Hg levels in these populations in 1999. This report summarizes NHANES results for 1999--2002 and updates previously published information (4,5). The findings confirmed that blood Hg levels in young children and women of childbearing age usually are below levels of concern. However, approximately 6% of childbearing-aged women had levels at or above a reference dose, an estimated level assumed to be without appreciable harm (>5.8 µg/L). Women who are pregnant or who intend to become pregnant should follow federal and state advisories on consumption of fish.

NHANES is a continuous survey of the health and nutritional status of the civilian, noninstitutionalized U.S. population; data are released and reported in 2-year cycles (6). Each participant undergoes a household interview and a physical examination. During the physical examination, blood is collected by venipuncture from all persons aged ≥1 year. For this analysis, whole-blood specimens were analyzed for total and inorganic Hg for children aged 1--5 years and women aged 16--49 years by automated, cold-vapor atomic absorption spectrophotometry in CDC's inorganic toxicology laboratory. The analytic method detection limit was 0.14 µg/L (ppb) for total Hg and 0.4 µg/L (ppb) for inorganic Hg (7). Blood Hg levels less than the limit of detection were assigned a value equal to the detection limit divided by the square root of 2 for the calculation of geometric mean (GM) values.

During 1999--2002, the GMs of total blood Hg concentrations for all childbearing-aged women and for children aged 1--5 years were 0.92 µg/L and 0.33 µg/L, respectively; the 95th percentiles of blood Hg for women and children were 6.04 µg/L and 2.21 µg/L, respectively (Table 1). The percentage of all women aged 16--49 years with Hg levels ≥5.8 µg/L (the Environmental Protection Agency's [EPA] Reference Dose [RfD]) was 5.66%.
Among children aged 1--5 years, the estimated percentage who had blood Hg levels \( \geq 5.8 \mu g/L \) during 1999--2002 could not be reported because the observed percentage was too low for the given sample size to calculate a statistically reliable national population estimate. Almost all inorganic blood Hg levels were undetectable, indicating that total blood Hg greater than or equal to the EPA RfD mostly reflected exposure to organic Hg (especially methyl-Hg).

**Reported by:** RL Jones, PhD, T Sinks, PhD, SE Schober, PhD, M Pickett, MPH, National Center for Environmental Health; National Center for Health Statistics, CDC.

**Editorial Note:**

This report updates NHANES 1999--2000 estimates of blood Hg levels (5), the first nationally representative estimates of U.S. women's and children's exposures to Hg based on biologic measures. The findings indicate that blood Hg levels in young children and childbearing-aged women usually are below levels of concern.

Among childbearing-aged women, for the 4-year period 1999--2002, estimates of the GM of blood Hg and the proportion with levels \( \geq 5.8 \mu g/L \) were lower than estimates for the 2-year period 1999--2000, reflecting apparent declines in these values for the 2-year period 2001--2002. However, when these differences were evaluated by comparing estimates for the two 2-year periods, the declines were not statistically significant: the GM of blood Hg for 2001--2002 was 0.83 \( \mu g/L \) (CI = 0.73--0.93), compared with 1.02 \( \mu g/L \) (CI = 0.80--1.24) for 1999--2000, and the percentage of women with blood Hg levels \( \geq 5.8 \mu g/L \) was 3.9% in 2001--2002 (CI = 2.40--6.43), compared with 7.8% in 1999--2000 (CI = 4.70--12.83). At least 2 more years of data are needed to best determine whether Hg exposure has declined among women of childbearing age in the United States.

Although NHANES data are released and often analyzed as 2-year periods, the estimates of blood Hg levels for 1999--2002 are the most reliable estimates of current exposure. The 4-year period provides greater geographic coverage, and estimates and sample errors are more stable, thus reducing variability caused by differing exposures to Hg across survey site locations. Accordingly, the National Center for Health Statistics advises users of these data that the most reliable estimates of current exposure are obtained when the 1999--2002 data are analyzed together (6).

The EPA RfD is based on measures of Hg in cord blood and is a level assumed to be without appreciable harm. The RfD was determined by applying an uncertainty factor of 10 to a dose (58 \( \mu g/L \)) that was the lower 95% confidence limit of a dose associated with an increased proportion of abnormal scores on the Boston Naming Test for children exposed in utero (2). All women and children in the 1999--2002 NHANES survey period had blood Hg levels below 58 \( \mu g/L \). The harm to a fetus from levels of exposure as measured by cord blood levels between 5.8 \( \mu g/L \) and 58 \( \mu g/L \) is uncertain.

The findings in this report are subject to at least two limitations. First, NHANES does not include an adequate sampling of women (e.g., sport fishers) who might eat large amounts of fish to characterize the distribution of total blood Hg in this group. Second, the ratio of Hg in cord to maternal blood (i.e., equivalent to NHANES measures) is uncertain (2,8). Therefore, NHANES values might not be directly comparable to the EPA RfD, which is based on cord blood Hg levels.

Fish are an important part of a diet, high in protein and nutrients and low in saturated fatty acids and cholesterol. The short-term strategy to reduce Hg exposure is to eat fish with low Hg levels and avoid or reduce consumption of fish with high Hg levels. Because exposure to methyl-Hg can harm fetuses, the Food and Drug Administration (FDA) advises that women who are or might become pregnant not eat shark, swordfish, king
mackerel, and tile fish (9). In addition, EPA and the Agency for Toxic Substances and Disease Registry have established daily consumption levels of Hg considered to be without harm (1). State-based fish advisories and bans identify fish species contaminated by Hg and their locations and provide safety advice (10). The NHANES program continues to collect Hg measurements in human tissue to monitor the effectiveness of efforts to reduce Hg exposure in the U.S. population.

References


Table 1
### Table 1

#### Geometric Means (GMs) and Selected Percentiles of Total Blood Mercury (Hg) Concentrations (µg/L) for Women Aged 16–49 Years and Children Aged 1–5 Years, by Selected Variables — National Health and Nutrition Examination Survey, United States, 1999–2002

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<th>No.</th>
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<th>3rd (95% CI)</th>
<th>10th (95% CI)</th>
<th>25th (95% CI)</th>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity</td>
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<tr>
<td>Mexican American</td>
<td>1,106</td>
<td>0.74 (0.64–0.84)</td>
<td>0.10 (0.08–0.13)</td>
<td>0.11 (0.12–0.23)</td>
<td>0.34 (0.24–0.45)</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>1,377</td>
<td>0.67 (0.70–0.99)</td>
<td>0.09 (0.09–0.10)</td>
<td>0.15 (0.13–0.19)</td>
<td>0.37 (0.34–0.45)</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>794</td>
<td>1.18 (1.00–1.36)</td>
<td>0.17 (0.12–0.25)</td>
<td>0.30 (0.24–0.38)</td>
<td>0.60 (0.55–0.73)</td>
</tr>
<tr>
<td><strong>Age group (yrs)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16–29</td>
<td>2,004</td>
<td>0.68 (0.60–0.76)</td>
<td>0.08 (0.07–0.09)</td>
<td>0.11 (0.09–0.14)</td>
<td>0.20 (0.25–0.37)</td>
</tr>
<tr>
<td>30–49</td>
<td>1,633</td>
<td>1.10 (0.97–1.24)</td>
<td>0.13 (0.10–0.16)</td>
<td>0.24 (0.20–0.29)</td>
<td>0.52 (0.45–0.60)</td>
</tr>
<tr>
<td><strong>Pregnancy status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>629</td>
<td>0.75 (0.60–0.90)</td>
<td>0.08 (0.07–0.10)</td>
<td>0.10 (0.08–0.20)</td>
<td>0.32 (0.24–0.44)</td>
</tr>
<tr>
<td>Not pregnant</td>
<td>2,978</td>
<td>0.94 (0.84–1.04)</td>
<td>0.10 (0.09–0.11)</td>
<td>0.18 (0.15–0.21)</td>
<td>0.41 (0.36–0.47)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3,607</td>
<td>0.92 (0.82–1.02)</td>
<td>0.09 (0.09–0.11)</td>
<td>0.17 (0.15–0.20)</td>
<td>0.40 (0.36–0.47)</td>
</tr>
<tr>
<td><strong>Children</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mexican American</td>
<td>526</td>
<td>0.35 (0.30–0.40)</td>
<td>...</td>
<td>0.08 (...–0.09)</td>
<td>0.13 (0.10–0.16)</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>447</td>
<td>0.29 (0.24–0.33)</td>
<td>...</td>
<td>0.07 (...–0.08)</td>
<td>0.09 (0.09–0.10)</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>424</td>
<td>0.50 (0.44–0.57)</td>
<td>0.00 (...–0.10)</td>
<td>0.10 (0.09–0.13)</td>
<td>0.22 (0.16–0.23)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,577</td>
<td>0.33 (0.30–0.37)</td>
<td>...</td>
<td>0.07 (...–0.08)</td>
<td>0.10 (0.09–0.12)</td>
</tr>
</tbody>
</table>

*Confidence interval.

*Below the limits of detection.

---

**Table 1 (Continued)** Geometric means (GMs) and selected percentiles of total blood mercury (Hg) concentrations (µg/L) for women aged 16–49 years and children aged 1–5 years, by selected variables — National Health and Nutrition Examination Survey, United States, 1999–2002

<table>
<thead>
<tr>
<th>Variable</th>
<th>50th (95% CI)</th>
<th>75th (95% CI)</th>
<th>90th (95% CI)</th>
<th>95th (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Women</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mexican American</td>
<td>0.73 (0.67–0.83)</td>
<td>1.27 (1.16–1.48)</td>
<td>2.38 (2.05–2.95)</td>
<td>3.60 (3.03–4.48)</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>0.81 (0.76–0.92)</td>
<td>1.09 (1.01–1.21)</td>
<td>3.13 (2.84–3.44)</td>
<td>6.17 (4.64–9.30)</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>1.15 (1.00–1.41)</td>
<td>2.12 (1.80–2.73)</td>
<td>3.98 (3.24–5.03)</td>
<td>5.54 (4.27–11.05)</td>
</tr>
<tr>
<td><strong>Age group (yrs)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16–29</td>
<td>0.64 (0.55–0.77)</td>
<td>1.34 (1.24–1.54)</td>
<td>2.58 (2.28–3.13)</td>
<td>3.87 (3.32–7.80)</td>
</tr>
<tr>
<td>30–49</td>
<td>1.02 (0.91–1.19)</td>
<td>2.10 (1.79–2.99)</td>
<td>4.56 (4.34–7.57)</td>
<td>6.97 (5.73–11.62)</td>
</tr>
<tr>
<td><strong>Pregnancy status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>0.73 (0.63–0.97)</td>
<td>1.50 (1.38–1.90)</td>
<td>3.11 (2.14–4.79)</td>
<td>4.86 (3.00–8.02)</td>
</tr>
<tr>
<td>Not pregnant</td>
<td>0.88 (0.80–1.00)</td>
<td>1.93 (1.85–2.11)</td>
<td>3.93 (3.26–4.93)</td>
<td>6.11 (5.12–10.90)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>0.86 (0.80–0.98)</td>
<td>1.81 (1.62–2.16)</td>
<td>3.89 (3.20–4.88)</td>
<td>6.04 (5.08–10.74)</td>
</tr>
<tr>
<td><strong>Children</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mexican American</td>
<td>0.28 (0.24–0.33)</td>
<td>0.63 (0.56–0.81)</td>
<td>1.36 (1.05–1.57)</td>
<td>1.85 (1.60–2.26)</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>0.20 (0.17–0.25)</td>
<td>0.49 (0.33–0.63)</td>
<td>1.15 (0.80–1.49)</td>
<td>1.78 (1.10–2.69)</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>0.47 (0.40–0.58)</td>
<td>0.88 (0.78–1.02)</td>
<td>1.54 (1.31–2.04)</td>
<td>2.37 (1.75–3.64)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>0.26 (0.23–0.29)</td>
<td>0.61 (0.56–0.76)</td>
<td>1.29 (1.08–1.69)</td>
<td>2.21 (1.89–3.66)</td>
</tr>
</tbody>
</table>

**Return to top.**

**Table 2**
<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>No.</th>
<th>% with Hg levels ≥5.8 μg/L (95% CI')</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mexican American</td>
<td>1,106</td>
<td>1.70</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>1,377</td>
<td>5.77</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>794</td>
<td>4.82</td>
</tr>
<tr>
<td>Total</td>
<td>3,637</td>
<td>5.66</td>
</tr>
</tbody>
</table>

* Confidence interval.
The US EPA established the US Reference Dose for methylmercury in 1999, based on the best evidence then available, using data from a long-term epidemiological study in the Faeroe Islands carried out by researchers at Harvard and elsewhere. Research since then has sharpened scientific understanding of the benefits of maternal fish consumption for prenatal cognitive development, of the harm done by methylmercury to that cognitive development, and of improved research designs for separating the two effects. Several recent studies suggest more strongly than ever that public health concern over methylmercury exposure is completely justified, and that the effort to guide women to pick low-mercury fish must be expanded and improved.

In 2007, the Faeroe Islands research team reanalyzed their data to adjust for maternal fish intake, and determined that after adjusting for nutritional effects of fish consumption, cognitive deficits attributed to methylmercury were actually about twice as large as had originally been reported. Similarly, a research team doing another long-term study, in the Seychelles Islands, which had previously reported no significant adverse effects of methylmercury on cognitive development, did a new analysis focused on measuring benefits of maternal fish consumption. In 2008, for the first time, the Seychelles researchers reported observing adverse mercury effects, which they concluded were probably masked by beneficial effects in their earlier analyses.

Two US studies have shown that developmental benefits of fish intake and adverse effects of methylmercury occur in babies whose mothers consume average American amounts of fish. A study in Boston has assessed verbal development at the ages of six months and three years; high fish consumption during pregnancy improved scores, while higher mercury exposure (from the higher-mercury fish those women ate) reduced scores. The effects were of roughly comparable magnitude in the affected groups, about 5 points on a 100-point scale. A New York City study tested children’s cognitive development at the ages of 12, 24, 36 and 48 months, using standard tests, and found similar results: High fish consumption enhanced performance, while elevated mercury exposure decreased performance on the same tests.

The populations in the Faeroes and Seychelles have high-fish diets, and the Faroese in fact get most of their methylmercury exposure from pilot whale meat. But the women in the Boston and New York studies had ordinary levels of fish consumption and mercury exposure. Only 7 percent of the Boston women ate two or more fish meals per week; about 5 percent of US women eat fish that often, according to CDC. The Boston research team classified a child as having high prenatal mercury exposure if his mother’s hair mercury value was above the 90th percentile, which was 1.2 ppm in the study population. The 90th percentile hair NHANES mercury level is 1.1 ppm. Oken et al. did not measure blood mercury, but NHANES regional data show that the 90th percentile blood mercury level for women in New England is 5.2 µg/l. The New York study measured blood mercury, but not fish consumption. The geometric mean blood mercury level in the
Further research is needed to better document the complex relationships between fish intake during pregnancy and cognitive development. But the available evidence strongly suggests that methylmercury exposure can have adverse effects even at doses associated with just one or two fish meals per week. There is no evidence of a threshold for this toxic effect. Since women are advised to consume fish while pregnant, for the nutritional benefits, it seems vitally important that advice also be provided that helps women identify and buy low-mercury fish, so they (and their babies) can simultaneously enjoy the nutritional benefits and minimize their exposure to methylmercury.


# FISH ADVISORY
## Women Under Age 45 and Children

Seafood contains important nutrients, including Omega-3 fatty acids, but also contains mercury, which can be harmful to women and children.

### DO NOT EAT
- Swordfish
- Shark
- Tilefish
- King Mackerel

Limit albacore tuna to one, 6-ounce serving a week, and eat no other fish that week.

Light canned tuna, however, may be eaten twice a week.

<table>
<thead>
<tr>
<th>High</th>
<th>Moderate</th>
<th>Lower</th>
</tr>
</thead>
<tbody>
<tr>
<td>(avoid)</td>
<td>(limit to one, 6-oz serving/week)*</td>
<td>(12-ounces or 2 servings per week)</td>
</tr>
</tbody>
</table>

- Fresh/Frozen Tuna and Sushi Tuna
- Spanish Mackerel
- Chilean Sea Bass
- Grouper
- Marlin
- Orange Roughy
- Snapper
- Skate
- Freshwater Perch
- Monkfish
- Halibut
- Sablefish
- Sea Trout
- Sea Bass
- Bluefish
- American Lobster
- Shrimp
- Sardines
- Tilapia
- Clams, Oysters, Scallops, Mussels
- Salmon
- Crayfish
- Freshwater Trout
- Ocean Perch/Mullet
- Pollock
- Atl. Mackerel
- Anchovy/Herring
- Sole, Flounder
- Crab
- Pike
- Butterfish
- Catfish
- Squid
- Atlantic Croaker
- Whitefish
- Pac. Mackerel/Chub
- Smelt
- Cod
- Canned Light Tuna
- Spiny Lobster

(1) * Women under age 45 and children who eat fish from the yellow category should eat no other fish that week.
(2) Fish are listed from lowest to highest mercury levels.
(3) For more information see www.epa.gov/mercury or www.fda.gov.
Title:

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

Issue you would like the Conference to consider:

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

Public Health Significance:

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

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

that a letter be sent to FDA recommending the addition of the following language to Section 3-603.11 of the Model Food Code, *Consumer Advisory*.

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

(D) Every FOOD ESTABLISHMENT that offers raw oysters harvested from the Gulf of Mexico (any oyster harvested from the Gulf waters bordering the states of Alabama, Florida, Louisiana, Mississippi, or Texas) shall provide a written warning to any person who orders raw oysters, stating:

**WARNING**

THIS FACILITY OFFERS RAW OYSTERS FROM THE GULF OF MEXICO. EATING THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS WHO HAVE LIVER DISEASE, CANCER, DIABETES, OR OTHER CHRONIC ILLNESSES THAT WEAKEN THE IMMUNE SYSTEM. If you eat raw oysters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician.

(E) Warnings under subsection (D) are not required whenever the FOOD ESTABLISHMENT has received a copy of a current verification letter from the dealer and tags or labels are as required by Section 3-202.18 of this Code demonstrating that the oysters have been subjected to an oyster treatment process sufficient to reduce *Vibrio vulnificus* to an undetectable level, as defined in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 2004 Edition.

**Submitter Information:**

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E-mail: sklein@cspinet.org
Attachments:

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

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*
The Demand for Eastern Oysters, *Crassostrea virginica*, from the Gulf of Mexico in the Presence of *Vibrio vulnificus*

WALTER R. KEITHLY, Jr., and HAMADY DIOP

Introduction

The bacteria *Vibrio vulnificus* is a naturally occurring organism in estuarine waters and is found in an unknown proportion of eastern oysters, *Crassostrea virginica*, harvested from the Gulf of Mexico (hereafter, the Gulf). The presence of *Vibrio vulnificus* is highly correlated with water temperature, and virtually all Gulf-harvested oysters contain some concentration of it in the warmer summer months (McQuaid, 1997). As noted by Corcoran (1998) in the Nutrition Action Healthletter: “[e]very year, more than 50 people become ill and at least 10 die after eating uncooked Gulf Coast oysters that are contaminated with *Vibrio vulnificus* bacteria.” Most of these illnesses and deaths occur between May and October.

California, in response to this health concern, initiated a program on 1 March 1991 which required anyone selling Gulf oysters to notify potential consumers that the “consumption of raw oysters can cause illness and death among people with liver disease, chronic illnesses, or weakened immune systems” (Liddle, 1991). California’s mandatory warning received extensive coverage in newspapers (and the trade literature) both there and across the country and particularly in the Gulf region.1

In a further step to promote public safety, the U.S. Food and Drug Administration (FDA) in 1994 proposed banning consumption of raw oysters from the Gulf from April through October when *Vibrio vulnificus* was most prevalent. After “heavy pressure from the Gulf oyster industry and members of Congress from Louisiana and other Gulf states,” the FDA backed away from its initial proposal and instead opted for a “public awareness campaign” to notify and educate those people at risk (McQuaid, 1997).

The primary goal of this paper is to examine the extent to which the demand for Gulf oysters has been reduced as a result of the mandatory warning labels and associated negative publicity, while the “winter” dockside price has been reduced by about 30%.

1 Subsequently, other states—most notably Louisiana and Florida—have enacted mandatory warning label programs similar to that of California.

Industry Overview

The U.S. oyster industry operates on both the U.S. east and west coasts. The primary oyster species harvested on the east coast (i.e. Atlantic and Gulf), the eastern oyster, produced average annual landings of about 31 million pounds during 1981–97 with an associated $77 million dockside value (NMFS). Annual landings of Pacific oysters, *Crassostrea gigas*, the primary west coast species, averaged about 9 million pounds valued at $18 million (dockside) during 1981–97.

Gulf oyster production averaged 20 million pounds annually during 1981–97, or about 60% of the total eastern oyster production. Louisiana, the primary producer there, accounted for almost 60% of the Gulf output, while Texas accounted for an additional 20%. Chesapeake Bay, once the nation’s largest oyster source, has seen production fall sharply since the early 1980’s.
due to habitat degradation, overfishing, and disease (Rothschild et al., 1994). Then averaging close to 17 million pounds annually, the Chesapeake’s output fell more than 90% to about 1.5 million pounds annually during 1995–97 (NMFS²).

Prior to 1991, annual dockside Gulf and Chesapeake oyster prices tended to “mirror” one another, with annual price differentials rarely exceeding $0.40 per pound (NMFS²) and an average price differential equal to only $0.26 per pound (Fig. 1). Since 1991, however, the prices in those regions have become decidedly more distinct, with the average annual price differential exceeding $1.00 per pound. The large price differential since 1991 provides some preliminary evidence that the mandatory warning labels and media attention may have impacted demand and, hence, price of the Gulf product.

Theoretical Basis and Literature Review

Strand (1999) reviewed the literature pertaining to consumer behavior with respect to food-borne contamination events, concluding that the information related to an event, which is subjectively evaluated by consumers, is critical to perception formation. He further suggested that uncertainty contained in the information can also be critical in perception formation. Finally, Strand suggested that the credibility of the information depends on its source.

Perceptions, of course, can alter consumer choice. Strand (1999) further concluded that consumers react to negative news by reducing demand for the product and/or by taking defensive actions to lower the level of health risk. Furthermore, as a result of uncertainty (e.g., uncertainty of the marketing channels through which they obtain their consumables), consumers may reduce demand even though there is no scientifically supported risk to them from normal consumption. Finally, Strand (1999) suggested that changes in demand owing to reports of persistent toxic compounds (like DDT) appear to be a reaction to cumulative news reports, and while the effects associated with news will decay over time, the decay is slow.

Strand’s synthesis of the literature provides several insights that are relevant to this study. First, one might hypothesize that consumers have reacted to the negative publicity concerning the consumption of raw Gulf oysters by reducing demand for the raw product and/or taking defensive actions to lower the level of health risk. Such actions may include increasing demand for the processed product vis-a-vis the raw product or by reducing consumption only in the...
“summer” months when health risks (in terms of mortality) from the consumption of raw oysters are greatest.

Second, uncertainty is likely to be a major factor in determining the change in demand for Gulf oysters. The uncertainty is inherent in both the information presented to the consumer as well as uncertainty presented to the consumer as to whether he/she possesses the health characteristics (i.e. liver disease, chronic illness, or a weakened immune system) that would make the consumption of raw oysters “risky.”

Third, one could argue that the change in demand for Gulf oysters is analogous to Strand’s (1999) discussion regarding changes in demand for food products resulting from reports of persistent toxic compounds. Specifically, while Vibrio vulnificus is not a toxic compound, like some such compounds, it is persistent in nature and continues to receive adverse publicity several years after the initiation of warning labels.

**Model Specification**

For purposes of analysis, the demand for Gulf oysters is specified as:

\[
egin{align*}
PG_t &= \beta_0 + \beta_1 VUL_t + \\
&\quad \beta_2 SEAS_t + \beta_3 QG_t + \\
&\quad \beta_4 INC_t + \beta_5 (QG^*VUL)_t + \epsilon_t
\end{align*}
\]

where \(PG_t\) denotes the deflated Gulf oyster dockside price in quarter \(t\), expressed in dollars per pound of meats (1997 Consumer Price Index equals base); \(VUL_t\) is a binary variable used to “capture” the change in demand due to warning labels and associated media attention (equal to 0 before 1991 and 1 thereafter); \(SEAS_t\) is a binary variable associated with warning labels and media attention while the variable \(SEAS_t\) was used to “capture” seasonal variation in demand.

Since the incidence of Vibrio is temperature dependent and is higher in the warmer months of the year, it is further hypothesized that the impact of \(VUL_t\) may vary by season with the impact on demand being greater in the “summer” months. To account for the possible variation in impact by season, an interaction term between \(SEAS_t\) and \(VUL_t\) is included in equation 1.

It is anticipated that price in quarter \(t\) responds inversely to changes in Gulf harvest (\(QG_t\)) and positively to changes in income (\(INC_t\)). Furthermore, given the interaction between harvest and season (\(QG^*SEAS_t\)), the response in price to a change in the quantity harvested is permitted to vary by season.

Louisiana and Texas, as noted, generally account for the majority of Gulf oyster production. There appears to be a premium attached to the price of oysters harvested from these two states, perhaps due to a larger average size. Hence, one would expect that the average Gulf price is positively related to the share of production derived from these two states. The variable \(LATX_t\) is included in equation 1 to “capture” the price effect resulting from product heterogeneity across states.

The variable \(LPG_t\) is used to model inertia in the change in dockside price (\(PG_t\)) to changes in exogenous variables. The value of \(\beta_8\) is expected to fall between 0 and 1 with a value approaching 0 indicating instantaneous adjustment in price to changes in the value of exogenous variables, while a value approaching 1 suggests a high degree of inertia.

Finally, substitute products are often entered as exogenous variables in demand models of this nature. One would hypothesize that oysters produced in other regions of the country might constitute substitutes for the Gulf product. Chesapeake oysters, given the similarity in the type of oyster produced and the geographic relation, were considered a potential substitute product, a priori. Initial inclusion of Chesapeake production in the Gulf demand equation did not prove to be successful and, hence

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\(^3\) (continued) occurred in the away-from-home market, and much of the information appears to occur in trade journals. Hence, one would need to isolate the impact related to information in trade journals from that of the more common news media. Finally, most studies that have evaluated the impact of negative information on demand are based on products for which the duration was of only a limited period of time. With respect to the impact of Vibrio vulnificus on the demand for Gulf product, the publicity is of longer or continuing duration.

\(^4\) A reviewer suggested that, because of leasing activities in Louisiana and Texas, quantity harvested may not be exogenous to the system. To examine this issue, a vector autoregressive model between Gulf price (\(PG_t\)) and quantity (\(QG_t\)) was estimated as follows:

\[
\begin{align*}
QG_t &= \alpha_0 + \alpha_1 QG_{t-1} + \alpha_2 PG_t + \alpha_3 PG_{t-1} + \xi_t \\
PG_t &= \beta_0 + \beta_1 Pg_{t-1} + \beta_2 QG_t + \beta_3 QG_{t-1} + \eta_t
\end{align*}
\]

where \(QG_{t-1}\) represents the Gulf landings lagged one period and \(PG_{t-1}\) is the Gulf price lagged one period. The Gulf oyster price is said to be block exogenous with respect to Gulf landings if the elements in Gulf price are of no help in improving the forecast of Gulf landings based only on lagged values of \(PG\). The null hypothesis is “\(PG\) is not exogenous to \(QG\)” which is equivalent to \(\alpha_0 = \alpha_1 = 0\). The test statistic follows a chi square distribution with one degree of freedom. The associated chi square statistic of 0.01 (significance level is 3.84) at the 5% significance level implies that \(PG\) is not exogenous to \(QG\). In contrast, the test statistic of 12.56 (significance level is 3.84) implies that \(QG\) is exogenous to \(PG\). These results agree with the hypothesis that current Gulf landings contribute significantly to the improvement of the forecasted price based only on lagged prices. However, current and lagged prices do not statistically improve the forecasted landings based only on lagged landing values.
the variable was not included in the final version of the model discussed in the following sections.\footnote{For comparison purposes, the model that includes Chesapeake production as an explanatory variable is included in the table that provides empirical results (Table 2).}

## Data and Estimation Issues

### Data Issues

The Gulf dockside demand model developed in the previous section was estimated with quarterly data for the 1981–97 period. Where appropriate (i.e., prices and income), the data were deflated using the 1997 Consumer Price Index. Some summary statistics for the variables included in the model are presented in Table 1. The deflated Gulf oyster price averaged $2.63 per pound, with the post 1990 price ($2.13 per pound) being nearly 30\% less than the pre 1991 price ($2.98 per pound). The quantity harvested averaged 5.2 million pounds per quarter during the period of analysis, with the pre 1991 quarterly production (5.4 million pounds) averaging about 8\% more than the post 1990 quarterly production (4.9 million pounds).\footnote{Much of the difference in pre and post 1990 production can be attributed to abnormally low production in Louisiana in 1991 and 1992. Low production in those years reflects massive oyster mortalities from excessive rainfall and, hence, lower salinity.}

In general, little price variation was evident during the 1981–97 period when examined on a seasonal basis, even though production during the “winter” season, which averaged 6.1 million pounds per quarter, exceeded the production during the “summer” season, which averaged 4.28 million pounds per quarter, by about 40\%. Since 1991, “winter” season production has averaged 5.7 million pounds per quarter compared to 4.2 million pounds per quarter in the “summer” season.

### Estimation Issues

The lagged dockside price (\(LPG_t\)), as noted, was included in the analysis, based on the premise that the response in price to a change in an exogenous variable may not be completed in that quarter in which the change in the exogenous variable occurred (i.e., there exists some inertia in the change in price). Assuming a geometric lag structure, this inertia, can be expressed as:

\[
Y_t = \alpha + \beta (X_t + wX_{t-1} + w^2X_{t-2} + ...) + \epsilon_t
\]

where \(w\) is the lagged weight (\(0 < w < 1\)) which declines at a geometric rate over time. As specified, equation 2 is difficult to estimate due to the infinite series of the lagged regressors. As shown by Madalla (1977) and Pindyck and Rubinfeld (1991), equation 2 can be rewritten as:

\[
Y_t = \alpha(1-w) + wY_{t-1} + \beta X_t + (\epsilon_t - w \epsilon_{t-1})
\]

Expressed in this manner, the geometric lag model can be easily estimated, given the finite series of the lagged variable (i.e., \(Y_{t-1}\)).

The implications associated with equation 3 are twofold. First, all past values of the exogenous variable (\(X_t\)) are captured in the endogenous variable (\(Y_t\)) lagged one period with impact of a change in \(X_t\) on \(Y_t\), decaying at a geometric rate over time. Second, lagging the dependent variable results in the introduction of serial correlation of the error term, assuming \(\epsilon_t\) in equation 2 does not exhibit an autocorrelation pattern.

Several methods have been proposed for estimating the geometric lag structured model in the presence of serial correlation. The most popular technique, and the one that is used in the current analysis, is the instrumental variable approach whereby an estimate of the lagged dependent variable is generated by regressing its value against the lagged values of the exogenous variables in the model. Then, the model is estimated using a maximum likelihood procedure.

Given the structure of a geometric lag model, it is useful to identify the long-run impact associated with a permanent change in the level of an exogenous variable. Madalla (1977) shows that this impact is equal to \(\beta / (1-w)\). Hence, as the value for \(w\) increases (\(0 < w < 1\)), the greater will be the amount of time which expires before the full impact of a one-time change in an exogenous variable is recognized. This, in turn, implies that the difference between the immediate impact (\(\beta\)) and long-run impact (\(\beta / (1-w)\)) increases in relation to an increasing value of the lagged weight (\(w\)).

### Empirical Results

Table 2 summaries the regression results associated with the Gulf dockside demand model. The estimated parameters, in general, agreed with prior expectations and, with few exceptions, all estimated parameters were significant at the 90\% confidence level. Furthermore, the estimated model explained almost 90\% of the variation in the deflated Gulf dockside price (Table 2, Fig. 2).

Overall, increased information related to *Vibrio vulnificus* was found to significantly influence the demand (price) for Gulf oysters. Specifically,
the warning labels and associated media attention (VUL) resulted in an immediate reduction in the "summer" dockside price by $0.93 per pound compared to a reduction in the "winter" price of $0.72 per pound. These reductions, however, reflect only the initial impact. The fact that the estimate of $\beta_8$, equal to 0.553, falls between 0 and 1 implies that as one moves further away from the date that warning labels were initially mandated, the greater the absolute value of the magnitude of the policy variable.

In the long-run, the impact of warning labels was estimated to result in a decline in the "summer" dockside price equal to $2.07 per pound and a "winter" reduction in price equal to $1.60 per pound. The actual "summer" price in 1997 equaled $2.16 while the actual winter price equaled $2.22, suggesting that the "summer" price has been reduced nearly 50% as a result of the warning labels and negative publicity, while the "winter" price has been reduced by about 30%.

One could hypothesize that the impact of warning labels and the associated negative publicity {\begin{itemize} \item \text{63(1), 2001} \item \text{51} \end{itemize}}
With respect to the Gulf landings (QG), the results suggest that a 1,000,000 pound increase (decrease) in “summer” harvest results in an immediate $0.22 decrease (increase) in price. An equivalent change in the “winter” harvest, by comparison, results in an immediate inverse price response of only $0.11 per pound, or about half of that estimated for the “summer” season. In the long-run, a 1,000,000 pound increase (decrease) in “summer” harvest was found to result in a $0.48 decrease (increase) in the Gulf dockside price, while a 1,000,000 pound increase (decrease) in the “winter” harvest was estimated to result in a price decrease (increase) of $0.24 per pound.

With respect to seasonality, the results suggest that the demand for Gulf oysters in the “winter” season exceeds demand in the “summer” season, with the expected price differential equaling about $0.07 per pound ceteris paribus, prior to 1991.8 After 1991, in association with the warning labels and media attention, the difference in demand between the “winter” and “summer” seasons resulted in an expected price differential of $0.21 per pound.

Income, as indicated in Table 2, was found to significantly influence the Gulf oyster dockside demand. Overall, the results suggest that a $100 billion dollar increase in real disposable income would result in an immediate $0.04 increase in price and a price increase equal to $0.08 increase in the long run.

Discussion and Conclusion

A model was developed and analyzed to examine the impact of mandatory warning labels and the associated negative publicity on dockside price of Gulf oysters. Results suggest that the impact has been significant. Specifically, the results suggest that the “summer” price has been reduced by about 50% as a result of the warning labels and associated negative publicity, while the “winter” price has been reduced by about 30%.

The results developed in this paper can be used to assess the impacts of various policy measures. For example, the FDA, as noted in the introduction, proposed a restriction on sales of raw oysters for consumption from April to October when the Vibrio vulnificus bacteria is most prevalent in Gulf waters. From a welfare economics perspective, such a ban would lead to a net increase in the welfare of society if the benefits of taking action (i.e. prohibiting raw oyster consumption) exceed the costs. Benefits reflect, primarily, the reduction in premature deaths and illnesses. Costs, on the other hand, reflect the reduction in consumer and producer welfare (i.e. surplus) which would be incurred as a result of the ban.

As noted by Corcoran (1998), at least 10 people die annually from the consumption of raw Gulf oysters, while more than 50 become ill (an average of 17 individuals died annually during 1996–98). While assigning an economic value to a statistical life is problematic (Kuchler and Golan, 1999), recent empirical work, based on labor market analysis, suggests that the value of a statistical life, expressed in 1997 dollars, falls in the neighborhood of about $4–8 million (Viscusi, 1993, and Moore and Viscusi, 1988 provide details).9 This suggests that the benefits from the proposed ban, excluding the reduction in illnesses, would approximate $40–80 million annually.

An “upper bound” estimate of the loss in consumer welfare associated with such a ban can be generated under the assumption that production is equal to zero in those months that would be impacted by the proposed ban.10 Based upon 1997 quarterly data and estimates, an “upper bound” estimate of the loss in consumer surplus in 1997 from the proposed ban would have been about $6,500,000 based on the 1997 dockside value of $21,200,000 (April through October).

While cost information on the Gulf oyster harvesting sector is insufficient to accurately estimate the loss in producer welfare associated with the proposed ban, it is obviously just a small fraction of the $21,200,000 in revenues generated during the April through October 1997 period. This fraction and the $6,500,000 loss in consumer welfare is considerably less than the $40–80 million annual benefits that would be forthcoming as a result of the ban. Hence, one could conclude that the welfare of society would be enhanced if the eating of raw Gulf oysters were seasonally restricted.

The FDA, as previously indicated, chose not to institute a ban on the consumption of raw Gulf oysters in the “summer” season, opting instead for a “public awareness campaign” to notify and educate those consumers at risk. As noted by Henson and Caswell (1999: 591), policy interventions by governments reflect an “...outcome of a complex trade-off between alternative demands that reflect the interests of the different groups that might be affected. In the case of food policy this will include consumers, food manufacturers, food retailers, and farmers, both at home and abroad, as well as government itself and taxpayers.” Whether the alternative strategy (i.e. the awareness and education program), derived via this complex trade-off between alternative demands, proves to be as successful as a seasonal restriction would be has yet to be determined.

Acknowledgments

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Literature Cited


Vibrio vulnificus Infection: Diagnosis and Treatment

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Vibrio vulnificus infection is the leading cause of death related to seafood consumption in the United States. This virulent, gram-negative bacterium causes two distinct syndromes. The first is an overwhelming primary septicemia caused by consuming raw or undercooked seafood, particularly raw oysters. The second is a necrotizing wound infection acquired when an open wound is exposed to warm seawater with high concentrations of V. vulnificus. Most patients, including those with primary infection, develop sepsis and severe cellulitis with rapid development to ecchymoses and bullae. In severe cases, necrotizing fasciitis can develop. Case-fatality rates are greater than 50 percent for primary septicemia and about 15 percent for wound infections. Treatment of V. vulnificus infection includes antibiotics, aggressive wound therapy, and supportive care. Most patients who acquire the infection have at least one predisposing immunocompromising condition. Physician awareness of risk factors for V. vulnificus infection combined with prompt diagnosis and treatment can significantly improve patient outcomes. (Am Fam Physician 2007;76:539-44, 546. Copyright © 2007 American Academy of Family Physicians.)

Patient information:
A handout on Vibrio vulnificus infection, written by the authors of this article, is provided on page 546.

Vibrio vulnificus is a species of gram-negative, motile, curved bacterium that is part of the Vibrio genus and the Vibrionaceae family. Other members of this family include V. cholerae (rare in the United States) and V. parahaemolyticus, both of which cause acute gastrointestinal illness characterized by severe diarrhea. Unlike other members of this family, V. vulnificus infection is extremely invasive. Even with prompt diagnosis and aggressive therapy, the case-fatality rate is 30 to 40 percent.1-3

Epidemiology
V. vulnificus is common in warm seawater and thrives in water temperatures greater than 68°F (20°C). The organism is not associated with pollution or fecal waste. The taste, appearance, and odor of seafood are not affected by V. vulnificus contamination, and proper cooking methods readily kill the organism. Although it is found in all coastal waters of the United States, most V. vulnificus infections are attributed to consuming raw oysters harvested in the Gulf of Mexico during the summer.2 Because these oysters are shipped throughout the United States, infections are not limited to endemic areas.4 Approximately 25 percent of V. vulnificus infections are caused by direct exposure of an open wound to warm seawater containing the organism. Exposure typically occurs when the patient is participating in water activities such as boating, fishing, or swimming. Infections are occasionally attributed to contact with raw seafood or marine wildlife.1

V. vulnificus is one of the few foodborne illnesses with an increasing incidence. The Centers for Disease Control and Prevention estimates that the average annual incidence of all Vibrio infections increased by 41 percent between 1996 and 2005.3 In 2004, V. vulnificus was documented in 92 infections; 64 patients with the infection had septicemia, and 28 patients had wound infections.1 These data emphasize the need for physicians to familiarize themselves with the risk factors and clinical characteristics of V. vulnificus infection.

Risk Factors
Table 12 includes risk factors for developing V. vulnificus infection. After the organism enters the body, several factors determine if significant illness develops. Patients with immunocompromising conditions, especially alcoholic liver disease or hepatitis B or C, have a higher risk of infection.3
Table 1. Risk Factors for Vibrio vulnificus Infection

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Patients with primary septicemia and the risk factor (%)</th>
<th>Patients with a wound infection and the risk factor (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumption of raw oysters in the week before becoming ill</td>
<td>96</td>
<td>—</td>
</tr>
<tr>
<td>Wound exposure to warm seawater or raw seafood juice in the week before becoming ill</td>
<td>—</td>
<td>100</td>
</tr>
<tr>
<td>Any chronic disease</td>
<td>97</td>
<td>68</td>
</tr>
<tr>
<td>Liver disease</td>
<td>80</td>
<td>22</td>
</tr>
<tr>
<td>Alcoholism</td>
<td>65</td>
<td>32</td>
</tr>
<tr>
<td>Diabetes</td>
<td>35</td>
<td>20</td>
</tr>
<tr>
<td>Malignancy</td>
<td>17</td>
<td>10</td>
</tr>
<tr>
<td>Renal disease</td>
<td>7</td>
<td>7</td>
</tr>
</tbody>
</table>

NOTE: Data are from the Centers for Disease Control and Prevention Gulf Coast Surveillance System. Information from reference 2.

Iron overload, documented by high transferrin saturation, is common in patients with liver disease and other immunocompromising conditions who develop V. vulnificus infection. In human and animal studies, high levels of free iron have markedly increased the growth and lethality of V. vulnificus. Patients with chronic liver disease have a much higher risk of septicaemia and death; approximately 80 percent of deaths occur in patients with liver disease.

Several characteristics of the organism facilitate the development of clinical disease. V. vulnificus strains with capsular materials are associated with high bacterial virulence. In addition, V. vulnificus produces several extracellular enzymes, including metalloproteinase, lecithinase, lipase, caseinolytic protease, deoxyribonuclease, mucinase, and elastase. Metalloproteinase destroys basement membrane collagen in blood vessels and has fibrinolytic properties that cause hemorrhage and edematous skin changes.

Clinical Presentations

Patients with primary septicemia caused by V. vulnificus infection require hospitalization. Characteristic symptoms include fever, diarrhea, nausea, and vomiting. One half of patients have changes in mental status, and almost one third are in septic shock at hospital admission. Within 24 hours of symptom onset, more than one half of patients develop the characteristic skin lesions of severe cellulitis with ecchymoses and bullae. V. vulnificus infection should be considered in patients with sepsis and severe skin lesions, and patients should be asked about raw oyster consumption and seawater exposure.

Patients with primary wound infections caused by V. vulnificus develop painful cellulitis that progresses rapidly. Marked local tissue swelling with hemorrhagic bullae is characteristic (Figure 1). Systemic symptoms include fever and chills. Almost one half of patients develop bacteremia, more...
than 10 percent develop hypotension, and almost one third develop changes in mental status.12

Rarely, patients with V. vulnificus infection present with common gastroenteritis.12 V. vulnificus infection should be considered in immunocompromised patients who have recently been exposed to seawater or consumed raw seafood.

Other presentations have occurred less often: infection of mucosal sites and corneal ulcers after handling seafood,15 tubo-ovarian abscesses after sexual activity in seawater,16 and peritoneal infection after receiving dialysis from seawater-contaminated equipment.17 A high index of suspicion is required to diagnose V. vulnificus infection with these rare presentations.

Illustrative Case
An 80-year-old man presented to the emergency department with excruciating pain in his right forearm. He reported spending the previous night fishing in Corpus Christi Bay (Tex.), where he accidentally pierced his right index finger with a live shrimp. Hemorrhagic bullae were present, extending from the hand to the upper arm. He also presented with confusion. His vital signs were a temperature of 100°F (38°C), blood pressure of 88/44 mm Hg, pulse rate of 113 beats per minute, and respiratory rate of 20 breaths per minute. The patient had a history of hypertension, chronic renal failure that did not require dialysis, congestive heart failure, and cirrhosis secondary to alcohol abuse. Laboratory studies revealed a white blood cell count of 6,600 per mm<sup>3</sup> (6.6 × 10<sup>9</sup> per L) with 26 percent bands, hemoglobin level of 13.1 g per dL (131 g per L), platelet count of 33,000 per mm<sup>3</sup> (33 × 10<sup>9</sup> per L), blood urea nitrogen level of 63 mg per dL (22.5 mmol per L), and creatinine level of 4.4 mg per dL (390 μmol per L). A Gram stain of the exudate showed a curved, gram-negative rod. Blood and wound cultures were obtained.

The patient was admitted to the intensive care unit and was treated with oxygen, fluid resuscitation, and intravenous ceftriaxone (Rocephin) and doxycycline (Doxycycline 100). Within six hours of admission, he required norepinephrine for blood pressure support. By the third day of hospitalization, dialysis was required because of worsening renal failure. On the fourth day of hospitalization, the patient markedly improved, answered questions appropriately, and no longer required pressor support. Wound culture confirmed the clinical diagnosis of V. vulnificus infection. After five days in the intensive care unit, he was in stable condition and was transferred to a local hospital.

Diagnosis
Table 2<sup>18,19</sup> presents etiologies for the differential diagnosis of aggressive soft tissue infection. Most of these infections involve a group A Streptococcus species or Staphylococcus aureus. Infections with necrotizing fasciitis are predominantly polymicrobial.<sup>20,21</sup>

At hospital admission, laboratory results of patients with V. vulnificus infection are indicative of severe bacterial infection, with a marked left shift in the white blood cell count. Renal injury with a rising serum creatinine level is common.<sup>22</sup> With severe
Table 2. Etiologies of Aggressive Soft Tissue Infections

<table>
<thead>
<tr>
<th>Infection</th>
<th>Patient history</th>
<th>Underlying conditions</th>
<th>Physical examination findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A Streptococcus species</td>
<td>Skin abrasion, trauma, recent herpes zoster infection, human bite, intravenous drug abuse</td>
<td>Diabetes, cancer, alcoholism, stasis dermatitis</td>
<td>Intense erythema, edema, lymphadenopathy, hemorrhagic and necrotic bullae</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Skin trauma, recent hospitalization or surgery, intravenous drug abuse</td>
<td>Obesity, diabetes, immunocompromising condition</td>
<td>Furuncles, local abscesses, diffuse macular erythrodema</td>
</tr>
<tr>
<td>Polymicrobial</td>
<td>Diabetic foot ulcer, recent surgery</td>
<td>Diabetes, immunocompromising condition, vascular disease</td>
<td>Moist gangrene with a foul odor and hemorrhagic and necrotic bullae</td>
</tr>
<tr>
<td>Pseudomonas species</td>
<td>Bacteremia, moist skin infection, severe burn, recent hospitalization</td>
<td>Immunocompromising condition</td>
<td>Hemorrhagic and necrotic bullae</td>
</tr>
<tr>
<td>Vibrio vulnificus</td>
<td>Exposure to raw or undercooked seafood or seawater</td>
<td>Liver disease, immunocompromising condition</td>
<td>Hemorrhagic and necrotic bullae, ecchymoses</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>Severe trauma with wound contamination, recent surgery, intravenous drug abuse</td>
<td>None</td>
<td>Pale skin, edema, hemorrhagic and necrotic bullae, foul-smelling discharge, gas formation</td>
</tr>
<tr>
<td>Pasteurella multocida</td>
<td>Cat or dog bite</td>
<td>None</td>
<td>Erythema, edema, serosanguineous discharge, lymphadenitis, tenosynovitis</td>
</tr>
<tr>
<td>Aeromonas hydrophila</td>
<td>Exposure to freshwater, skin abrasion</td>
<td>Usually none; sometimes an immunocompromising condition</td>
<td>Erythema, bullae, necrosis, possible gas formation</td>
</tr>
</tbody>
</table>

Information from references 18 and 19.

V. vulnificus or Streptococcus pyogenes infection, the creatine kinase level is often elevated when necrotizing fasciitis or myonecrosis is present.23

Radiographic studies (e.g., ultrasonography, computed tomography, magnetic resonance imaging) of affected tissues typically show nonspecific changes such as soft tissue edema and pockets of fluid. These findings may help exclude other conditions and guide aspiration attempts and the timing of surgical intervention.

Because sepsis is common, routine blood cultures should be performed when V. vulnificus is suspected. Bullae, ecchymoses, and abscesses are often productive sites to aspirate material for Gram stain and culture. In addition, Gram stain, culture, and frozen-section analysis of tissue is helpful to rapidly visualize bacteria and diagnose necrotizing fasciitis.20 Additional cultures are guided by clinical symptoms and may include ocular, peritoneal, sputum, cervical, and stool cultures. Stool cultures require a thiosulfate citrate bile salts sucrose agar for isolation.24

Treatment and Prognosis

The recommended antibiotic therapy for V. vulnificus infection is doxycycline, 100 mg intravenously or orally (Vibramycin) twice a day; plus cefazidime (Fortaz), 2 g intravenously every eight hours. Alternative antibiotic therapies are cefotaxime (Claforan), 2 g intravenously every eight hours; or ciprofloxacin (Cipro), 750 mg orally or 400 mg intravenously twice a day.25,26

In addition to antibiotics, many patients require aggressive supportive therapy in the intensive care setting. Aggressive and prompt wound care is essential. Surgical debridement; incision and drainage of abscesses; and, sometimes, amputation have been shown to reduce mortality and shorten...
Table 3. Recommendations for Reducing the Risk of *Vibrio vulnificus* Infection

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid contact with raw seafood juices; use separate cutting boards and knives for seafood and nonseafood</td>
</tr>
<tr>
<td>Avoid eating raw oysters or seafood, especially if an immunocompromising condition or chronic liver disease is present; the risk is highest with seafood harvested in the summer</td>
</tr>
<tr>
<td>Cook shellfish thoroughly:</td>
</tr>
<tr>
<td>In the shell: boil until the shells open, then boil for another five minutes; or steam until the shells open, then steam for another nine minutes (do not eat shellfish that do not open during cooking)</td>
</tr>
<tr>
<td>Shucked oysters: boil for at least three minutes, or fry for at least 10 minutes at 375°F (191°C)</td>
</tr>
<tr>
<td>Promptly refrigerate leftover seafood</td>
</tr>
<tr>
<td>Wear gloves when handling raw oysters or shellfish</td>
</tr>
<tr>
<td>Persons with open wounds:</td>
</tr>
<tr>
<td>Avoid contact between open wounds and seawater, especially if water temperature is more than 68°F (20°C), or raw seafood</td>
</tr>
<tr>
<td>Wash any wound that is exposed to seawater with soap and clean water</td>
</tr>
<tr>
<td>Immediately seek medical care for any wound that appears infected</td>
</tr>
</tbody>
</table>

Information from reference 29 and 30.

hospitalization.\textsuperscript{20,27,28} Patients presenting with painful, rapidly progressive hemorrhagic bullae should receive prompt surgical evaluation for possible debridement.\textsuperscript{20,27,28}

*V. vulnificus* infections are commonly fatal, and the prognosis is directly linked to the speed and accuracy of diagnosis and treatment. When treatment was delayed by as little as 24 hours in patients with sepsis, mortality rates increased from 33 to 53 percent. Mortality rates increased to 100 percent in patients who were not treated within 72 hours.\textsuperscript{12} Recent data show that when all types of *V. vulnificus* infections are combined, the overall mortality rate is 35 percent.\textsuperscript{1}

Prevention

*Table 3\textsuperscript{29,30} includes recommendations for reducing the risk of *V. vulnificus* infection. Because *V. vulnificus*-related sepsis is usually caused by consuming raw oysters, most disease can be prevented by not eating this food. Limiting consumption of raw oysters to the winter months also can reduce the risk of infection. Patients with chronic liver disease or immunocompromising conditions are particularly vulnerable to infection and should be advised to avoid raw or undercooked seafood. Persons with open wounds should avoid contact with warm seawater.\textsuperscript{4,29,30}*

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Author disclosure: Nothing to disclose.

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Vibrio vulnificus Infection: What You Should Know

What is Vibrio vulnificus infection?
Vibrio vulnificus (VIB-ree-oh vul-NIF-i-cus) is a germ found in warm seawater. If you eat shellfish (especially oysters) or other seafood that has the germ, you can get an infection.

Who gets infected?
V. vulnificus infection is uncommon. Most people get it by eating raw oysters. If you have an open cut, you can get the germ by going in the ocean or touching raw seafood. You can't get it from other people.

What are the symptoms?
Most healthy people don't get sick even if they are infected. People with liver disease, kidney disease, or diabetes can get very sick if they are infected.

If you get sick from V. vulnificus, you might have a fever, vomiting, and diarrhea. You may also have redness, swelling, blisters, and bruising on your skin. If you have a cut, it could get infected.

What if I think I am infected?
Go to your doctor or the hospital right away. Do not wait because the infection spreads quickly.

Your doctor may test your blood or the blisters to tell if the infection is caused by V. vulnificus. Your doctor may give you medicine to stop the infection. Some patients need surgery.

How can I avoid getting infected?
Be sure to cook seafood thoroughly to kill the germ. Try not to touch raw seafood juices, and make sure to wash kitchen utensils in hot, soapy water.

If you have an illness that makes it more likely that you will get sick, avoid eating raw or undercooked seafood. If you have an open cut, you shouldn't do activities in seawater (for example, swimming, fishing, or boating).

Where can I get more information?
Your doctor

Centers for Disease Control and Prevention
Web site: http://www.cdc.gov/ncidod/dbmd/diseaseinfo/go to Vibrio vulnificus)

U.S. Food and Drug Administration
Web site: http://www.cfsan.fda.gov/~dms/vvfact.html

August 2007

This handout is provided to you by your family doctor and the American Academy of Family Physicians. Other health-related information is available from the AAFP online at http://familydoctor.org.

This information provides a general overview and may not apply to everyone. Talk to your family doctor to find out if this information applies to you and to get more information on this subject. Copyright © 2007 American Academy of Family Physicians. Individuals may photocopy this material for their own personal reference, and physicians may photocopy for use with their own patients. Written permission is required for all other uses, including electronic uses.
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 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 binominal and common name of the mushroom species.

   b) Name and address of person who harvested the wild mushroom.
c) Name and certificate number of the person responsible for identifying the wild mushrooms.

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

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

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

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

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

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

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

Submitter Information:

Name: Lisa Brown
Organization: State of Maine DHHS, Health Inspection Program
Address: 286 Water St. Key Bank Plaza 3rd Floor, 11 SHS
City/State/Zip: Augusta, ME 04333
Telephone: 207-287-5691
E-mail: lisa.brown@maine.gov

Attachments:

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

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.
Wild Mushroom Partnership Proposal

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

Background and Rationale for Partnership Agreement

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

3-201.16 Wild Mushrooms.*
(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is identified by the Latin binomial name in the fresh state by a person with local mushroom picking experience and training recognized by a national mycological organization.

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

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

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

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

2. **Partnership purpose and goals:**

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

- Make clear the process needed to establish and maintain certification as a wild mushroom forager in order to sell or barter wild mushrooms on a retail or wholesale basis and,

- Detail the training needed for personnel of retail establishments including restaurants, farmers markets, and retail stores, in order for them to purchase wild foraged mushrooms for resale. There is no intention to regulate the sale of cultivated exotic mushrooms through this program, e.g. cultivated maitake, oyster, lion’s mane, etc.

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

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

   - Draft language to revise the Maine Food Code as required to establish the parameters under which wild foraged mushrooms may be purchased and sold in Maine and to detail a process for training and certification of foragers and purchasers of foraged mushrooms for resale to the public.

   - Establish an accepted list of wild mushrooms approved for collection and sale under the certification program in the state of Maine.

   - Develop a curriculum, a training manual, and processes to train and certify foragers and retail buyers of wild foraged mushrooms in the skills needed to recognize approved mushrooms. Foragers will be trained in methods of harvesting mushrooms in a sustainable manner.
Develop a state-sanctioned exam for certification of chefs, foragers, brokers, buyers and sellers of wild foraged mushrooms upon successful completion of the training program.

Establish and staff a series of training seminars to carry out the goals of this program. The seminars will be self-supporting using the income generated through tuition charges.

3. **Program areas and activities for the Partnership:**

   a. **Program area for the partnership include:**

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

   b. **Cooperating Agency/organization/public contacts:**

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

c. **Statutory basis for Partnership Agreement:**

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

4. **Responsibilities:**

**Joint:**

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

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

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

**Maine Mycological Association and University of Maine:**

- Provide expertise to develop a list of approved mushrooms in coordination with area foragers and restaurant personnel.
- Assist in the development of training curricula and materials as needed.
- Develop a specific manual of approved mushrooms, look alikes and potentially
toxic species for use in the education of foragers and retail sellers of wild foraged Maine Mushrooms.

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

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

**Northern New England Poison Control Center:**
- Provide expertise and input regarding toxicology and protection of the public as related to the use of edible wild foraged mushrooms.
- Provide resources as needed to support development and printing of a manual for training on approved edible wild foraged mushrooms.

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

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Estimated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of Mushroom ID Manual</td>
<td>$750.00</td>
</tr>
<tr>
<td>Marketing and registration of training program</td>
<td>$500.00</td>
</tr>
<tr>
<td>Printed Material</td>
<td></td>
</tr>
<tr>
<td>- Other printed materials</td>
<td>$250</td>
</tr>
<tr>
<td>- Wild Foraged Mushroom Manual</td>
<td>$8,000.00</td>
</tr>
<tr>
<td>Payment of Training staff</td>
<td>$1500.00</td>
</tr>
<tr>
<td>Travel expenses</td>
<td>$500.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$11,500.00</strong></td>
</tr>
</tbody>
</table>

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

*Maine state employees, UMO specialist, NNE Poison Control and Maine Restaurant Assoc personnel time are in-kind donations
6. **Assessment mechanisms:**
Foragers and others completing a mushroom identification training program will be tested for knowledge gained and retained by completing identification of approved wild foraged mushroom species. Scores on tests will be used to assess training effectiveness. Numbers of restaurants and retail establishments completing training will be used as one method to assess the breadth of the program statewide. Feedback from foragers and retailers completing a training seminar will be gathered as a means of fine-tuning the training curricula and materials.

7. **Signatures of responsible parties:**
## List of Wild Mushroom Species Approved for Sale

### Ranking

1- easy to identify and prepare

2 – caution in identifying, requires special care in preparing

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

### Edible Mushrooms for Cooking

<table>
<thead>
<tr>
<th><strong>Latin Binomial</strong></th>
<th><strong>Common name</strong></th>
<th><strong>Other common names and comments</strong></th>
<th><strong>Ranking</strong></th>
<th><strong>Comments</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Agaricus arvensis</em></td>
<td>Horse mushroom</td>
<td>Pink bottom, field mushroom</td>
<td>1</td>
<td>Look-alikes: A. Xanthodermus (yellow), Lepiotaceae and Amanitaceae (white spored)</td>
</tr>
<tr>
<td><em>Agaricus campestris</em></td>
<td>Meadow mushroom</td>
<td></td>
<td></td>
<td>Complex of species</td>
</tr>
<tr>
<td><em>Armillaria mellea</em></td>
<td>Honey mushroom</td>
<td>Includes A. mellea and A. ostoye</td>
<td>2</td>
<td>Needs to be cooked thoroughly, boil 5 minutes</td>
</tr>
<tr>
<td><em>Boletus bicolor</em></td>
<td>Two color bolete</td>
<td></td>
<td>3</td>
<td>Caution for identification, must be distinguished from look-alikes</td>
</tr>
<tr>
<td><em>Boletus edulis</em></td>
<td>Cep</td>
<td>Porcini, king bolete</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><em>Calvatia cyathiformis</em></td>
<td>Dark-spored puffball</td>
<td></td>
<td>1</td>
<td>should be purple spored puffball</td>
</tr>
<tr>
<td><em>Calvatia gigantea</em></td>
<td>Giant puffball</td>
<td></td>
<td>1</td>
<td>bland for restaurant use but may be found at farmers markets</td>
</tr>
<tr>
<td><strong>Cantharellus cibarius</strong></td>
<td>Golden chanterelle</td>
<td>Chanterelle, pfifferling</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Coprinus comatus</strong></td>
<td>Shaggy mane</td>
<td>Shaggy ink cap</td>
<td>1</td>
<td>Very short shelf life</td>
</tr>
<tr>
<td><strong>Craterellus cornucopioides</strong></td>
<td>Black trumpet</td>
<td>Horn of plenty, black chanterelle, Formerly called C. fallax</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Craterellus ignicolor,</strong> <strong>C. xanthopus</strong></td>
<td>Yellow foot chanterelle</td>
<td>Flame-colored chanterelle</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Craterellus tubaeformis</strong></td>
<td>Trumpet chanterelle</td>
<td>Winter chanterelle</td>
<td>1</td>
<td>Can be spelled <em>C. tubiformis</em>, some recognize <em>C. infundibuliformis</em> as a synonym</td>
</tr>
<tr>
<td><strong>Grifola frondosa</strong></td>
<td>Hen of the woods</td>
<td>maitake</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Gyroporus castaneus</strong></td>
<td>Chestnut bolete</td>
<td>2</td>
<td>Caution for identification</td>
<td></td>
</tr>
<tr>
<td><strong>Hericium spp. complex</strong></td>
<td>Lion’s mane, comb tooth</td>
<td>club tooth</td>
<td>1</td>
<td>Includes <em>H. americanum, H. ramosum</em></td>
</tr>
<tr>
<td><strong>Hydnum repandum</strong></td>
<td>Hedgehog</td>
<td>Sweet tooth</td>
<td>1</td>
<td>formerly <em>Dentinum repandum</em> and <em>D. umbilicatum</em></td>
</tr>
<tr>
<td><strong>Hydnum umbilicatum</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypomyces lactifluorum</strong></td>
<td>Lobster mushroom</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Laccaria ochropurpurea</strong></td>
<td>Purple gilled laccaria</td>
<td>2</td>
<td>Caution for identification</td>
<td></td>
</tr>
<tr>
<td><strong>Lactarius deliciosus complex</strong></td>
<td>Orange latex milky</td>
<td>saffron milky</td>
<td>1</td>
<td>includes <em>L. thynios</em> and <em>L. deterrimus – L. deliciosus</em> is old name and the European sp.</td>
</tr>
<tr>
<td><strong>Laetiporus</strong></td>
<td>White</td>
<td>2</td>
<td>Caution, Cannot be collected from conifers. Must be</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Type</td>
<td>Notes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------------------</td>
<td>----------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>cincinnatus</em></td>
<td>pored chicken mushroom</td>
<td>collected young.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Laetiporus sulphureus</em></td>
<td>Chicken of the woods</td>
<td>2 Caution, Cannot be collected from conifers. Must be collected young.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Lepiota procera</em></td>
<td>Parasol mushroom</td>
<td>3 Expert to identify, requires extra training. Many similar mushrooms, poisonous Amanitas or Lepiotas can be mistaken for it.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Lepiota rachodes</em></td>
<td>Shaggy parasol</td>
<td>3 Expert to identify, requires extra training. Many similar mushrooms, poisonous Amanitas or Lepiotas can be mistaken for it.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Lepista nuda</em></td>
<td>Blewit</td>
<td>3 Caution for identification, requires extra training. Difficult to identify, can be confused with purple Cortinarius species.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Marasmius oreades</em></td>
<td>Fairy ring mushroom</td>
<td>2 Cannot be collected from golf courses or pesticide-treated lawns, can be confused with <em>Clitocybe dialbatra</em> and <em>Inocybe umbratica</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Morchella elata</em></td>
<td>Black morel</td>
<td>2 Caution for cooking: Needs to be well cooked</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Morchella esculenta</em></td>
<td>Blond morel</td>
<td>2 Caution for cooking: Needs to be well cooked</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Pleurotus ostreatus</em></td>
<td>Oyster mushroom</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Pleurotus populinus</em></td>
<td>Oyster mushroom</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Polyporus squamosus</em></td>
<td>Pheasant back</td>
<td>1 Useable when young and tender</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Stropharia rugosoannulata</em></td>
<td>Wine cap stropharia</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Tricholoma</em></td>
<td>White</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Mushrooms for possible medicinal uses**

<table>
<thead>
<tr>
<th>Latin Binomial</th>
<th>Common name</th>
<th>Other common names and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Ganoderma lucidum</em></td>
<td>Ling chih / Reishi</td>
<td>1</td>
</tr>
<tr>
<td><em>Ganoderma tsugae</em></td>
<td>Reishi</td>
<td>Hemlock varnish shelf</td>
</tr>
<tr>
<td><em>Inonotus obliquus</em></td>
<td>Chaga, clinker polypore</td>
<td>Birch clinker</td>
</tr>
<tr>
<td><em>Trametes versicolor</em></td>
<td>Turkey tail</td>
<td>2</td>
</tr>
</tbody>
</table>
Maine Wild-Harvested Mushroom Certification Manual

Manual Overview

INTRODUCTION

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

PART I. BACKGROUND INFORMATION

WHAT IS A MUSHROOM? WHY ARE MUSHROOMS IMPORTANT?

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

ANATOMY OF MUSHROOMS

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

HOW TO IDENTIFY MUSHROOMS

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

NOMENCLATURE

- Why Names are Important
• Scientific Names versus Common Names

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

Expectations FOR A CERTIFIED FORAGER
RESPONSIBLE COLLECTING
• Collecting for a Sustainable Mushroom Supply
  o Protection of the Habitat
  o Avoiding Overharvesting

Whose Land is it?
• Access to Open Land in Maine
• Commercial Foraging on Public and Private Lands
• Securing Permission to Collect- “Ask First”

Responsible Sales Practices
• Education of Buyers/ Final User
  o Proper storage
  o Proper / Safe Preparation

COLLECTION AND STORAGE OF WILD MUSHROOMS
• Harvesting Mushrooms in Good Condition
• Collecting Techniques
  o Separation of Mushroom Species for Safety
  o Ensuring a High Quality Product

• Grading and Storage of Wild Mushrooms

RECORD KEEPING
• The Regulations
• Tips for Good Record Keeping
  o Foragers
  o Brokers
  o Chefs and Retailers

PART II. THE MUSHROOMS
MUSHROOMS APPROVED FOR COMMERCIAL COLLECTION AND SALE IN MAINE

LEVEL I MUSHROOMS (Alphabetical by Genus)

LEVEL II MUSHROOMS (Alphabetical by Genus)

LEVEL III MUSHROOMS (Alphabetical by Genus)

PART III. APPENDICES

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

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

Introduction and History of Use

Description:
Narrative Description
Typical size:
Cap: Size
Color:
Shape
Texture
Spore-bearing surface type (gills, pores, teeth…)
Color
Unique features
Stem: Size
Color
Shape
Texture
Ring +/-
Cup +/-
Flesh: Color and texture
Spore print color:

Habitat / Ecology
Occurrence / Season

Look Alikes: Edible
Non Edible
Toxic- See Following Description

Collection / Storage

Preservation / Preparation / Use History

Special Instruction / Potential Risk

Summary

Example of a Species Entry (without Photographs)

Name: Agaricus arvensis
Accepted Common Name: Horse Mushroom
Other Common Names in Wide Use: None

Introduction and History of Use: This large and stately mushroom is known from grassy areas across cooler regions of North America and Europe and widely collected for food. Agaricus is the genus of the Western World’s most economically important and widely used cultivated edible mushroom, A. bisporus including the button mushroom, Crimini and Portabella. Several wild species are commonly collected and used as food throughout the US. All Agaricus species share a few features making them fairly easy to distinguish. All have gills that start out light cream, become pink to reddish as the cap opens and then mature a dark bittersweet chocolate brown. The spore color is also dark chocolate brown. Almost all species have gills that are free of the stalk and the stalk has a noticeable ring (annulus) that can be single, double or pendulous. At times the annulus disappears in mature fruiting bodies. In dry weather or for individuals fruiting in open sunlight, the annulus can remain fixed to the margin of the cap and get pulled off in tatters remaining attached to the cap edge. The stalk base lacks any form of volva or cup from a universal veil, but it may be swollen in some species. There is one other notable characteristic of Agaricus; if you give the stalk of an Agaricus a gentle twist it will separate cleanly from the cap without any gill fragments.

Description: Agaricus arvensis

Typical size: Large mushroom up to 8 inches in diameter
Cap: Size: 4-7 inches in diameter
Color: White to cream
Shape: Convex to almost flat
Surface Texture: smooth, becoming scaly with age.

**Spore-bearing surface:**
- Gills: Free of the stem and closely spaced;
- Color: maturing from grayish white to pink to reddish to dark brown.

**Stem:** Size: 3-5 inches long and up to 7/8 in. wide.
- Color: White
- Shape: equal to tapering upward
- Texture: smooth and firm
- Ring: Present, membranous and fragile
- Cup: Absent

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

**Spore print color:** Dark bittersweet chocolate brown

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

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

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

**Look Alikes:** Edible: *Agaricus macrosporus* is primarily a European mushroom seen occasionally in Maine growing in association with Spruce. It is of very similar size but
lacks any yellowing color and is usually associated with trees, especially spruce.

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

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

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

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

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

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

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

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

Issue you would like the Conference to consider:

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

Public Health Significance:

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

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

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

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

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

**3-603.12 Recall Notification.**

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

(1) DISCLOSURE shall include:

1. A sign indicating that a Class I Recall is in effect for the relevant product, which shall be:
   1. 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
   2. Within 3 feet of the cash register or point of purchase, and
   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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*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.*
Title:
USFDA Recall Policy Revision

Issue you would like the Conference to consider:

Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process.

Consider:

> FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR

> Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA

> Firms affected by the recall throughout the complex food system (distributers, sub-producers, brokers) have no official FDA guidance

> There is no time limit for executing a Class I Recall, or any other Class

> There are no minimum requirements for the information required in a recall notice

> There is no consideration of cost to benefit

> Current Classification system is ambiguous and confusing:

Current Classification System from FDA web site for Industry:

Recall Classifications
• **Class I recall**: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

• **Class II recall**: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

• **Class III recall**: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

• **Market withdrawal**: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

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

**Public Health Significance:**

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

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

that a letter be written to the FDA urging creation of a committee/task force to redesign the administration of food recalls. The committee should include FDA, USDA, State Public Health, academia, and industry, including primary and secondary producers, brokers, and distributors.
The following model is offered as a starting point for the revised administrative guidelines to be developed by the committee/task force. There are only three categories, each with an expanded definition and actions required of industry:

Class I:

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

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

Class II:

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

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

Class III:

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

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

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Attachments:

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

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*
Chapter 7
RECALL PROCEDURES

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7-1 PURPOSE

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

7-2 BACKGROUND

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

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

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

Guidelines delineating the responsibilities of industry in conducting recalls are in 21 CFR 7.40-7.59. An additional document titled “Product Recalls, Including Removals and Corrections - Industry Guidance” is available on the Internet at the FDA web site. It is designed for all FDA regulated industry and provides guidance both in the conduct of recalls and in the information needed by FDA to classify, monitor, and assess the effectiveness of a recall.
7-3 SUMMARY OF FDA RESPONSIBILITIES AND PROCEDURES

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

1. Initiation of a Recall. Includes voluntary, FDA requested, and FDA mandated.

2. Classification and Strategy. FDA formalizes the recall action by reviewing the information, including the recall strategy provided by the firm, assessing the health hazard presented by the recalled product, and classifying the recall.

3. Notification and Public Warning. FDA notifies the firm of the classification and necessary changes in its recall strategy, including the need for press releases for those recalls conducted voluntarily. The agency notifies the firm of FDA requested or mandated recalls and the need for publicity. FDA publishes all recalls on the FDA Internet site and ensures that the public is warned about products that are hazardous to health. FDA provides recall information to other federal and state government agencies and to foreign governments.

4. Monitoring and Auditing the Recall. FDA develops and implements a recall audit program to ensure that the recall action has been effective.

5. Termination of a Recall. FDA determines when a recall should be terminated and, upon such determination, provides written notification of termination to the recalling firm.

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

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

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

OE/DCMO is the agency’s headquarters contact and focal point for information, advice, and direction for field recall operations and remains involved with each recall throughout its process. If required, OE/DCMO may direct appropriate follow up actions by the field. OE/DCMO, with the district coordinators and Center Recall Unit (CRU) evaluates firms’ recall performance. The recall staff encourages timely district and industry action on recalls. In the case of FDA requested recalls, as well as all Class I recalls for which the ACRA has not delegated classification authority to center directors, OE/DCMO is the liaison between the districts, the CRUs and the ACRA. The recall staff reviews and makes recommendations to the ACRA regarding concurrence with the Action Memoranda. OE/DCMO will forward its recommendation to the ACRA within one working day unless additional or supplemental review
of the health hazard evaluation or recall classification or status is required. OE/DCMO periodically reviews all agency recall activities to ensure that current policy and procedures are being applied to recalls and recommends changes as appropriate. OE/DCMO informs OE/DCIQA (Division of Compliance Information and Quality Assurance) of recalls that may affect government agencies, and, in turn, OE/DCIQA informs the appropriate government agencies of such recall information, when applicable. OE/DCMO evaluates the overall effectiveness of recall activities. OE/DCMO communicates trends, common causes of recalls, control weakness, etc., to units having the need for this information.

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

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

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

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

7-4 RECALL ENTERPRISE SYSTEM

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

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

The RES increases efficiency in processing recall information by:

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

5. providing a central, searchable database to more efficiently track information and generate and disseminate reports of recall activities;

6. using a uniform Health Hazard Evaluation (HHE) form or a form equivalent to the HHE form to promote consistency in evaluating potential health hazards and/or risks agency-wide while supporting wider use of electronic precedent health hazard assessment files to expedite recall classifications; and,

7. Providing the public with “real-time” information about the FDA recall process

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

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

7-5 INITIATION OF A RECALL

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

7-5-1 Firm Initiated Recalls

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

The district:

1. submits a Recall Alert;

2. gathers information about the recall. It may conduct an establishment inspection and collect samples of the recalled or other suspect products;

3. submits a Recall Recommendation and other information about the recalled product to the appropriate center;

4. offers guidance to the recalling firm;

5. monitors the recall; and,
6. terminates Class II and III recalls and recommends termination for Class I recalls.

The above district activities are described as follows.

1. **Recall Alert**

   The district, as soon as possible, but preferably within 24 hours, after learning of a recall either planned or in progress, should notify the appropriate CRU and OE/DCMO Recall Operations Staff (HFC-210). The district should submit this Recall Alert through RES by completing, at a minimum, all the fields identified in Attachment A, and may submit any other information at the same time. Additionally, the district will scan and e-mail or fax to the CRU a copy of the recalling firm’s recall communication and press release, if any. A copy of the press release is also to be forwarded to OE/DCMO and to the OPA Field Liaison. Alerts have not been required for device recalls under section 518(e), biologics recalls for which CBER issued an "alert to possible recall," and corrective action program (CAP) recalls involving radiation emitting medical devices and electronic products. These exemptions will continue under RES.

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

2. **Recall Recommendation and Related Information**

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

a. In conjunction with the recall recommendation, the district will submit to the appropriate CRU, as soon as possible:

   i. legible copies of all labeling, including operations manuals, brochures, flyers, or any other product related literature that will aid in determining the violation and evaluation of the product problem;

   ii. product specifications, formulation and related documents;

   iii. FDA and/or state laboratory worksheets and/or the firm’s pertinent quality control or analytical records for all products involved;

   iv. if the district does not have a physical sample to demonstrate the defect and the potential hazard, other documentation of the justification for recall, such as a copy of the FDA-483 documenting serious violations of GMPs, or epidemiological evidence; and,

   v. if not previously submitted at time of the Alert, a copy of all of the recalling firm’s communications to the CRU. For potential Class I recalls, also forward a copy to OE/DCMO.
This material should closely follow the submission of the RR and should be submitted by the fastest means possible, for example, by scan delivered via e-mail, by fax, or by guaranteed overnight delivery.

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

b. Notes:

i. When requested by OE/DCMO or the CRU, submit a Recall Recommendation for a product removal as a result of actual or alleged tampering with individual unit(s) where there is no evidence of manufacturer or distributor responsibility. The district should recommend the action be classified as a market withdrawal as, although the situation may present a health hazard, there is no one identified as responsible for the violation. This will allow documentation and monitoring of specific corrective actions meeting the market withdrawal definition but considered significant to the agency.

ii. FDA regulated products manufactured by U.S. firms for foreign distribution and which are in violation of United States laws will be processed, classified, and published the same manner as domestic recalls.

iii. FDA regulated products manufactured by foreign firms recalled in the U.S. will be processed, classified and published (including entered in RES) the same as products manufactured in the U.S. If the U.S. Agent initiates the recall on behalf of the foreign firm, the U.S. Agent gets copies of the FDA correspondence on the recall. However, if the US agent refuses (or, otherwise fails) to initiate the recall and the foreign firm performs the notification to its first line distributors, then the foreign firm is the recalling firm and receives the classification and termination letters from the ACRA, center or district.

iv. If the CRU or OE/DCMO finds the RR information lacking in any way, either may request that the district obtain the additional information. This may be done by telephone, email, or the electronic return of the recall record with comment.

3. Establishment Inspection

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

The establishment inspection should, in addition to other activities:

a. Obtain the recalling firm's proposed recall strategy [21 CFR 7.46(a)], if not previously submitted by the firm.
b. Collect copies of all labeling associated with the product.

c. Obtain complete distribution of all shipments of the suspect lot(s), including complete names and addresses of all foreign consignees.

d. Obtain supporting documentation that will assist the agency in identifying and evaluating the problem such as product complaints, product specifications and test results, including the methods used to obtain the results.

e. For medical device recalls, obtain marketing status of the device being recalled, that is, 510(k) or PMA number(s), or preamendment device with proof of status.

f. Assess the root causes of the problem. Determine how and when the problem occurred and how and when it was discovered. Obtain the firm’s corrective action to prevent future occurrences.

g. Verbally apprise management that the district office should be consulted prior to the reconditioning or destruction of any returned product. Management should also be advised that FDA must witness or otherwise verify product disposition. Prior to initiating an establishment inspection, district personnel should determine whether similar complaints have been entered into FACTS. For devices, search CDRH’s MAUDE database or contact CDRH’s Division of Surveillance Systems, Information Analysis Branch (HFZ-531) to retrieve complaints. For drugs, contact CDER’s Division of Compliance Risk Management and Surveillance, (HFD-330) regarding complaints reported in the Drug Product Defect Reporting system. Center offices managing other reporting systems may be contacted where applicable to a particular problem.

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

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

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

If the responsible firm is out of business or is unable to conduct an effective recall for any reason, the district should notify the CRU and OE/DCMO. The district and the CRU
should develop an appropriate course of action to recommend to the ACRA. In significant situations involving a serious health hazard, this could involve issuance of press to notify the public and/or FDA notifying consignees directly.

4. **Official Samples**

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

5. **Guidance to the Recalling Firm**

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

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

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

Letters to direct accounts and sub-accounts should include a postage-paid, self-addressed post card, envelope, or other arrangement to enable the consignee to report the amount of the product available and its disposition. If none of the product is on hand, the letter should direct that the consignee submit a negative report. It should stress prompt return of the card or other report. (See Exhibits 7-4, 7-5, 7-6, and 7-7 for model letters, envelopes, and cards.)
7-5-2 FDA Requested Recall

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

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

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

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

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

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

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

The district office will offer the same guidance to the recalling firm as outlined above and will
assist the firm in arranging the text of recall communications to consignees so that the product will be promptly removed or corrected.

**7-5-3 FDA OrderedRecalls**

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

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

1. **Mandatory DeviceRecalls**

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

2. **Mandatory Recall of Biological Products**

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

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

   On November 21, 2004, FDA issued regulations requiring human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; record keeping; and the establishment of a quality program (GTP final rule 69 FR 68612). FDA promulgated the new regulations under the legal authority of section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). The regulations at 21 CFR 1271.440 include a provision for orders of retention,
recall, and/or destruction, and a new provision for orders of cessation of manufacturing in certain circumstances. Such orders are intended for use in situations when needed to prevent the introduction, transmission, or spread of communicable diseases. HCT/Ps subject to the provisions in 21 CFR 1271.440 include, but are not limited to bone, ligaments, skin, dura mater, heart valves, corneas, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen and other reproductive tissue. The regulations at 21 CFR 1271.440 do not apply to vascularized organs such as livers, hearts, and kidneys, human milk or any tissues currently regulated by FDA as human drugs, medical devices, or licensed biological products. See RPM Chapter 5, Order of Retention, Recall, Destruction, and Cessation of Manufacturing Related to Human Cell, Tissue, Cellular and Tissue-Based Products (HCT/Ps), for detailed procedures.

4. **Infant Formula**

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

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

5. **Interstate Milk Shipments**

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

7-6 **RECALL CLASSIFICATION AND STRATEGY**

The Center Recall Unit (CRU):

1. initiates a health hazard evaluation;

2. finalizes a recall strategy;

3. classifies the recall and, for Class I recalls, prepares an Action Memorandum for Center Director or his/her designee concurrence before forwarding it to OE/DCMO and the ACRA; and,
4. updates RES with classification, audit strategy, and any recommendations, and posts the information to the Internet.

7-6-1 Health Hazard Evaluation

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

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

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

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

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

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

7-6-2 Classification Process

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

The CRU will then review, correct, edit or add information necessary for the FDA Recall web page and then submit it for updating. (The actual updating will occur automatically, once daily, at midnight, so all updates from the previous day will be available the following morning.)
The ACRA has approval authority for all Class I recalls. However, the ACRA has delegated approval of certain Class I recalls to center directors. This has been done to streamline the recall classification process in the center, expedite the handling of the recall by industry and FDA district offices, and in certain situations, to have it universally understood that these recalls represent potentially serious to life-threatening health hazards. The center director may further delegate within the center compliance office the authority for review and classification of recall actions previously established by the ACRA as Class I. Specifically, for CFSAN, this includes precedent situations such as Listeria monocytogenes, salmonella species, various allergens, and pathogens in ready to eat foods.

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

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

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

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

7-6-3 Classification Notification And Routing

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

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

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

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

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

1. **Elements of a Recall Strategy**

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

   a. Depth of recall. The recall may extend to the consumer or user level, the retail level, or the wholesale level.

   b. Public warning. In urgent situations, consideration should be given to the need for a press release that could be nationwide or to affected geographical areas only. In some cases, special communication with specific segments of the population (e.g., physicians, pharmacists, veterinarians, and hospitals) may be appropriate. When the CRU believes that there is a need for a FDA press release or a Talk Paper, in addition to the FDA Recalls web page posting, they should coordinate with the appropriate press officer on OPA’s Media Relations Staff (HFI-20). Similar Information may also be posted on Med Watch.

   c. Effectiveness Check Level. This includes the method(s) to be used for and depth of recall effectiveness checks.

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

2. **Recall Strategy Review or Development**

   In reviewing or developing a recall strategy, the CRU should take into account the health hazard evaluation, type or use of the product, the ease in identifying the product, the degree to which the product’s deficiency is obvious to the consumer or user, the amount of product remaining unused in the marketplace, distribution pattern, validated salvage or rework plan, and the continued availability of essential products.
For firm initiated recalls the CRU will review and change as indicated or concur with the firm’s recall strategy and the district's recommendations for the FDA audit program. For firm initiated recalls, center coordinators should obtain current assessment of recall effectiveness from the field. The center will communicate recommended changes in the firm’s recall strategy and effectiveness checks and the FDA audit program to the District Recall Coordinator and OE/DEMO and update RES.

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

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

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

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

### 7-7 NOTIFICATIONS AND PUBLIC WARNING

#### 7-7-1 Reports And Reporting Procedures

1. **Identification of Recall Documents**

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

2. **Status Reports**

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

   For certain Class I recalls and Class II recalls, when required by the audit program, the district office will send a weekly progress report to the CRU and OE/DCMO until the recall is completed or until advised otherwise by OE/DCMO.
Monthly or bi-monthly status reports on recall actions within the districts are not required by headquarters, but may be prepared at the discretion of district management for district recall operation monitoring purposes only.

### 3. District Notification to the Recalling Firm

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

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

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

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

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

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

### 4. Audit Check Reports

Report all recall audit checks on form FDA 3177, Recall Audit Check Report. See Exhibit 7-12A for a copy of the report and Exhibit 7-12 for the audit check report instructions.
OE/DCMO is responsible for maintaining contacts and notifying headquarters organizations about significant recalls. These include the Center Recall Unit, Division of Federal State Relations (DFSR), Office of International Programs, Media Relations Staff in the Office of Public Affairs, and the Division of Compliance Information and Quality Assurance (DCIQA) in the Office of Enforcement. In emergency recall situations, DCMO will keep FDA’s Emergency Operations center apprised of recall status. DCMO advises the USDA, DOD, and other federal government agencies of recalls in which they are involved. DCMO also advises government officials in Canada and Mexico of recalls, in accordance with existing MOU’s and CUMCIG (Canada-United States-Mexico-Compliance Information Group).

1. **Notification of State and Local Officials**

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

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

2. **Foreign, Military, and Other Federal Government Distribution**

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

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

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

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

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

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

   For all Class I recalls involving foreign consignees other than Canadian, OIP/IRS summarizes and transmits essential information to the appropriate counterpart agency
in the foreign country. It provides a copy of the foreign notification to the CRU and OE/DCMO.

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

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

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

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

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

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

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

7-7-3 Public Warning

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

It is FDA’s policy that press releases issue for Class I recalls unless specific circumstances indicate that a press release would not be beneficial to the public. Publicity may be issued by either the recalling firm or by FDA. Agency policy gives the recalling firm the first opportunity to prepare and issue publicity concerning its recall. The field recall coordinators will work with the
recalling firm to prepare a press release. The OPA Media Relations Staff, the CRU and/or OE/DCMO Recall Staff are available to provide assistance. The CRU will also assist the OPA Media Relations Staff, along with the district recall coordinator and OE/DCMO, in the preparation of FDA publicity.

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

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

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

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

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

   Note: As soon as the Internet portion of RES is released to the public, recall information provided by the field and centers will be uploaded on a real time basis onto a FDA web page without OPA involvement with one exception. The Website Management Staff will be provided press releases from recalling firms and/or state agencies. The link to the press release will then be provided on the specific recall web page.
e. In cooperation with the CRU and OE/DCMO, prepares "Talk Papers" on high interest recalls that do not warrant a press release;

f. Evaluates the effectiveness of recall publicity and, if determined to be inadequate, initiates action to ensure effective notice; and,

g. Handles or coordinates responses to all media calls regarding recall situations.

7-8  MONITORING AND AUDITING RECALL EFFECTIVENESS

This section includes the following subsections:

7-8-1  Recall Effectiveness

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

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

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

7-8-2  Managing FDA’s Audit Program

1. FDA Recall Audit Program Development

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

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

Factors in Audit Program Development include:

a. Special procedures for monitoring the recall at the firm

b. Level and type of audit checks to be conducted

c. Special reporting requirements

OE/DCMO concurs in the use of personnel resources for audit checks for ORA.
2. **District Responsibilities**

In summary, the districts:

a. Issue audit check assignments (monitoring district)

b. Complete assigned audit checks (monitoring and other districts)

c. Notify the CRU and OE/DCMO of progress on recalls and ineffective recalls

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

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

3. **Audit Check Issuance**

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

4. **Audit Check Completion**

The district receiving audit checks assignments should consider them high priority and should accomplish them as soon as possible. Submit copies of audit check reports to the monitoring district. If possible, complete assignments within 10 working days from receipt of the assignment. For Class I recalls, provide audit check reports to the monitoring district at least once a week or more often if so directed.
Visits, rather than telephone calls, are preferable for Class I recall audit checks. Visits are also preferred for Class II audit checks. However, resource restraints may make it necessary to conduct the audit checks by telephone. Ineffective telephone audit checks may need to be followed by a visit to ensure effectiveness of the recall action. Exceptions to Class I and II audit checks will be made only when circumstances indicate that such checks will be of no significant value in FDA’s audit of the recall. Audit checks are not normally performed for Class III recalls. However, the responsible district and CRU must consider the need for such checks in each recall situation.

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

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

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

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

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

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

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

b. **Sub-Recall Indicated.**

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

c. **Sub-Recall Refusals.**

If the direct or sub-account refuses to initiate recall promptly, the district performing the audit check will advise the monitoring district, OE/DCMO, and appropriate CRU of the situation, and indicate what additional steps the district is taking to achieve a
satisfactory sub-recall. Options for consideration include meetings between district management and top management of firms, notification of consignees directly, reporting to State and local officials, recommendation for FDA requested recall, and initiation of administrative proceedings or enforcement actions.

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

e. Injury/Illness/Data.
Injury/illness reports or other product related complaints should be reported promptly (separately from the audit check report) to the monitoring district and OE/DCMO. The monitoring district should inquire whether or not the adverse event(s) has/have been reported to FDA through programs such as MedWatch.

6. **Ineffective Recall**

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

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

7-8-3 **State Audits**

1. **Purpose**

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

2. **When State Audits are Considered**

FDA may consider state audits in any of the following situations:
a. The volume of audits approved by center(s) demonstrates the need for state help to accomplish audit check activities in a timely manner. (“Timely” is based on the health risk of the product subject to the recall.)

b. FDA is receiving numerous complaints about recalled product still on retail shelves after a firm has issued a recall notification or public warning.

c. FDA determines that the recall is ineffective based on audit check results.

d. The recalling district determines that an ineffective recall letter may be necessary.

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

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

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

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

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

4. **Strategy for State Audits**

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

a. What consignees have done to discontinue the use and/or distribution of all intact containers of recalled product and the segregation of these products from those products not subject to the recall.

b. The methods distributors use for handling and/or disposing of undistributed recalled products in their warehouse.

c. Whether distributors have communicated recall instructions to their consignees, and, if so, by what mechanism (e.g., phone, letter).

d. How users may identify (or have identified) recalled products; especially when the products do not have a lot code printed on the individual unit.

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

5. **Reporting Audit Results**
a. General

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

b. Reports by States

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

c. Reports by Districts

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

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

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

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

a. Recall Expansion

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

b. Additional state audits

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

c. Issuance of Ineffective Recall Letter

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

d. Public Information

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

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

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

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

7-9 **RECALL TERMINATION**

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

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

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

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

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

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

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

7-10 ATTACHMENTS, EXHIBITS, AND APPENDIX

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

ATTACHMENTS:
A    Recall Alert Information  
B    Recommendation for Recall Classification  
B1   Recommendation for Recall Classification and Termination  
C    Recall Termination or Recommendation for Termination  
D    Health Hazard Evaluation Worksheet  
D1   21 CFR 7.41(a) Guidance to Health Hazard Evaluation Committees  
F    Recalls of Infant Formula  
G    Recalls of Medical Devices, Section 518(e)  
H    Methods for Conducting Recall Effectiveness Checks

EXHIBITS:
7-1    Model Effectiveness Check Letter (Industry)  
7-2    Model Effectiveness Check Response Format (Industry)  
7-3    Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry)  
7-4    Model Recall Letter (Generic, All Centers)  
7-5    Model Recall Return Response Form  
7-6    Model Recall Envelope  
7-7    Model Notification of Classification Letter (FDA to Recalling Firm)  
7-8    Model Recall Ineffective Recall Letter  
7-9    Model Recall Termination Letter  
7-10   Model Combined Recall Notification of Classification and Termination Letter  
7-11   Request for Audit Check Format
7-12   Audit Check Report Instructions/Explanation By Section
7-12A  Audit Check Report
7-13   Weekly Class I Recall Status Report (Optional)

APPENDIX:
A      Forms/Attachments for State Audits
Attachment A – Recall Alert Information

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

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

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

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

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

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

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

2. **Code Information (RES Product Details page)**

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

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

   **Recalling Firm Information fields:**
   
   FEI field- provide FEI number and click search. If the firm is in the OEI, the firm name and address is provided. Complete any fields not automatically populated. If FEI is unknown, or does not exist, type in “unknown” in the FEI field and then fill in all following
information fields. Under the “Comment” box, identify the type of firm, i.e., manufacturer, importer, broker, repacker, own label distributor.

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

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

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

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

a. Include any analytical findings in qualitative and/or quantitative terms, indicating whether firm, FDA, State, or private firm analysis. Indicate the analyzing laboratory. Explain all State involvement in the recall, including sample collection or analysis, recall agreement or initiation, recall monitoring, and product disposition.

b. Provide inspectional (GMP) or other evidence where appropriate.

c. In cases where a veterinary drug product is being recalled due to subpotency of active ingredients prior to labeled expiration date, provide the following information:
   1. The firm’s stability testing plan (including analytical methodology) which established the labeled expiration date.
   2. Specific batch numbers in the stability studies and assay values that are the basis of the firm’s recall.
   3. Potency specifications which the firm uses for recall purposes.
   4. Final assay values for the active ingredients which were the basis of the initial release of the batch.

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

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

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

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

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

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

Manufactured From field – Provides dates.

Expected Life - This could include products such as pacemakers, which have a calculable life span.
Shelf Life - This primarily references perishable foods but may also be used for medical devices, biologics, and certain drugs.

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

6. Distribution Pattern (RES Event Details page)

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

Consignee Details fields

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

Number of Domestic Consignees – Provide number

Number of Foreign Consignees – Provide Number

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

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

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

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

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

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

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

9. District Audit Program (RES Event Details page)

Effectivness Check Level field – Provide the firm’s planned or district recommended effectiveness level.

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

Audit/Effectiveness Check Modification box - This box should be used to provide any modifications to the recommended levels, e.g. “Recommend level C (10%) audit checks at distributor accounts and level D (2%) not to exceed five sub accounts of each distributor audited.” Provide the firm’s recall effectiveness history when recommending low levels of, or no audit checks, and monitoring of recall status from the firm’s own records. This box may also be used to provide the district’s proposed program for monitoring the recall, including the time table for follow-up visits or firm contacts for reviewing the recall status. State what actions have already been taken by FDA such as inspections, sample collections, etc.
Attachment B1 - Recommendation for Recall Classification and Termination

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

1. **Product:** See Attachment B.

2. **Codes:** See Attachment B.

3. **Recalling Firm/Manufacturer:** See Attachment B.

4. **Reason for Recall Recommendation:** See Attachment B.

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

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

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

7. **Firm’s Recall Strategy:**

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

8. **Violation:**

   Provide the section of law violated.

9. **Preventive Action:**

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

10. **District Audit Program:**

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

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

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

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

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

HEALTH HAZARD EVALUATION

1. PRODUCT/IDENTIFICATION NUMBER/USAGE (e.g. unit, lot, serial number, catalogue number, order number, etc.)

2. FIRM NAME, ADDRESS, IDENTIFICATION NUMBER(S)

3. NATURE OF PROBLEM

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

   [ ] No
   [ ] Yes - Attach copies or explain

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

   [ ] No
   [ ] Yes - Attach copies or explain

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

   [ ] No
   [ ] Yes

5. What is the risk to the general population?

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

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

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

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

7. Within the population at risk, could individuals suffering from any particular conditions or diseases be more or less at risk and if so, why? [e.g. Immune system debilities, diabetes, cardiac problem, concomitant medications, etc.]

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

____ Life-Threatening (death has or could occur)

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

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

____ Temporary or reversible (without medical intervention)

____ Limited (transient, minor impairment or complaints)

____ No adverse Health Consequences

____ Hazard cannot be assessed with the data currently available

Explanation:

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

____ Every Time _____ Reasonable Probability ____ Remote

____ Unlikely _____ Unknown

Explanation:

Signature Date

Signature Date

Signature Date
Recall Product: ______________________________

MARKET ASSESSMENT

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

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

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

__________________________

Center Recall Unit Assessment of Recall

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

[ ] The product is violative and there is a reasonable probability that use of or exposure to the product will cause serious adverse health consequences or death. (Class I)

[ ] The product is violative and use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences (life threatening/death) is remote. (Class II)

[ ] The product is violative and use of or exposure to the product is not likely to cause any adverse health consequences. (Class III)

[ ] The product involves a minor violation or no violations. (Market Withdrawal)

Signature(s):  Date:
Attachment D1 – 21 CFR Part 7, Guidance to Health Hazard Evaluation Committees

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

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

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

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

7.41(a)(2) - Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard.
Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
1. Name the specific clinical conditions (e.g., diabetes, heart problems, etc.) which, if they exist, might render a person or animal more susceptible to experiencing a health hazard on exposure to the product.
2. How would these clinical conditions contribute to or change the risk of exposure to the products?
3. Could these clinical conditions mask or otherwise disguise the risk of exposure to the product?
4. What other products being used to treat these clinical conditions could contribute to or, conversely, lessen the risk of exposure to the product?

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

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

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

1. Are the health hazards likely to be acute (lasting several days to a few weeks) or chronic (lasting weeks to months)?
2. Describe the degree of seriousness of the health hazard if it did occur, and which specific segment of the population might be at risk? Express in terms of the following:
   a. Life threatening - death could occur
   b. Severe - permanent significant disability
   c. Moderate - transient but significant disability; permanent minor disability
   d. Limited - transient minor disability; annoying complaints
   e. None - no disability or physical complaints anticipated
7.41(a)(5) - Assessment of the likelihood of occurrence of the hazard.
1. How frequently have deaths, diseases, injuries, or other adverse reactions already occurred? How does the frequency of occurrence relate to the total extent of product exposure (e.g., number of devices implanted, number of prescriptions, etc.). How has this frequency been documented?
2. If deaths, diseases, injuries, or other adverse reactions have not already occurred, estimate the likelihood of occurrence in each segment of the population at risk.

7.41(a)(6) - Assessment of the consequences (immediate or long range) of occurrence of the hazard.
1. What are the immediate consequences of the health hazard?
2. What are the long-range consequences of the health hazard?
3. If the product being recalled or considered for recall is used to treat a medical condition, are alternate forms of therapy available?

SUMMARY OF HEALTH HAZARD EVALUATION

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

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

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

Recalls Conducted Under Subchapter C of the Act:

1. Center for Devices and Radiological Health (CDRH) Learns of Defect or Noncompliance

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

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

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

3. Proposal of Corrective Action Plan by Manufacturer

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


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

a. Product description (including all model and serial numbers used) and the total number of units of this product that are involved.

b. Consignee list (foreign and domestic).

c. Description of the defect (including all reports, documents, memos, etc., of meetings, technical reviews, etc., which pertain to the analysis of the problem and the development of a "fix").

d. Proposed steps to be taken to correct the product in the field and steps taken to prevent future occurrences.

e. Proposed effectiveness checks to be conducted.

f. Proposed date of completion and appropriate interim dates for design, fabrication, and implementation of the correction.

g. Any and all injury/death investigations or reports.

h. Pertinent complaints on file.

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

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

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

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

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

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

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

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

6. Time Frames

The timeframes associated with electronic products recalls are considerably different than for general FD&C recalls. At the time the Center identifies a problem, the manufacturer is often unaware that any problem exists. Opportunity is provided to the manufacturer to examine and
possibly refute the Agency’s evidence, or to request exemption, or to locate all products and to formulate a CAP. The time between declaration of noncompliance and CDRH approval of the CAP varies widely depending upon the product, the nature of the problem, and the thoroughness of the proposed correction.
Attachment F – Recalls of Infant Formula

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

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

Other than the above timeframe, recalls of infant formulas are to be handled under the same procedures as other recalls with two important additions:
1. Section 412(f)(3) of the Act requires that the manufacturer post written notice of the recall of an infant formula at each retail establishment where the infant formula is sold. The content of such notices should be reviewed by the Agency prior to the posting, and the duration of posting should be part of the firm's recall strategy with agency concurrence. Audit checks should verify adequate posting.
2. Section 412(f)(1) of the Act requires that the manufacturer submit a report on the recall not later than 14 days after the initiation of the recall and at least every 14 days thereafter until the recall is terminated. The Agency is to review these reports at least once every 15 days.
Attachment G – Recalls of Medical Devices, Section 518(e)

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

BACKGROUND

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

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

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

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

PROCEDURES:

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

Actions under section 518(e) may be initiated by the Center or recommended by the field. Factors to be considered when deciding to recommend a 518(e) recommendation are:
1. Does the hazard meet the criteria for a Class I recall situation, i.e., there is a strong likelihood that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death?
2. Are other administrative or enforcement actions more appropriate to address the problem? Seizure or detention may be a lesser agency burden and may address the health risk situation more effectively.

3. GMP issues alone will not support the contention that use of the device will cause serious adverse health consequences.

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

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

1. The product labeling, and product advertising and/or newsletters to consumers, if pertinent.

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

3. Because a hearing may take place quickly, include one extra copy of ALL information for the Office of Chief Counsel (OCC). All written materials which FDA will rely on for support at the hearing (for example, the EIR) must be turned over to the opposing side at least one day before the informal hearing.
Do not delay other regulatory actions (e.g., seizure) pending the 518(e) review. In addition, do not stop collecting data, as the issue can still potentially result in a trial, seizure, Congressional hearing, etc.

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

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

**INFORMAL HEARING**

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

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

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

As soon as OC determines that a 518(e) action is appropriate, the field fact witnesses should
immediately prepare for possible testimony in anticipation of the informal hearing. Each should prepare a narrative memo of findings of facts pertaining to the device, i.e., inspectional findings, analytical findings, etc. The Office of Chief Counsel will need the narrative memo three (3) days before the hearing, and will follow-up with a telephone call to the CSO involved. The Center will also be gathering documentary support and locating expert witnesses to testify at the hearing. Expert identification and preparation is a difficult and time-consuming process. The field office should be alert to potential experts and provide their names to CDRH. A pre-meeting of FDA participants and CC will be held 1-2 days prior to the informal hearing, to discuss the issues and prepare our strategy for the hearing.

If a hearing is to be public, it will be announced on the public calendar. If FDA wants the hearing to be closed to the public, it must state one of the reasons contained in 21 CFR 16.60. If the company wants the hearing to be closed to the public, the company must state its reason under 21 CFR 16.60 in its request for a hearing. The Hearing Officer will make the final determination as to whether a hearing is to be open to the public or closed.

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

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

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

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

Similarly, an amended order cannot include recall of a device from user facilities if FDA determines that the risk of recalling it from the facilities presents a greater health risk than the health risk of not recalling the device, unless the device can be replaced with an equivalent device by the recalling firm (including a competitor’s product equivalent to the device).
Attachment H –Methods for Conducting Recall Effectiveness Checks

INTRODUCTION

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

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

METHODS

1. General

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

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

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

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

As a questionnaire is returned and/or completed, it is placed with the control file card for the consignee for “logging in” purposes.
2. **Mail**

There are four elements to the use of mail:

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

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

In conducting a recall effectiveness check, there are certain basic questions that need to be asked. The purpose of these questions is to determine whether: the recall notification was received; the product involved was handled as instructed in the recall notification; the product was further distributed by the consignee before receipt of the recall notification; and, if so, were the additional consignees notified. Other questions may need to be asked depending upon the nature of the recall. Also, the design and format of the questionnaire may vary depending upon the method of contact to be used.
Exhibit 7-1
MODEL EFFECTIVENESS CHECK LETTER (INDUSTRY)

Consinee
Name and Address Date

(Pressure Sensitive Label)

Dear Sir:

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

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

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

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

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

Thank you for your cooperation.

Sincerely,

NOTE: If this letter is sent to distributors who may have further sold the product to other distributors or to retail outlets, the third paragraph should include the fact that the recall notice requested the direct consignees to conduct sub-recalls by notifying their customers of the recall situation.
Exhibit 7-2
MODEL EFFECTIVENESS CHECK RESPONSE FORMAT (INDUSTRY)

C ons ignee  N ame and  A ddress
( Pressure S ensitive  Label)

Rec all  E ffectiveness
C heck s-M ail  M ethod

JOHN DOE PRODUCT RECALL

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

DATE_______________

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

   YES_____         NO_____

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

   YES_____        NO_______

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

   YES______  NO_______

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

   YES_______   NO______

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

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

   YES_______ NO________

   If yes, please provide details.

Name of person completing questionnaire:

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

Conee Name and Address
(Pressure Sensitive Label)

JOHN DOE PRODUCT RECALL

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

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

DATE_____________

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

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

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

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

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

__________________________________________________________

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

YES_______  NO_______

If yes, please provide details.

Thank you for your cooperation.

And your name is ________________________________

And what is your title please?_______________________________

Interviewer____________________________

Date______________________________

IF RESPONDENT HAS ANY FURTHER QUESTIONS, ASK HIM/HER TO CONTACT THE
JOHN DOE COMPANY, SOMEPLACE, SOMEWHERE 12345
Exhibit 7-4
MODEL RECALL LETTER (GENERIC, ALL CENTERS)

<COMPANY LETTERHEAD>

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

<DATE>

Contact name or Dept.>
Firm Name>
Address>
City/state/zip>

Dear < >:

This is to inform you of a product recall involving:

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

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

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

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

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

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

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

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

This recall is being made with the knowledge of the Food and Drug Administration.
Enclosure(s)
Exhibit 7-5
MODEL RECALL RETURN RESPONSE FORM

<COMPANY LETTERHEAD>

<insert product>
<insert lot numbers>

Please check ALL appropriate boxes.

I have read and understand the recall instructions provided in the <date> letter.

I have checked my stock and have quarantined inventory consisting of _____ <units or cases>.

Indicate disposition of recalled product:

- returned (specify quantity, date and method)/held for return;
- destroyed (specify quantity, date and method);
- relabeled (specify quantity and date);
- quarantined pending correction (specify quantity);
- transfused – Blood or blood products (specify date and quantity);
- implanted (specify date and quantity)

I have identified and notified my customers that were shipped or may have been shipped this product by (specify date and method of notification); <or>

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

Any adverse events associated with recalled product?  Yes  NO
If yes, please explain: _____________________________________________________

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

- wholesaler/distributor
- grocery corporate headquarters
- repacker
- manufacturer
- pharmacy - retail
- hospital pharmacies
- manufacturer
- other: __________________________________________________________

Name: ______________________________
Title: ______________________________
Tel. number: (____) ______________________________
Firm name: __________________________________________
address: __________________________________________
city/state: __________________________________________

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

OR MAIL TO: FIRM NAME AND ADDRESS

NOTE: This MODEL is intended to serve as guidance for recalling firms. It may not conform to your firm’s recall strategy. Please make any appropriate modifications to the response form. IT IS ADVISABLE TO SUBMIT THE PROPOSED RECALL LETTER AND RESPONSE FORM TO YOUR LOCAL FDA RECALL COORDINATOR FOR REVIEW, PRIOR TO ISSUANCE.
Exhibit 7-6
MODEL RECALL ENVELOPE

FIRST CLASS MAIL

JOHN DOE
Somewhere, U.S.A. 12345

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

(red print) URGENT: DRUG RECALL
Exhibit 7-7
MODEL NOTIFICATION OF CLASSIFICATION LETTER (FDA TO RECALLING FIRM)

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

Re: Recall No. D-000-9

Dear Mr. Doe:

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

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

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

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

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

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

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

Either method should be done under the supervision of an investigator from this office.
We request that you advise us within ten days of the steps you have taken or will take to ensure that the recalled merchandise is properly inventoried and maintained to prevent unintended use or shipment, and provide your proposed method of disposition of the returned goods.

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

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

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

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

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

Sincerely yours,

District Director
________ District

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

Dear Mr. Doe:

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

1. Review of your submitted recall status reports found that (number and type of consignees) have not responded to your recall communication.

2. Review of documentation at your firm found that sub-recall was not initiated by (number) wholesale distributors.

3. Audit checks conducted by FDA found that ...

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

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

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

Sincerely,

District Director
_______ District
Exhibit 7-9
MODEL RECALL TERMINATION LETTER

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

Dear Mr. Doe:

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

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

Sincerely,

District Director
_________ District
Exhibit 7-10
MODEL COMBINED RECALL NOTIFICATION OF CLASSIFICATION AND TERMINATION LETTER

Re: Recall No. Z-000-5

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

Dear Mr. Doe:

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

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

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

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

Sincerely,

District Director
______District
Exhibit 7-11
REQUEST FOR AUDIT CHECK FORMAT

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

Include the following Information:

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

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

List any additional data required but not entirely included on the audit check
report form. Provide any specific reporting instructions.
Exhibit 7-12
AUDIT CHECK REPORT INSTRUCTIONS/EXPLANATION BY SECTION

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

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

2. Program Data:
   Completion of Section 2 is required only if the credit sheet is to be used for program data reporting. Form FDA 2123 may also be used for reporting audit check data. If time is reported on either a FDA 2123 or another FDA 3177, check the box and do not complete Section 2.
   a. Accomplishing District - Enter the code for the district conducting the audit check.
   b. Home District - Enter the code for the home district of the recalling establishment listed in 1b.
   c. Operation Code for Audit Checks - Operation 17, has been pre-printed.
   d. Operation Date - Provide the date the audit check was conducted. When multiple checks are reported, use the date of the last audit.
   e. Central File Number or FEI - Provide the CFN or FEI for the recalling establishment listed in Block 1b.
   f. PAC Code - Enter appropriate PAC code.
   g. Employee - Self-explanatory.
   h. Provide a breakdown of the number of visits and phone audits conducted. Time for each type of check should be listed under the Hours column.

3. Audit Accounts: The form has been designed so that it may be used at the tertiary level of distribution, that is, as far down the distribution chain as consignees of secondary distributors.

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

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

6. Action and Status Data: Self-explanatory

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

8. Self-explanatory.


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

The Recall Audit Check Report is to be signed by the individual conducting the check as well as the individual endorsing the report to the monitoring district.
Exhibit 7-12A
AUDIT CHECK REPORT

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

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

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

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

5. NOTIFICATION DATA
   a. FORMAL RECALL NOTICE RECEIVED?
      (IF "NO" SKIP TO ITEM 6c)
      [] YES [] NO [] CANNOT BE DETERMINED
   b. RECALL NOTIFICATION RECEIVED FROM:
      [] Recalling Firm
      [] Direct Account
      [] Sub-Account
      [] Other (Specify) ____________
c. DATE NOTIFIED
d. TYPE OF NOTICE RECEIVED (e.g. letter, phone)

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

7. SUB-RECALL NEEDED?
   Did Consignee Distribute to any other Accounts?
   (If "Yes give Details in "Remarks" or Memo) [] YES [] NO

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND.

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

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

    TO:___________________________________DATE:_________

    ENDORSEMENT:______________________________________

    SIGNATURE OF SCSO OR RECALL COORDINATOR:______________________________

    SIGNATURE OF CSO/CSI:________________________________

    DISTRICT:_________________________________DATE OF CHECK:
Exhibit 7-13
WEEKLY CLASS I RECALL STATUS REPORT (OPTIONAL)

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

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

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

Product:

Recalling Firm:

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

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

Provide any additional information pertinent to Center and OE evaluation of the recall's progress or effectiveness.
Appendix A
FORMS/ATTACHMENTS FOR STATE AUDITS

1. Form FDA 3177

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

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

Block 1. Recall Information:
   a. Recall Number: Leave Blank
   b. Recalling Establishment: Provide the name and address of the firm responsible for issuing the recall notification.
   c. Recalled Code(s): Provide the lot, batch, or serial number under recall.
   d. Product: Provide the name of the product under recall. If numerous products are involved, use generic term, e.g., ice cream, dried fruit, etc.

Block 2. Program Data: Leave Blank

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

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

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


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


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

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

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

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

3. Other Materials

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

Submitter Information:
Name: Janet Lane, R.S., M.P.H.
Organization: Harris County Public Health & Environmental Services
Address: 2223 West Loop South
City/State/Zip: Houston, TX 77027
Telephone: (713) 439-6267
E-mail: jlane@hcphes.org

Attachments:
• "Food Employee Reporting Sign"

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

**Report** to your supervisor immediately

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

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

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

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

*You could make your customers sick*

*Reporting your illness or symptoms is mandatory under:*

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

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

Employee Written Agreement for Employee Health Reporting

Issue you would like the Conference to consider:

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

Public Health Significance:

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

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

The following paragraphs of Annex 3 of the 2009 FDA Food Code emphasize the importance of educating employees regarding their personal responsibility in reporting certain health conditions that have the potential of transmitting foodborne disease.
2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees.

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

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

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

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

Recommended Solution: The Conference recommends...:

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

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

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

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

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

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

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

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

Report - Criticality Implementation and Education Committee

Issue you would like the Conference to consider:

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

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

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

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

Public Health Significance:
Food establishment operators are required to operate their facilities in a manner that receives, stores, prepares, packages, displays and sells safe food. There are many facets to the operation of the food establishments, but the ultimate goals are the prevention of foodborne illness and injury and to protect the consumer. The regulatory inspectors and industry must recognize, measure, and prioritize risks associated with each step of the operation. The US Food and Drug Administration Food Code has long categorized infractions or violations into two designations, "Critical and Non-Critical". The 2009 Food Code now goes further to break these two designations into three criticality designations based on risk. Providing a training tool for all stakeholders becomes valuable as a means to incorporate the use of the new designations into action plans, intervention strategies, and effectiveness measures.

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

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

**Submitter Information:**

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**Attachments:**

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

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*
Committee Name: Criticality Implementation and Education

Council: I

Date of Report: December 4, 2009

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

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

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

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

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

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

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

- Essential, Sensitive, Fundamental
- Focal Point, Focal Foundation, Core
- Priority, Foundation, Core
- Class I, Class II, Class III
- Priority I, Priority II, Priority III
- High Risk, Medium Risk, Low Risk
- Red, Orange, Yellow
- Priority, Significant, Basic
- Level I, Level II, Level III
- Risk Factor (and Intervention), Critical, Good Retail Practices
- High, Med(ium), Low
The committee also sought guidance in regard to “focal group” and learned from FDA (Dr. Jordan Lin in the Consumer Science Division) that…

1. Focus groups and one-on-one interviews provide you with a range of opinion, not consensus. They are also good at explaining why and how people think about an issue. The Committee will then have to tease the conclusions out of the responses.

2. There are inherent biases in focus groups (not so much with one-on-one interviews) – some people like to talk more than others and some people are swayed by others in the group so not everyone will get equal time or provide unbiased opinions in a group.

3. Focus groups are usually done in person but could be done by conference call, provided certain things are done.
   a. Set up an appointment when they are not rushed and give the individual the list of choices and the questions ahead of time (by e-mail, mail or drop off in person).
   b. Stick closely to a scripted set of questions. We wouldn’t have to be concerned about preconceived ideas or bias of the moderator in a focus group. This would also allow more than one individual to conduct interviews in different locations if they were careful to follow the questions exactly and not project their own opinion which may be biased.

4. The number of interviewees should be large enough to represent the divergent viewpoints in the group of stakeholders we are interested in.
   a. Do we want to consider having representatives from the food service industry, retail food store industry, state agencies, local agencies, trainers?
   b. Can you think of any other groups of stakeholders?
   c. Dr. Lin suggested that 10-15 people be interviewed in each group.

5. The scripted questions should be short and very clear. Dr. Lin offered to review our proposal once it is put together. Possible questions include:
   a. Rank the list of terms (provided beforehand) from #1 (most preferred) to #12 (least preferred). – We could also pare down the numbers of choices as a committee so they won’t have so many to choose from.
   b. Explain why you ranked the first one as #1 and the last one as #12.
   c. Why did you like your top two choices?
   d. How much does your top choice convey the importance or priority of that definition?
   e. Can you think of any other term that would be better?

6. We need to have a prepared description of why we are interviewing these people for the interviewer to read.

7. We should put together a proposal and address the following issues:
   a. Statement of the problem
   b. Objectives
   c. Methodology
   d. Expected conclusion

Based on this in-depth analysis of how a true focal group would and should function and due to the limited amount of time the committee had to fulfill its charge to the Executive Board by December 2008, the Committee determined to forgo an external group process and proceed using the knowledge and experiences of its committee members.
The committee (taking the sets of terms proposed) narrowed the list to five preferred, then to three preferred and finally to two preferred sets of terms. The final two preferred sets were “Priority, Foundation, Core” (PFC) and “Priority I, Priority II, Priority III” (P1, P2, P3). After a final vote of the committee, we had a majority (70%) of the committee for PFC and a strong minority (30%) for P1, P2, P3. Unable to come to a consensus the committee sent to the Executive Board our work and requested acceptance of the majority opinion.

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

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

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

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

**Requested Actions:**

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

1. Final Report from the Criticality Implementation and Education Committee.

2. Criticality Implementation and Education Committee – Criticality Training Slides. Request the PowerPoint presentation titled “Re-Designation of Food Code Provisions” be approved and placed in a downloadable format under the “Conference Developed Guidance and Documents” section of the CFP website. “Re-designation of Food Code Provisions” PowerPoint Slides and Speaker Notes are included as an attachment to the issue.

Request the Committee developed FAQ Document be forwarded to the FDA and that the FDA provide answers available for stakeholders on or before June 30, 2010. “Frequently Asked Questions” Document is included as an attachment to the issue.
4. Criticality Implementation and Education Committee - Timely Correction of Violations

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

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

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

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Vakesha Brown
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Recommendation for future charge;

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

Committee Member Roster:

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

Attachment:
Criticality Implementation and Education Committee Members November 2009.
<table>
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<tr>
<th>Last Name</th>
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<th>Position</th>
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Re-designation of Food Code Provisions

By the 2008-2010 CFP Criticality Implementation and Education Committee
Objectives of Criticality Implementation Training

#1 – Explain the **three new definitions** and the **risk assessment process** used to define the level of risk of Food Code provisions and their relationship to preventing foodborne illness.

#2 – Provide clear and concise **training** for regulators, operators and trainers in restaurants, retail food stores, institutions and vending with examples and how to communicate this information in an effort to reduce the incidence of foodborne illness and injury.
Objectives of Criticality Implementation Training

- #3 – *Increase awareness and understanding of the changes* in compliance and enforcement sections of the Food Code related to the re-designated provisions

- #4 – Give different examples of where and how to **apply the new designations** of Food Code provisions in routine activities to achieve long term behavior change, including in training, active managerial control and inspections
Introduction to Re-Designated Food Code Provisions - History

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

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

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

- “Priority item” means a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.

- “Priority item” includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and

- “Priority item” is an item that is denoted in this Code with a superscript – P.
Priority Item

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

“Priority Foundation Item”

“Priority foundation item” means a provision in this Code whose application supports, facilitates or enables one or more Priority Items.

“Priority foundation item” includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and

Priority foundation Item” is an item that is denoted in this Code with a superscript Pf – Pf.
Priority Foundation Item^Pf

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

“Core Item”
- “Core item” means a provision in this Code that is not designated as a Priority Item or a Priority Foundation Item.
- “Core item” includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.
A Core Item is a good retail practice (GRP) which is not intended to control a particular hazard but hazards in general.

A Core Item has no superscript in the Food Code.

Core Items include:
- General sanitation requirements
- Sanitation Standard Operating Procedures (SSOPs)
- Equipment design
- Design & construction of facilities and structures
- General maintenance & repair
- Operational controls
Relationship between Priority Items and Imminent Health Hazards

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

- **Not all Priority Item violations are imminent health hazards**, only those that affect the operation of the entire establishment or a large part of that operation
A qualitative risk assessment is used to rank risk of foodborne illness or injury in very complex situations such as a food service/food store or provisions in the Food Code.

A qualitative risk assessment process considers:
- The likelihood of causing foodborne illness or injury
- The characteristics of the hazard (virulence and severity)
- The size and/or number of outbreaks (infectivity or potential for illness or injury)
- Any contributing factors (contamination, proliferation or survival) identified in previous foodborne outbreaks reported to CDC.
What does this change to a risk assessment process mean to me?

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

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

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

* See Annex C for more examples and explanations of hazards in foods.
Chemical hazards* include, for example:

- General chemical contamination (cleaning compounds, sanitizers, allergens, additives)
- Scombroid toxin (*B. proteus* breaks histadine down to histamine in certain temperature-abused fish)
- Ciguatera toxin (natural toxin in reef-fish)

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

Physical hazards* include, for example:

- Bone
- Bandage
- Hair
- Metal fragments
- Jewelry

* See Annex C for more examples and explanations of hazards in foods
Risk Assessment Process
Initial Evaluation

After identifying the hazard associated with that provision, determine which of the 3 defined terms (P, Pf or C) most clearly describes this provision, e.g.,

- Cook poultry to 165ºF for 15 sec. (CL) destroys vegetative pathogens (Priority Item)
- No date marking system used on RTE potentially hazardous/TCS food to limit shelf life and control *Listeria* (Priority foundation Item)
- Floor in grill area dirty – general sanitation (Core Item)
Risk Assessment Process
Other Characteristics

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

Assess characteristics of the hazard:

- Virulence or severity of hazard - **MEDIUM**:
  - medium potential for ill food worker to spread hazard to food or patrons
  - medium infectious dose
  - unlikely secondary infection
  - high incidence of hospitalization but few deaths
Risk Assessment Process (cont’d.)

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

Other Characteristics

Assess size & number of outbreaks based on infectivity of the hazard in the absence of control provided by the Code:

- **High** – large outbreaks, large number of outbreaks
- **Medium** – small outbreaks, small number of outbreaks
- **Low** – individual cases, sporadic cases
Risk Assessment Process

- Identify relevant CDC contributing risk factors including contamination, proliferation or survival
- Revise the initial designation based on additional information
- Provide rationale for the decision and references that explain or support designation
What criticality changes were made in the Food Code?

- Three new definitions were added to Chapter 1:
  - Priority Item
  - Priority Foundation Item
  - Core Item
- Section 2-102.11(A) Demonstration (of Knowledge) was changed to say one of the ways the PIC could show compliance with the Code was by having no Priority Item (instead of critical item) violations during the current inspection.
- A superscript (\(P\) or \(Pf\)) is used to identify Priority or Priority Foundation Items in Chapters 2-8, Core Items have no superscript.
- Five sections in Chapter 8 were amended to change Critical Item and/or Non-Critical Item to Priority Item, Priority Foundation Item and/or Core Item.
Section 8-401.20 Performance- and Risk-Based (inspection frequency)

Prioritize and conduct more frequent inspections based on:

- Food establishment’s history of non-compliance with P & Pf items in the Code or HACCP Plan
- Numerous or repeat violations of C items

This section of Chapter 8 is recommendation only and not enforceable
Chapter 8 Compliance & Enforcement (8-403.10)

Section 8-403.10 Documenting Information and Observations (documentation on inspection forms)

- Document on an inspection report non-compliance with P and Pf Items
- This section of Chapter 8 is recommendation only and not enforceable
Section 8-405.11 Timely Correction

- Correct P or Pf Items at the time of inspection
- Implement corrective actions for a required HACCP plan provision that is not in compliance with its critical limit (CL)
- The Regulatory Authority may agree to a longer time for correction (usually for Pf Items), not to exceed 10 days, based on the potential hazard and complexity of the corrective action
  - The P Item it supports must be in compliance using some other procedure, method, equipment, etc. for an extended period for compliance
Section 8-405.20 Verification and Documentation of Correction

- Record correction of P and Pf Items or corrected HACCP Plan deviations observed during an inspection on an inspection report.
- After receiving notification that a violation of a P or Pf Item or a HACCP Plan deviation has been corrected, the Regulatory Authority will verify and document correction of the violation.
- This Section of Chapter 8 is recommendation only and not enforceable.
Section 8-406.11 Time Frame for Correction

- Correct C Items by a date and time agreed to by the Regulatory Authority but no later than 90 days after the inspection

- The Regulatory Authority may approve a longer compliance schedule:
  - If it is provided in writing
  - If no health hazard exists or will result from the extended compliance schedule
Who can use the new terms?

The new terms allow focusing and prioritizing of tasks, training* and corrective actions for the

- Inspector
- Person-in-charge
- Trainer

* See Annex A – Effective Behavior Change and Annex B – Communication Techniques for training assistance
How can the new terms be used?

- New terms P, Pf and C:
  - Designations help identify issues for “Active Managerial Control”
  - They guide regulatory inspections and enforcement.
  - They aid trainers focus their courses on the most important food safety information for their students
How can regulators, QA & 3rd party inspectors use the new terms?

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

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

Shift attention to Priority Items in:

- Management systems
- Standard Operating Procedures
- Recipes
- Self inspections
- 3rd Party Audits
How can the food industry use the new terms?

They will help prioritize…

- Corrective actions for “out of compliance” inspection findings
- Monitoring, walk throughs
- Training content for employees within food establishments
- Limited resources of time and money
How can the food industry use the new terms?

They can build in compliance for Priority Items….
- during Plan Review
- during construction
- during remodeling
- during training
How can food safety trainers use the new terms?

Trainers can explain:

- The new definitions, 3-tiered re-designation system with examples of each
- Immediate correction of Priority Items because of direct connection to foodborne illness
- Priority Foundation Items provide options to correct, manage and control Priority Items
- Core Items are general good practices
- How to prepare for accredited Food Protection Manager Certification examinations
What do you think about this?
Scenario #1

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

When I arrived at the location the following day, I found store personnel repairing and painting the dry storage area. Painting requires ventilation, therefore all receiving doors were propped open. Guess what? The excess fly activity that was once outside was now inside the stockroom and kitchen.
What do you think about this?
Scenario #1

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

A risk-based inspection process:

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

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

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

The following examples will provide the:

- **Violation** of a P, Pf or C Item
- **Provision** in the Food Code that, if Out of Compliance, will result in potential hazards in food that will cause foodborne illness or injury
- **Rationale** or explanation of why/how violation of that provision is a P, Pf or C Item.
Priority Item Examples
Example of Priority Item\textsuperscript{P} Violation

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

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

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

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

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

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

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

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

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

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

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

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

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

Direct connection between building sewer line and drain line of ice machine storage bin and 3-compartment sink

- **Provision** of Food Code: 5-402.11 Backflow Prevention
- **Correction**: Provide an air gap on the drain line between the drain/waste line and the ice machine and 3-compartment sink
- **Rationale**: Air gap prevents possible backflow of waste water into ice machine and 3-compartment sink
Example of Priority Item\textsuperscript{P} Violation

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

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

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

- PIC does not monitor employees for necessary handwashing
  - **Provision** of Food Code: 2-103.11(D) Person in Charge (Duties)
  - **Correction**: It is the PIC’s duty to monitor employees for handwashing at appropriate times
  - **Rationale**: There is no management procedure to control (monitor and verify) employee handwashing to prevent fecal contamination of food
Example of Priority Foundation Item\textsuperscript{Pf} Violation

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

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

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

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

- 5 gallons of chicken stock in stock pot at 110ºF cooling in walk-in cooler for 1 ½ hrs. (put in cooler at 135ºF)
  - Provision of Food Code: 3-501.15(A)(1) to (A)(7) Cooling Methods
  - Correction: Use an appropriate cooling method or combination of methods to cool PHF/TCS food within required criteria (including shallow pans, smaller portions, blast chiller, stirring, ice stick, ice bath, etc.)
  - Rationale: Specific cooling methods that enable rapid cooling would allow product to safely meet cooling parameters
No date marking system used on RTE, PHF/TCS food (leftovers, opened containers of commercially processed foods) in the facility

- **Provision** of Food Code: 3-501.17(A) RTE, PHF (TCS Food), Date Marking
- **Correction**: Date mark RTE, PHF/TCS food (not exempted) held more than 24 hrs. to show when 7 day shelf life has expired
- **Rationale**: Use of a date marking system enables PIC to discard or use RTE, PHF/TCS product before high levels of *Listeria* are present
Example of Priority Foundation Item Pf Violation

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

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

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

**Violation**

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

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

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

- **Provision** of Food Code: 6-501.111(C) Controlling Pests
- **Correction**: Implement a pest control plan such as seal entry holes, place traps, remove harborage, and routinely inspect for water and food sources, as well as presence of pests
- **Rationale**: A pest control plan enables PIC to systematically rid establishment of pests which may carry disease—causing organisms to the facility
Example of Priority Foundation Item Pf Violation

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

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

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

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

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

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

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

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

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

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

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

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

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

Scenario #2

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

- Dirty fan guards and dirty shelves
- Broken light covers
- Dirty floors
- Raw chicken (dripping) stored above an uncovered container of salad dressing
- Many leftovers including two 3-gallon stock pots full of refried beans at 40ºF on lower shelf – not date marked and not covered
First, identify & rank the violations according to risk level (P, Pf or C):

- **Priority Items**
  - Raw chicken dripping over salad dressing - 3-302.11(A)(1)(b)
  - Disposition of undate marked RTE, PHF/TCS food not date marked - 3-501.18)

- **Priority Foundation Items**
  - Refried beans cooled in 3 gallon stock pots - 3-501.15(A)(1-7) (DISCUSS)
  - No date marking system used – 3-501.17(A)

- **Core**
  - Dirty fan guards & shelves – 4-601.11(C)
  - Broken light shield – 6-202.11(A)
  - Uncovered food – 3-302.11(A)(4)

Next, immediately correct P items, then Pf items, then C items as able
Then, remind or retrain responsible individuals
Finally, monitor those activities in the future
What should you do now?

Scenario #3

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

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

Scenario #3

First, identify & rank violations according to risk level (P, Pf or C):

- Priority Item
  - Cook has not reported fever & sore throat to PIC (exclude for HSP in nursing home, restrict for others) – 2-201.11(A)(1)(d)
  - Reheating Spanish rice (verify final reheated temp. reached 165°F in 2 hrs. or before service) – 3-403.11(A)

- Priority Foundation Item
  - No thermometer to measure food temps – 4-302.12(A)
  - Spanish rice in 6” pans – 3-501.15(A)(1) (method unlikely to meet cooling parameters, need to verify procedure for cooling)

- Core Item
  - Broken thermostat in steam table – 4-502.11(C)

Immediately correct P items, then Pf items, then C items

Then, remind or retrain responsible individuals

Finally, monitor those activities in the future
What should you do now?  
Scenario #4

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

- The cook is mixing the slaw and dressing with his bare hands
- The back door is propped open so it will not close and there are a lot of flies inside the kitchen
- Several pans on the clean utensil rack are caked with dried food
- Cases of meat labeled “Keep Frozen” are setting on the floor and leaking
- Utensils are being washed in 3-compartment sink and chlorine sanitizer is available but not used
- There is no soap at the handwashing sink
What should I do now?  
Scenario #4

First, identify & rank violations according to risk level:

- **Priority Items**
  - Mixing slaw with bare hands – 3-301.11(B)
  - No sanitizer used in 3-compartment sink – 4-701.11(C)(1)

- **Priority Foundation Items**
  - No soap at handwashing sink – 6-301.11
  - Pans stored with dried food – 4-601.11(A)
  - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11(A)
  - Many flies, not using some method of fly control – 6-501.111(C)

- **Core Items**
  - Cases of meat on floor – 3-305.11(A)(3)
  - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11

Immediately correct P items, then Pf items, then C items
Then, remind or retrain responsible individuals
Finally, monitor those activities in the future
How to Use the Annexes

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

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

How can regulators, operators and trainers effectively change behavior?
Effective Behavior Change

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

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

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

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

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

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

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

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

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

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

What are some communication techniques to help convey our messages of food safety?
Food Workers as Oral Culture Learners

- Effective communication is necessary to get your message across.
- Inspectors and QA staff are usually print culture learners
  - They read for primary information
  - They have linear, analytical thoughts, are task oriented and able to strategize
- Food workers are often oral culture learners
  - Most workers like to give and receive information verbally
  - Workers are less likely to follow rules made by someone they do not know or trust
Oral Culture Learners

- Verbal information, repeated regularly and reinforced with signs, posters, handouts is an effective way to communicate
  - Fewer words and more pictures is better
- Storytelling is an important method of getting information for oral culture communicators
- Many owner/managers think employees should read food safety rules to learn
  - This thinking reveals a lack of understanding of how oral culture communicators learn and process information
Effective Communication

- Communication has to be 2-way to be effective
  - Explain/demonstrate the issue and have it explained/demonstrated back to you
    - Hands on training reinforces explanation
    - Feedback that they are “doing it right” is important
  - Oral culture communicators require interaction to internalize knowledge and change behavior
  - Active listening skills help pinpoint misunderstanding or lack of understanding
    - There is no other way to know if their communication was effective or even heard
    - This promotes joint problem solving
Communication by Behavior

- Effective communication shapes behavior
- We want to change unsafe food behavior and attitudes that disregard food safety processes
- 80-90% of what we communicate is by non-verbal behavior rather than by what we say
- Doing and correctly practicing the behavior internalizes the information communicated
- It is important for regulators, operators and trainers to consider different methods and their appropriateness to communicate risk and change poor behavior.
Communication by Behavior

- Correct behavior is often not modeled by management
  - “Do as I say, not as I do” doesn’t work
  - Role models (managers, co-workers, inspectors) are important
- Correct behavior is often not a priority
  - “If it’s not important to you, it’s not important to me”
Use Plain Language

- Use “I,” “you” and “we” and avoid “it”
- Use short sentences, limit subjects to one per sentence
- Use vertical lists with parallel construction
- Avoid technical and legal jargon or “big words”
- Use terms listeners or employees are familiar with
- Make factual statements and avoid subjective statements that imply judgment
Communication

- Pertinence to job duties
  - People learn if they understand the importance of their job behavior
  - Communication is best understood when it is personal
    - Related to assigned job duties
    - Described with vivid, real-life examples
    - Connected to their own family, health and well being
Communication

- General statements may not be considered relevant to the job – be specific
  - Why is something important?
  - What is the right way to do it?
  - Can the right way be demonstrated?
- Provide options/examples that are specific to that job
  - Use easily available equipment, utensils or materials
  - Give employees a choice and ask which one they prefer
  - Ask employees to try it out
What doesn’t work well?

- Presenting all training in written form such as signs, pamphlets, on-line computer training, handout materials
- Using examples that aren’t related to their job duties
- Using negative reinforcement (by itself)
- Saying something only once
- Using unfamiliar language or terminology
Annex C

What are common food safety hazards?
Each provision in the Food Code is intended to prevent, eliminate, reduce to an acceptable level or control hazards that could directly or indirectly contribute to a foodborne illness or injury.

A hazard is a biological, chemical or physical property or agent that may cause an unacceptable consumer health risk.

A hazard must be identified as the first step in conducting a risk assessment.
Biological Hazards

- Biological hazards consist of microbiological pathogens, including:
  - Spore-forming bacteria
  - Vegetative bacteria
  - Viruses
  - Parasites

- Most yeast and molds are spoilage organisms and do not cause illness or injury
New Foodborne Pathogens Identified Since 1977

More than 70 foodborne pathogens are known with the following added to the list since 1977

- *Campylobacter jejuni*
- *Cryptosporidium parvum*
- Shiga-toxin producing *E. coli*
- Noroviruses
- *Vibrio vulnificus*
- *Yersinia enterocolitica*
- *Salmonella Typhimurium DT 104*
- Spongiform encephalopathy prions

- *Campylobacter fetus ssp. Fetus*
- *Cyclospora cayentanensis*
- *Listeria monocytogenes*
- *Salmonella Enteritidis*
- *Vibrio cholerae 0139*
- *Vibrio parahaemolyticus*
Controls for Biological Hazards

Provisions in the Food Code control biological hazards by eliminating, preventing, and/or reducing to acceptable levels or holding numbers unchanged by:

- Cooking, pasteurization
- Retorting
- pH/acidity
- Water activity
- Competing organisms
- Bacteriocins, nicin
- Preservatives
- Hot holding

- Cooling
- Refrigeration
- Sanitizers
- Fermentation
- Irradiation
- High pressure
- Nitrites, nitrates
Spore-Forming Bacteria

- *Clostridium botulinum, Clostridium perfringens, Bacillus cereus*
- Spores are able to survive cooking & other adverse conditions
- Spores do not multiply in this form so require no nutrients, water, etc. to survive
- Spores germinate & start to multiply when conditions are right – best control at this stage to prevent growth
- Retort processing (high temp & pressure) is necessary to destroy spores
- Toxins form after germination when the spore is actively growing
Vegetative Bacteria

- The growth phase of spore-forming and non-spore-forming bacteria
- Nutrients, water, and adequate environmental conditions (pH, aw, temperature, etc.) are necessary for growth
- May form toxins in food or in the body
- Susceptible to cooking and many other environmental factors on a case-by-case basis
- Controlled by refrigeration although some vegetative bacteria can multiply slowly at refrigeration temperatures (e.g., *Listeria*, non-proteolytic *Clostridium botulinum*)
Viruses

- Viruses are pathogens which cannot multiply outside of a living cell
- Norovirus, hepatitis A and rotavirus are the most common foodborne viruses
- Infected human beings (not animals) are the usual source
- Preventing contamination (exclude infected workers, handwashing, no hand contact) and thorough cooking control viruses
- Viruses are very heat resistant
Typical Sources of Biological Hazards

- Field and farm crops – soil, birds, other infected animals, failed septic systems, sludge and bio-solids contaminate food products
- Animals – manure, slaughtering process (skin, intestinal tract), service animals, pets and petting zoos contaminate food
- Fish and seafood – marine bacteria, histamine producing bacteria and fish parasites contaminate food
Typical Sources of Biological Hazards

- Infected workers – fecal material, vomitus, nasal discharge, coughing, sneezing and pus from infected lesions
- Cross-contamination from other sources during transport and storage
- Contaminated equipment, utensils and surfaces
- Water – irrigation, contaminated well water or ice, water main break, backflow or back siphonage
Characteristics of Pathogens

- Infectivity – potential or ease of transfer, infectious dose
- Severity – virulence of the pathogen, length & severity of illness, hospitalization or death
- Spore formers/vegetative cells – ability to survive adverse conditions
- Acid resistance – susceptibility to pH
- Heat resistance – ability to survive cooking
- Biofilm formation – ability to form a protective polysaccharide covering resistant to cleaning & sanitizing
- Association with certain foods – SE with eggs, *E. coli* O157:H7 in meat, cider, etc.
### Minimal growth requirement for *C. botulinum*

<table>
<thead>
<tr>
<th>Property</th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Proteolytic Type A, B, F</td>
<td>Non-Proteolytic Type B, F, E</td>
</tr>
<tr>
<td>Inhibitory pH</td>
<td>4.6</td>
<td>5.0</td>
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<tr>
<td>Inhibitory NaCl</td>
<td>10%</td>
<td>5%</td>
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<tr>
<td>Minimum $a_w$</td>
<td>0.94</td>
<td>0.97</td>
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<tr>
<td>Temp. optimum</td>
<td>98°F</td>
<td>86°F</td>
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<tr>
<td>Temp. range</td>
<td>50 -118°F</td>
<td>38 -113°F</td>
</tr>
<tr>
<td>Toxin production</td>
<td>$\geq 50°F$</td>
<td>$\geq 38°F$</td>
</tr>
</tbody>
</table>
**Clostridium botulinum**

- *C. botulinum* is an obligate anaerobe, spore-former, common in soil & aquatic environments (salt and fresh water)
  - Proteolytic *C. bot* – more pH & salt resistant, more resistant to low $a_w$, only grows & produces toxin down to 50ºF
  - Non-proteolytic *C. bot* – less pH & salt resistant, less able to grow at low $a_w$, can grow and produce toxin down to 38ºF
- Preformed toxin is heat labile (boiling 10 min.)
- Improper canning, retorting and reduced oxygen packaging (ROP) are risks
**Clostridium perfringens**

- *C. perfringens* is an anaerobic spore-former found in humans, animals, soil and vegetation
- Cooking heat shocks spores
- Generation time can be 8 minutes starting at 122 - 127°F
- Contributing factors for illness include:
  - Slow cooling (allows germination of spores)
  - Inadequate refrigeration (allows growth of cells)
  - Inadequate reheating (allows survival of cells)
- Vegetative cells sporulate (return to spore form) in gut and release toxin
- Large numbers of cells ($\geq 10^5$) are required to cause illness
Bacillus cereus

- B. cereus is an aerobic spore-former
- Spores are ubiquitous in the soil & environment
- 2 types of toxins can be formed:
  - Emetic is heat stable, formed in food
  - Diarrheal is heat labile, formed in intestine
- Slow cooling and inadequate refrigeration allow spore germination and growth to high numbers
- Toxin is not produced at temperatures < 50°F
- $10^5 - 10^6$ cells needed to produce toxin
Salmonella Spp.

- Commensal organism in the lower gut of mammals
- High survival rate in the environment (up to several months)
- More than 2000 species of *Salmonella* are known
- Relatively heat tolerant
- Infected food workers, poor handwashing, hand contact, and cross-contamination are contributing factors to illness
- *Salmonella* is invasive in the gut and causes systemic infections
Escherichia coli O157:H7

- Cattle and other animals are reservoirs
- Survives well in the environment
- Forms biofilms resistant to washing and sanitizing
- pH resistant
- Transmitted mainly through the ingestion of food contaminated with ruminant feces
**Escherichia coli O157:H7**

- Inadequate cooking and cross-contamination of RTE food are contributing factors
- Shiga-toxin produced in the gut is absorbed into the blood stream
- Damages small blood vessels
  - Leading to bloody diarrhea, kidney failure and death
  - Causes 90% of diarrhea and associated HUS
Staphylococcus aureus

- People are carriers (skin, nasal passages, infected lesions) as well as dogs, fowl, cows with infected udders
- Non spore-former produces toxin at $a_w$ too low for competing bacteria
  - Growth at $a_w = 0.83$,
  - Toxin production requires $10^6 - 10^7$ CFU/g
  - Toxin produced at $a_w = 0.88$
  - Pre-formed toxin produced in food
- Reheating destroys cells but toxin is heat stable
- Food likely to be contaminated by hand contact with RTE food and infected lesions
Listeria monocytogenes (Lm)

- **Listeria** is ubiquitous in the environment
- Lm forms biofilms resistant to washing & sanitizing in high moisture niches
- Lm multiplies slowly at refrigeration temperatures down to 32°F
- Controls include addition of listeriocides to food, short shelf life (datemarking), preventing contamination from the environment, refrigeration, cooking, adequate cleaning & sanitizing
- Fetuses (miscarriages), babies, pregnant women and the elderly are particularly susceptible – high case fatality rate
Norovirus (NOV)

- Human beings are the reservoir for NOV
- Norovirus is reported as the single most common cause of gastroenteritis in the western world
- NOV is transmitted by:
  - Fecal-oral route (through food)
  - Inhalation (breathing vomitus droplets)
  - Person-to-person (touching someone contaminated)
  - Environment to person (touching contaminated surfaces)
Norovirus

- NOV infectious dose is 1 particle (a cluster of 200-300 viruses), highly infectious
- $10^9 - 10^{10}$ particles/g feces (the size of the tip of a fingernail)
- NOV is highly resistant to disinfectants
- Projectile vomiting or diarrhea episode
  - Needs to be contained (covered)
  - Then double wash and disinfect surfaces
  - Discard protective clothing and cleaning materials
- Virus survives in environment hours to days
Hepatitis A (HAV)

- HAV is spread from human beings through:
  - Contaminated sewage in wells, seafood harvest areas, recreational waters
  - Fecal-oral route (contaminated food)
  - Person to person
- HAV is shed at $10^8$ viral particles /g feces
- Shed in feces midway through incubation period before symptoms appear
- Symptoms can last 6-9 months
- Controls are handwashing, no bare hand contact with RTE foods, exclusion with jaundice, shellfish certification & tag retention for 90 days
Parasites

- *Anisakis*
  - The motile larval stage burrows into the stomach walls
  - Infection caused by eating raw or undertreated marine fish

- *Cryptosporidium parvum*
  - Infects 45 different species besides man
  - Oocysts (infective stage) often associated with contaminated drinking & recreational water
  - Oocysts are highly resistant to disinfection
Parasites

- **Cyclospora cayentanensis**
  - Oocysts are infective
  - Often found in contaminated water

- **Giardia lamblia**
  - Reservoir is human beings & wild animals
  - Protozoan cysts & trophozoites shed in feces
  - Often associated with contaminated water or person-to-person transfer in day cares
Chemical Hazards

- A chemical hazard may be naturally occurring or may be added during processing or preparation
- Normal cleaners, sanitizers and other chemicals used in a facility may be a food hazard
- Scombrotoxin (histamine poisoning)
  - Formed by bacteria that convert histidine to histamine
  - Found in tuna, mackerel, skipjack, bonito, mahi mahi, blue fish and certain cheeses
  - Temperature abuse allows bacterial growth and histamine formation
Chemical Hazards

- Ciguatoxin
  - Found in tropical reef fish (i.e., barracuda, a predator fish)
  - Dinoflagellates and algae that produce the toxin are consumed by fish
  - Causes temperature reversal (hot ↔ cold) and other neurological symptoms, often for years
Chemical Hazards

- **Tetrodotoxin**
  - Certain fish (e.g., puffer fish, fugu, blow fish) produce toxin in their skin and viscera
  - Tetrodotoxin is heat stable – cooking will not destroy
- **Aflatoxin**
  - Mycotoxin produced in corn, nuts and other grains
- **Patulin**
  - Mycotoxin produced in rotten apples
  - Not destroyed by pasteurization or cooking
Chemical Hazards

- Monitoring shellfish harvest areas for certain phytoplankton prevents shellfish poisoning.
- Common shellfish poisoning includes:
  - Paralytic shellfish poisoning (PSP)
    - Molluscan shellfish, lobster and crab concentrate saxitoxin from certain dinoflagellates (“red tide”)
    - From a heat stable toxin
    -Flushed from animal within weeks
Chemical Hazards

- Common shellfish poisoning includes:
  - Diarrhetic shellfish poisoning (DSP)
    - Molluscan shellfish concentrate toxins from certain dinoflagellates
    - Heat stable toxin
  - Neurotoxin shellfish poisoning (NSP)
    - Molluscan shellfish concentrate brinetoxins from algal blooms
    - Toxic to fish, birds and sea mammals too
Chemical Hazards

- Common shellfish poisoning includes:
  - Amnesic shellfish poisoning (ASP)
    - Shellfish, Dungeness crabs and anchovies concentrate domoic acid produced by a diatom
    - Produces short term memory loss
  - Toxic mushroom species – False morels, Little Brown Mushrooms, Jack-O’-Lantern, Green-Spored Lepiota, Deathcap, Death Angel
  - Toxic plant species – Belladonna, bloodroot, buckeyes, castor bean, foxglove, hemlock, holly berries, Lily of the Valley, mandrake, May apple, mistletoe, rhubarb leaves, snakeroot
Physical Hazards

- Illness and injury can result from foreign objects in food including:
  - Glass – from lights, bottles and jars, utensils, gauge covers
  - Wood – from fields, pallets, boxes, buildings
  - Stones, metal fragments – from fields, buildings, machinery, wire
  - Bone – from improper plant processing
  - Plastic – from packaging materials, pallets
  - Personal effects – jewelry, buttons, bandaids, etc.
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 website. Further, the committee recommends that the Conference send a letter to FDA requesting the same presentation be made available on the FDA website.

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 website.
2. That a letter be sent to FDA requesting the same PowerPoint presentation and speaker notes be made available through its website.
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Attachments:
• "Re-designation of Food Code Provisions" PowerPoint Slides and Speaker Note"

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

By the 2008-2010 CFP Criticality Implementation and Education Committee
# Objectives of Criticality Implementation Training

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

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

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

The new system of designating the provisions of the Food Code according to the level of risk of causing foodborne illness or injury will help focus attention so operators, regulators and trainers prevent rather than react to a foodborne illness or injury.
Issues were submitted to CFP since 2000 to remove “critical” and “non-critical” designations of Food Code provisions and replace them

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

Members of the Conference for Food Protection have tried since 2000 to remove the terms “critical” and “non-critical” as code provision descriptors. The main reason appeared to be a misunderstanding that “critical” was related to HACCP (as in critical control point or critical limit). The definition of “critical item” was also considered to be a little unclear. More information about the issues that were submitted and the results of the Committees and work groups that considered the issues can be found at CFP’s website, http://www.foodprotect.org under Previous Biennial Meetings.
In 2008, FDA submitted a new 3-tiered set of definitions along with a qualitative risk assessment in response to a charge from CFP in 2004 and 2006. The new designation system for the provisions in the Food Code were based on risk of foodborne illness or injury.

This was a 4 year process where FDA’s work group collaborated with the CFP Critical Items Committee, as CFP stakeholders, to develop the process and re-designations.

While there was some disagreement over the name of the designated terms used in the risk assessment, there was good agreement on the process itself. Neither the present committee nor the CFP Executive board were able to come to a full consensus on new terms. Therefore, FDA used the original terms as submitted to the Conference in 2008 to amend the 2009 Food Code.
New Definition of Priority Item

- “Priority Item”
  - “Priority item” means a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.
  - “Priority item” includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
  - “Priority item” is an item that is denoted in this Code with a superscript – P.

Note in the “Priority Item” definition:
- These provisions contribute directly to the elimination, prevention or reduction to an acceptable level, hazards (or agents) associated with foodborne illness or injury.
- A test to determine if this is a Priority Item or not is to ask if there is another provision that more directly controls the identified hazards.
- Priority items always have a quantifiable measure (or critical limit) that will indicate control of the hazards.
  - Examples are time/temperature parameters, chemical concentrations, presence/absence, etc.
When a Priority Item in the Food Code is out of compliance, it has the highest risk of causing foodborne illness or injury. Compliance with a Priority Item eliminates, prevents or reduces to an acceptable level, biological, chemical or physical hazards that directly cause foodborne illness or injury (see Annex C – What are common food safety hazards?). No other provision more directly controls the hazard. There is a quantifiable measure or critical limit for each Priority Item. The term Priority Item implies an importance and need for immediate correction.

Note that a Priority Item directly controls a hazard:
• It is designated by a superscript P in the Code.
• Annex C, “What are common food safety hazards?” provides introductory information about hazards that the Food Code provisions are designed to control, either directly or indirectly.
New Definition of Priority Foundation Item

- “Priority Foundation Item”
  - “Priority foundation item” means a provision in this Code whose application supports, facilitates or enables one or more Priority Items.
  - “Priority foundation item” includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and
  - Priority foundation Item” is an item that is denoted in this Code with a superscript Pf – Pf.

The second defined term is a “Priority Foundation Item”
- A Priority Foundation Item when applied, supports, facilitates or enables a Priority Item
- These provisions are usually actions, equipment or procedures that help or support the control of a hazard by a Priority Item
- A provision is designated by a Pf in the Code.
Priority Foundation Item

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

- There is usually a clear link between a Pf and P Item so the Pf Item supports or enables the P Item.
- Using Pf items, industry control systems or active managerial control can support the compliance of P Items.
  - Annex A, “How can regulators, operators, and trainers effectively change behavior?” and Annex B, “What are some communication techniques to help convey our messages of food safety?” can assist us achieve more effective training.
  - Policies, procedures, documentation, HACCP plans (if required), labeling, equipment, infrastructure, etc. provide a foundation for achieving a Priority Item.
New Definition of Core Item

- **“Core Item”**
  - "Core item” means a provision in this Code that is not designated as a Priority Item or a Priority Foundation Item.
  - "Core item” includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

A Core Item is usually a general provision that is not directly related to a specific Priority Item but rather to the entire facility.

General sanitation, SSOPs, facility or equipment design and construction, and general maintenance are examples of Core Items.

A Core Item has no specific superscript designation in the Code.
Core Item

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

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

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

- The Food Code in Section 8-404.11 calls for an Operator to cease operation and report to the Regulatory Authority in case of an imminent health hazard because of an emergency situation.
- An imminent health hazard is a significant threat to public health in the entire establishment and requires the facility to cease operation if immediate correction is not possible.
- The emergency is usually directly related to Priority Items such as:
  - Floods,
  - Extensive smoke or fire damage
  - Extended electrical or water outage
  - Extended lack of hot water
  - Sewage backup
  - Foodborne outbreak
  - Misuse of toxic substances (i.e., pesticides)
  - Gross insanitary conditions

- **Note**: that not all Priority Item violations are imminent health hazards, only those that affect the entire establishment operation.
- **Note** also that often corrective actions can be taken in a short time, i.e., a few hours, to resolve the situation. The situation should be reported to the Regulatory Authority to work out what would be acceptable to continue operating. For example, bottled water could be used for a short time before repairs when a water main breaks or heating water for washing hands and using single-service items could be done when the hot water heater breaks down but can be replaces soon.
Qualitative Risk Assessment Process

- A qualitative risk assessment is used to rank risk of foodborne illness or injury in very complex situations such as a food service/food store or provisions in the Food Code.

- A qualitative risk assessment process considers:
  - The likelihood of causing foodborne illness or injury
  - The characteristics of the hazard (virulence and severity)
  - The size and/or number of outbreaks (infectivity or potential for illness or injury)
  - Any contributing factors (contamination, proliferation or survival) identified in previous foodborne outbreaks reported to CDC.
What does this change to a risk assessment process mean to me?

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

- This is a change from critical and non-critical, often difficult to categorize, to a risk-based system that prioritizes enforceable Food Code provisions.
- This is done by ranking the provisions as Priority (P), Priority Foundation (Pf), or Core (C) according to the risk of causing foodborne illness if the provisions are uncontrolled (Out of Compliance)
- The risk assessment process with definitions provides a scientific decision making process for ranking the provisions.
- Annex 2 and 3 of the 2009 Food Code provide additional information about the ranking process.
What does this change to a risk assessment process mean to me?

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

- Because the provisions have already been ranked according to their level of risk, operators and regulators can use the ranking (P, Pf, or C) to prioritize their food safety activities.

- When a Food Code provision contains a quantifiable measure or critical limit, that usually means it is a P item.
The risk assessment process starts by identifying the food safety hazard(s) each provision in the Code will control. Biological Hazards* include, for example:

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

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

The decision-making process in assigning a risk level to a provision first starts with identifying a food safety hazard(s) that is typically controlled by that provision. Biological hazards that may be controlled by a provision include some or all of the following:

- Vegetative and spore-forming bacteria, viruses and parasites
- Annex C, “What are common food safety hazards?” contains additional information about the hazards that may be controlled by that provision. The slides can also be used as a stand-alone training course.
Risk Assessment Process

- Chemical hazards* include, for example:
  - General chemical contamination (cleaning compounds, sanitizers, allergens, additives)
  - Scombroid toxin (*B. proteus* breaks histadine down to histamine in certain temperature-abused fish)
  - Ciguatera toxin (natural toxin in reef-fish)

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

Chemical hazards that are controlled by particular Food Code provisions include:
  - Common chemicals used in a food establishment (cleaners, sanitizers, allergens, additives, etc.)
  - Scombrotoxin (histamine) poisoning from certain temperature abused fish.
  - Ciguatera and other phytotoxins that are contained in dinoflagellates and other microscopic plants that are consumed by fish.
Risk Assessment Process

Physical hazards* include, for example:

- Bone
- Bandage
- Hair
- Metal fragments
- Jewelry

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

• Physical hazards in food which must be controlled include:
  • Non-food items such as bone, metal, glass, bandages, hair and more.
Risk Assessment Process
Initial Evaluation

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

- Make an initial determination of the provision designation by considering the hazard, which of the 3 definitions most likely applies and whether there is a quantifiable measure (something measureable).
- If the initial choice is P, ask whether there is another provision that more directly controls the hazard. If so, the provision may not be a P but will probably be a Pf.
Risk Assessment Process
Other Characteristics

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

- Once the initial determination has been made, the consideration of other factors in conjunction with the definitions confirm or change the designation.
- Virulence or severity of the hazard’s effect is controlled by the provision under consideration.
  - For example, a highly virulent hazard controlled directly by a provision confirmed the provision as a Priority Item.
- The virulence of the controlled hazard can also indicate the priority of attention that provision should receive, that is, the more virulent a pathogen is that is being controlled, the greater attention it should receive.
Risk Assessment Process
Other Characteristics

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

- A medium severity for a particular hazard may change the immediacy of corrective action compared to a highly virulent hazard but will not change the fact, for example, that a provision is a Priority Item and directly related to causing foodborne illness.
Risk Assessment Process (cont’d.)

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

• A low severity of the hazard associated with that provision does not usually change the designation (P, Pf or C) but may affect the order of response when other violations of the same designation are present.
Risk Assessment Process
Other Characteristics

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

• Infectivity of the hazard does not change the designation, e.g., P, Pf or C. That is based on the definition.
• Infectivity of a biological hazards often has an impact on the number of people involved in an outbreak.
  • Norovirus is a good example. This virus is highly infective and often causes large outbreaks, therefore infectivity will be high.
  • C. botulinum does not cause large numbers of ill or large numbers of outbreaks but it is highly virulent (the symptoms of botulism are very severe).
Risk Assessment Process

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

• The CDC contributing factors can help point out the activities related to contamination, proliferation or survival of particular hazards.
• The number or percentage of a particular contributing factor should not be used to designate or rank provisions because the collated data which CDC summarizes and publishes is incomplete. Nearly half of all outbreaks reported to CDC do not contain identified contributing factors.
What criticality changes were made in the Food Code?

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

• The 2009 Food Code was amended to remove the terms “critical,” “non-critical” and “swing” items and replace them with the terms “Priority,” “Priority Foundation” and “Core.”
• The new terms P, Pf and C were defined in Chapter 1 of the Code to show how closely linked an individual provisions was to preventing, eliminating or reducing to an acceptable level hazards that cause foodborne illness.
• The terms Priority (designated by a superscript P), Priority foundation (designated by a superscript Pf) and Core (no superscript designation) are defined in Chapter 1 and used in Chapter 2 and 8.
• Section titles, statements that work in conjunction with the following provision and italicized language are not designated because they are not enforceable.
Chapter 2 Management and Personnel (2-102.11)

Paragraph 2-102.11(A) Demonstration (of Knowledge)

One of the options open to operators of food establishments to show demonstration of food safety knowledge as it applies to their facility is to have no violations of Priority Items during the current inspection.

• An operator of a food establishment must be able to demonstrate to the regulatory inspector that he/she has knowledge of foodborne disease prevention, application of HACCP principles and requirements of the code in the jurisdiction where the facility is located.

• The operator can demonstrate this knowledge by having no violations of Priority Items during the current inspection according to paragraph (A) in 2-102.11.

• The other two options available to the operator or person in charge are:
  • Being a certified food manager based on an accredited test
  • Responding correctly to questions from the inspector about specific areas of knowledge as they relate to that establishment.
Chapter 8 Compliance & Enforcement (8-401.20)

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

• The system used to set the frequency of inspection for food establishments should include consideration of the history of non-compliance with P and Pf Items.

• When an establishment’s management control system does not effectively control P and Pf items, the Regulatory Authority should require more frequent regulatory inspections.

• NOTE: this provision is not enforceable (Section 8-401.20 ends in .20 based on the Food Code writing convention).
Chapter 8 Compliance & Enforcement (8-403.10)

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

• The subparagraphs ((B)(3) and (B)(6) in Section 8-403.10 recommends the inspector document violations on an inspection report observed during an inspection for all P and Pf violations as well as non-conformance with critical limits of any required HACCP Plan (e.g., variances, ROP with or without a variance, packaged juice).

• NOTE: This is a recommendation and not a requirement (Section number ends in .10).
Section 8-405.11 Timely Correction

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

Section 8-405.11 requires correction of P and Pf Items at the time of an inspection because of their direct and supporting roles, respectively, in controlling hazards that cause foodborne illness and injury.

It also requires correction of provisions of a required HACCP plan not in compliance with their critical limits (equivalent to a P Item).

Paragraph (B) is an exception which allows a Regulatory Authority (inspector) to extend the time for correction of P, Pf or HACCP Plan provisions with a critical limit up to 10 days based on the severity or virulence of the hazard or on the complexity of the corrective action, i.e., extensive repairs are needed, something must be ordered from a supplier.
Section 8-405.20 Verification and Documentation of Correction

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

- This section recommends that any P or Pf Item or HACCP Plan deviation that is corrected during the inspection (COS or corrected on-site) should be noted on the inspection report.
- NOTE: This is a recommendation and not required.
Chapter 8 Compliance & Enforcement (8-406.11)

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

- Time for correction of Core Items may be extended up to 90 days or longer if the operator or permit holder submits a written plan of correction, i.e., when the facility intends to make the correction when the facility is next remodeled.
Who can use the new terms?

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

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

• The inspector has a responsibility to conduct food safety inspections to prevent foodborne illness.
• The Person in Charge (PIC) has a responsibility and duty (see Sec. 2-103.11) to explain, train and then monitor employees in certain food safety activities.
• The trainer helps both the inspector and PIC train employees in food safety practices to protect consumers against foodborne illness.
• The new designation terms (P, Pf and C) allow the PIC, inspector and trainer to prioritize and focus on activities that are most directly related to causing and preventing foodborne illness and injury.
• NOTE: Annex A on effective behavior change and Annex B on communication techniques provide additional information to help accomplish these objectives. These annexes are not mandatory.
How can the new terms be used?

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

- These terms give a credible, science-based way to identify the most significant activities requiring incorporation into the:
  - Management’s food safety systems
  - Inspector’s risk-based inspections
  - Trainer’s food safety training
How can regulators, QA & 3rd party inspectors use the new terms?

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

• Inspections, whether done by a regulatory authority, 3rd part auditor or the manager as he/she does a walk-through, should focus on issues that have the most impact on preventing, eliminating or reducing to an acceptable level, factors that cause foodborne illness or injury.

• The new designation of terms allows them to do that.
Potential Uses - Compliance & Enforcement

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

• Regulatory agencies (or companies) can develop specific long term strategies to change behaviors that contribute to foodborne illness, especially those related to P items.
  • Use summary data to identify where attention is needed
  • Change codes, policies and procedures to focus attention on new terms
  • Require immediate correction of P Items that directly relate to foodborne illness or injury but allow longer periods for correction of Pf Items where there may be other ways to support the item.
How can the food industry use the new terms?

Shift attention to Priority Items in:
- Management systems
- Standard Operating Procedures
- Recipes
- Self inspections
- 3rd Party Audits

Operators and managers can review their policies and procedures to determine if all applicable P Items are addressed in:
- Management systems
- SOPs
- Recipes
- Self inspections, walk-throughs and 3rd party audits
• The retail food store and food service industries can use the new terms P, Pf and C to help prioritize:
  • Corrective actions
  • Activities for specific monitoring
  • Training content for employees
  • Use of limited time and money
How can the food industry use the new terms?

They can build in compliance for Priority Items….
  - during Plan Review
  - during construction
  - during remodeling
  - during training

• Since prevention is always more effective than reacting after the fact, build in compliance for P and Pf Items before violations occur during:
  • Plan reviews
  • Construction
  • Remodeling
  • training
How can food safety trainers use the new terms?

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

• Trainers for both regulators and industry managers and employees can help their students better understand the new 3 tiered system to designate Food Code provisions by explaining:
  • The definitions of P, Pf and C items and giving examples
  • Why immediate correction of P Items decreases the risk of foodborne illness and injury the most
  • Why C Items or good sanitation practices are general good support for food safety.
  • How the new system relates to preparing for and using Food Protection Manager Certification.
What do you think about this?
Scenario #1

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

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

• This scenario and other that follow will help you understand how to prioritize your response to real life situations in food establishments, based on the three-tiered designation system for Food Code Provisions P, Pf and C.
What do you think about this?
Scenario #1

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

• After identifying the violations and their designation (P, Pf or C), prioritize the corrective response so P Items are corrected first, then Pf Items and finally C Items. This gives the greatest reduction in risk of foodborne illness and injury in the shortest time and also will result in correction of P Items if only some violations are corrected.

• In addition, consider unintended consequences of your corrective actions,
  • Leaving the door open for ventilation allows flies into the establishment
  • Repairmen contaminating food products or making it difficult for employees to wash hands, etc.
What is a risk-based inspection process?

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

• A risk-based inspection process is another way to put more focus on factors that are more directly related to the causes of foodborne illness.

• Frequency of inspection and inspection time should be greater for establishments with more Out of Compliance P and Pf Items.
What is a risk-based inspection process?

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

• To reduce the risk of foodborne illness and injury most effectively, corrective actions are required for P and Pf Items at the time of inspection with explanations and options offered for long term correction.

• A Risk Control Plan in which the inspector and PIC mutually agree to a plan of action that will correct an Out of Compliance Priority Item helps change behavior. Record keeping will encourage employees to document the critical limits or quantifiable measures and continue to do so for a period of time that should result in long terms behavior change (4-6 weeks). The PIC has the responsibility of monitoring (verifying) the behavior and record keeping done by employees and reporting that to the inspector.
What is a risk-based inspection process?

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

• Time with the PIC during an exit interview after an inspection can be most effective at decreasing the risk of foodborne illness and injury when the focus of attention is P and Pf Items. This will ensure that everyone’s valuable time is spent discussing correction of violations that have the greatest impact on food safety.
Examples of P, Pf and C Violations

The following examples will provide the:

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

•The following examples of P, Pf and C Items on slides #47 – 93 will help explain the new re-designation terms.
Priority Item Examples
Example of Priority Item\(^P\) Violation

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

- Vomiting is a typical symptom of foodborne illness.
- Employees should have been informed that they should stop work and report their symptoms to the PIC.
- The PIC should exclude from work the employee exhibiting symptoms of vomiting unless they have a physician’s note to say the vomiting is from a non-infectious cause such as pregnancy, etc.
- This is a P Item (as are the other symptoms of foodborne illness – diarrhea, jaundice, sore throat with fever and unprotected lesions with pus on hands and arms because food employees can contaminate food and food contact surfaces. This often results in foodborne illness unless controls such as reporting and exclusion are in place.
Example of Priority Item\textsuperscript{P} Violation

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

• The rationale for reporting an uncovered, infected lesion on hands or arms is similar to that for vomiting while working (see previous slide) except that the correction is less severe (covering with two layers of impermeable bandages) because the resulting illness from an infected lesion (usually from *Staphylococcus*) is less severe.
Example of Priority Item\textsuperscript{p} Violation

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

• Each part of the handwashing procedure, including vigorous rubbing of hands contributes to the reduction in pathogen load.
Example of Priority Item® Violation

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

- Processing of low acid canned foods (LACF) such as green beans requires stringent controls to prevent hazards such as *Clostridium botulinum* from growth and toxin production.

- Most foodborne outbreaks now from *C. botulinum* are related to home-conned foods.

- **Note**: Many provisions in Chapter 3 Food apply specifically to PHF/TCS food. Before applying a provision to a food or process, first consider whether the food meets the definition of PHF/TCS food.
  - Factors that will help you make this determination include:
    - Whether the food is raw/heat treated animal food
    - Whether the food is heat treated plant food
    - Whether the food is raw seed sprouts
    - Whether the food is cut melons, cut tomatoes or cut leafy greens
    - Whether the food is unmodified (not acidified) garlic-in-oil.
  - pH and/or water activity can also show whether the food is or is not PHF/TCS food
  - Past epidemiologic history of the food can also give an indication whether it supports the growth of foodborne pathogens.
Example of Priority Item Violation

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

• Even if employees report symptoms of foodborne illness and the PIC restricts or excludes as necessary AND handwashing takes place:
  • Asymptomatic employees (infected but not showing symptoms yet, recovering from illness but still shedding pathogens in stool, or in the carrier state where they are infected but not showing any symptoms at all (i.e., Typhoid Mary) may still contaminate food.
  • Employees may not always wash hands thoroughly enough to remove all pathogens present or all supplies such as warm water, soap and towels may not be present to ensure good handwashing
• The last barrier to prevent infected employees from contaminating food is to prohibit bare hand contact with RTE food.
Example of Priority Item\textsuperscript{P} Violation

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

• Since chicken has a higher pathogen load than other meats, a higher cooking temperature is needed to destroy pathogens present.
Example of Priority Item\(^p\) Violation

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

• When a non-continuous cooking process is used (interrupting the cooking process before it reaches the required time/temperature, then cooling the product to 41°F, storing it for a period of time under refrigeration and then completing the final cooking process to 165°F), a higher final cooking temperature is required no matter what the food is to overcome any additional pathogen growth from germinating spores or cross-contamination during cooling and cold holding.
Example of Priority Item\textsuperscript{p} Violation

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

While you are unable to observe the entire cooling process, the cook confirmed that the chili was made in the afternoon of the previous day and at 57°F at 9:30 am the next morning, still hasn’t reached the required 41°F within 6 hours total. Even allowing for cooling starting in the late afternoon, the chili has been cooling for more than 15 hours and didn’t reach 41°F in less than 6 hrs. This is a P Item violation according to 3-501.14(A)(2).

While cooling large volumes of food in large, deep containers will generally not meet cooling parameters without the assistance of other procedures, (ice bath, stirring, ice paddle, adding ice to food, etc.), this could be considered a “double mark” by some and is discouraged. Corrective methods including experimenting to find the method or combination of methods that are able to meet the requirements with logging times and temperatures for a time to verify that (A Risk Control Plan), should be part of the discussion with the PIC.
Example of Priority Item Violation

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

- Developing and using a date marking system (3-501.17) is a Pf Item because it enables the operator to determine a safe shelf life for refrigerated foods that support the growth of *Listeria monocytogenes*.

- Disposal of foods that support growth of *Listeria monocytogenes* (when no date marking system was used or because the storage time exceeded 7 days at 41°F or less) is the actual Priority Item that the date marking system supports or enables.
Example of Priority Item Violation

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

- The provisions in 3-502.12 are processes that allow certain foods to be processed and packaged using ROP technology without a variance because a validated process was submitted to FDA for approval and inclusion in the FDA Food Code.

- Without any secondary barriers in place besides refrigeration at 41°F (such as pH ≤ 4.6, aw ≤ 0.91, high levels of competing organisms, curing with nitrite and salt or intrinsic factors in certain cheeses).

- The storage temperature must be decreased to prevent growth of non-proteolytic C. botulinum and Listeria monocytogenes.

- Since cooked chicken has no secondary barriers, it must be held at 34°F for a shelf life of 30 days or at 38°F for 72 hrs. or a validated process (inoculation study) must be provided according to Section 3-502.11(D).
Example of Priority Item Violation

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

• The hazard in using galvanized metal in contact with acid fruit juices is that the acid product will leach tin from the container, producing toxic metal poisoning when consumed.
Example of Priority Item\(^p\) Violation

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

• A surface temperature of 160\(^\circ\)F is the control for sanitization that reduces the pathogen load to an acceptable level.
• The requirement for 180\(^\circ\)F final rinse water in 4-501.112 (see slide #73) along with other factors such as wash temperature, method of racking dishes, clear spray nozzles, etc. is a Pf Item because it enables the 160\(^\circ\)F surface temperature.
Example of Priority Item P Violation

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

• A backflow prevention device directly prevents contamination of the drinking water supply in case of a drop in water pressure.
Example of Priority Item Violation

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

• An indirect connection on the ice machine drain line will prevent backflow of waste water into ice in the ice machine storage bin.
Example of Priority Item Violation

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

• Improper storage (no separation) of toxic pesticides with food could result in cross-contamination.
Example of Priority Item\textsuperscript{p} Violation

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

• If the manufacturer of the chemical sanitizer has not petitioned and received approval from EPA for safety and efficacy of the chemical sanitizer, it may not effectively sanitize food contact surfaces as advertised.
Priority Foundation Item
Examples
No designated person in charge (PIC)

- **Provision** of Food Code: 2-101.11(A) Assignment
- **Correction**: Identify a PIC during all hours of operation
- **Rationale**: A PIC facilitates management control systems (monitoring, verification, training, etc.) that ensure Priority Items are in compliance

• If no one has been specifically identified as the person in charge, times when the regular manager (PIC) is absent from illness or other duties, no one person has the responsibility to make decisions and verify that corrective actions are done and conduct other activities related to active managerial control.
Example of Priority Foundation Item Pf Violation

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

• If the PIC does not monitor handwashing for appropriate time and method used, he/she will not be able to enable this important control for contamination of food and food contact surfaces and will not be able to take corrective action such as explaining and retraining.
Example of Priority Foundation Item Pf Violation

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

- Initial orientation training, refresher training and corrective training at the time inappropriate activities occur enable the PIC to support and enable employees to correctly carry out controls required by Priority Items.
Example of Priority Foundation Item\textsuperscript{Pf} Violation

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

- Maintaining and refilling supplies for proper handwashing enables employees to wash and dry their hands when necessary.
- Lack of paper towels at one hand sink is not a P Item because an employee who needs to wash and dry their hands could get paper towels from the store room or go to another hand sink for handwashing.
- If they wash hands without using a sanitary hand towel for drying (e.g., they use their clothes or a dirty cloth or don’t dry them at all, then this is a P violation (2-301.12)).
- The friction of drying hands with a towel can add another log reduction of pathogens to the handwashing procedure.
Example of Priority Foundation Item Pf
Violation

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

• Proper ingredient labeling enables consumers to make decisions about consumption because of allergens or other health reasons.
Example of Priority Foundation Item\textsuperscript{Pf} Violation

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

• Writing the date shellfish were last sold on the tag enables the foodborne illness investigator to bracket the time the shellfish could have been consumed, facilitating tracebacks and stopping shipment for shellfish that may be responsible for an outbreak.
### Example of Priority Foundation Item\(^{Pf}\) Violation

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

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• Although the chicken stock still has ½ hour to cool to 70°F to meet the first part of the cooling parameters (that is, to cool from 135°F to 70°F within 2 hrs. so this is not a cooling violation yet), your experience and ample research tells you that this method of cooling will not achieve 70°F for this large volume of product within the required time. You should make every effort to take a temperature later before you leave the facility to confirm the violation.

• A Pf Item requires use of specific actions or procedures by industry management to attain control of certain risk factors (P Items). The procedure or method of cooling 5 gallons of PHF in large containers does not adequately meet cooling parameters. The hazard, *Clostridium perfringens*, has a rapid generation time once any spores present have germinated.

• Always check with the PIC or specific individual responsible for moving the containers to be cooled into the walk-in cooler for the times and procedures they normally use so you can understand the process. Work with the PIC to identify methods to meet the cooling parameters.
Example of Priority Foundation Item\textsuperscript{Pf} Violation

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

In this slide, the operator has not developed and implemented a date marking system for RTE, PHF?TCS food held for more than 24 hrs. This system or procedure, 3-501.17, a Pf Item, enables the PIC to identify and discard food that is not served or sold within 7 days. The actual P Item, to prevent a hazard (infective doses of Lm) that could cause foodborne illness, is discarding RTE, PHF/TCS food that has been stored longer than 7 days.
Example of Priority Foundation Item Pf Violation

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

- A variance showing a validated procedure is used and a HACCP Plan that documents and verifies the use of this procedure to acidify rice to pH 4.1 or less enables the PIC to safely hold this product, previously PHF/TCS food, at room temperature.
Example of Priority Foundation Item\textsuperscript{Pf} Violation

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

The temperature gauge for the final rinse in a hot water sanitizing warewashing machine, measuring sanitizing water temperature at the manifold as it sprays out, gives an indication (enables the operator to judge) whether the sanitization process will be effective. Therefore this is a Pf Item. If the gauge shows a temperature less than required (i.e., 160ºF instead of 180ºF), this is an indication that something is wrong and sanitization at the surface of the utensil will likely not occur. The booster heater may not be operating properly. The water heater may be set too low. (A booster heater can only raise the temperature of water from the hot water heater about 40ºF) The temperature gauge may also be inaccurate.

A surface temperature of 160ºF or more on the utensil to achieve sanitization is the P Item that this provision supports. Other problems that can contribute to ineffective sanitization include racking dishes so some surfaces are masked from the sanitizing final rinse, clogged spray nozzles, altered spray pattern (nozzles bent), etc.
Example of Priority Foundation Item\textsuperscript{Pf} Violation

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

• Without the appropriate equipment (thin probe temperature measuring device), it is not possible to accurately measure final cook temperatures of PHF/TCS food. Cooking temperatures is the P Item.
Example of Priority Foundation Item

Violation

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

- Sampling and testing well water enables the PIC to determine if the water source provides safe drinking water free of pathogens and chemicals. If testing shows that it does not meet the standards, the PIC can treat the water to remove the impurities or use an alternate source of water.
Example of Priority Foundation Item<sup>Pf</sup> Violation

- **Hot water at handwashing sink is 70°F**
  - **Provision** in Food Code: 5-202.12(A) Handwashing Sink, Installation
  - **Correction**: Adjust water heater, sink mixing valve, etc. to provide 100°F water for handwashing
  - **Rationale**: Maintaining 100°F water for proper handwashing facilitates optimum temperature for use of soap and more effective removal of food soils and pathogens from hands

- Many food greases tend to solidify at lower temperatures, making them more difficult to remove.
- In addition, employees may be less likely to wash hands in cold water because of comfort levels.
Example of Priority Foundation Item Pf Violation

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

- Because of the fast-paced environment in food establishments, employees may not leave the immediate area of their work station if there is no nearby hand sink for handwashing.
Example of Priority Foundation Item Pf Violation

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

• A pest control plan which includes prevention, monitoring and eradication measures enables the PIC to keep the establishment free of pests which can contaminate food and food contact surfaces.
<table>
<thead>
<tr>
<th>Example of Priority Foundation Item&lt;sup&gt;Pf&lt;/sup&gt; Violation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unlabeled spray container of green liquid</strong></td>
</tr>
<tr>
<td>- <strong>Provision</strong> of Food Code: 7-102.11 Common Name</td>
</tr>
<tr>
<td>- <strong>Correction</strong>: Label working containers of poisonous</td>
</tr>
<tr>
<td>or toxic chemicals such as cleaners</td>
</tr>
<tr>
<td>- <strong>Rationale</strong>: Labeling working containers of cleaners</td>
</tr>
<tr>
<td>prevents mix-ups with food products or the wrong</td>
</tr>
<tr>
<td>chemical and accidental ingestion of chemicals that</td>
</tr>
<tr>
<td>can cause illness, injury or death</td>
</tr>
</tbody>
</table>

- Labeling on containers allows employees to distinguish between foods and chemicals and also between different chemicals which may have different uses and different toxicities.
Example of Priority Foundation Item\textsuperscript{Pf} Violation

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

• This labeling provides information to improve food safety handling of fresh meat and poultry in the home.
Core Item Examples
Example of Core Item Violation

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

• A hair restraint prevents loose hair, a direct and indirect vehicle of contamination, from falling into food and may deter employees from touching their hair.
Example of Core Item Violation

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

+ Storing food on the floor prevents employees from carrying out good sanitation practices such as cleaning, pest control inspections, etc.
Example of Core Item Violation

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

- Drainboards allow separation of dirty and clean dishes and utensils and control the runoff of draining water.
- Lack of a drainboard could promote storage of wet utensils (wet nesting)
Example of Core Item Violation

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

• Heavy grease build up on equipment allows microorganisms to reach high levels in the environment, a potential source for cross-contamination, and also provides an attractant and food source for pests (roaches, mice, etc.)
Example of Core Item Violation

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

• In addition to attracting pests and eroding fixtures, dripping faucets increase costs and waste water. If the faucet is turned off at the shut off valve, it also discourages employees from washing hands.
Example of Core Item Violation

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

- Uncovered garbage is an attractant which provides food and breeding grounds for pests. They can then easily enter the food establishment to contaminate food and food contact surfaces.
Example of Core Item Violation

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

• Broken and missing floor tiles can allow spills and cleaning water to deteriorate subfloors and also prevent easy cleaning and good sanitation practices.
Example of Core Item Violation

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

- Designing ventilation food systems above cooking appliances so the grease filters close off the entire space ensures that greasy air is filtered before being exhausted decreases the buildup in ductwork
- The PIC should ensure that a full set of grease filters is replaced when they are removed for cleaning.
Example of Core Item Violation

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

- Protecting outer openings (around doors, windows, utility lines that pass through the building walls, etc.) prevents the entry of pests from the environment around the facility.
Example of Core Item Violation

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

• If employees do not have a safe and separate area designated for the personal belongings, they will likely keep them nearby their work stations which could potentially contaminate food and food contact surfaces.
Example of Core Item Violation

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

- Jewelry, if not easily cleanable, can act as a reservoir for pathogenic organisms and cross-contaminate food.
- Stones and metal work from decorative jewelry can also fall off and become a physical hazard.
What should you do now?
Scenario #2

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

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

• This is another scenario to help you identify out of compliance provisions and prioritize or rank them according to their risk of causing foodborne illness.
• Once the priority Items in violation are identified, they should be corrected immediately.
What should you do now?
Scenario #2

First, identify & rank the violations according to risk level (P, Pf or C):

Priority Items
- Raw chicken dripping over salad dressing - 3-302.11(A)(1)(b)
- Disposition of undate marked RTE, PHF/TCS food not date marked - 3-501.18

Priority Foundation Items
- Refried beans cooled in 3 gallon stock pots - 3-501.15(A)(1-7) (DISCUSS)
- No date marking system used – 3-501.17(A)

Core
- Dirty fan guards & shelves – 4-601.11(C)
- Broken light shield – 6-202.11(A)
- Uncovered food – 3-302.11(A)(4)

Next, immediately correct P items, then Pf items, then C items as able.
Then, remind or retrain responsible individuals.
Finally, monitor those activities in the future.

The two P Items are RTE salad dressing cross-contaminated with drippings from raw chicken and disposition of many containers of leftover RTE, PHF/TCS food with no date marking.

Immediate correction of the cross-contaminated salad dressing (discard) but disposition of RTE PHF/TCS food with no date marking is more complicated. Section 3-501.18 says undate marked RTE PHF/TCS food must be discarded but there are a number of criteria and exemptions.

- The food must be held more than 24 hrs for required date marking.
- A management system where no food prepared on-site or opened, commercially prepared food is held overnight requires no date marking.
- Some RTE, PHF/TCS foods have natural or added intrinsic factors that inhibit Listeria, the pathogen of concern, so no date marking is required. Examples include:
  - Commercially processed deli salads (generally with a listeriocide added)
  - Hard, semi-soft, or pasteurized process cheese made under a standard of identity.
  - Cultured dairy products (yogurt, sour cream or buttermilk) with live cultures and lowered pH
  - Preserved (pickled or salted) fish products
  - Shelf stable (no refrigeration required), dry fermented sausages (pepperoni or Genoa salami)
  - Shelf stable, salt-cured products (prosciutto or Parma ham)

- When it is confirmed with the PIC that the foods with no date marking are not exempted and should have been date marked, the foods should be discarded if a reasonable way to identify how old they are (daily work orders, etc.) is not available.
- Double marking both 3-501.17 (no date marking system) and 3-501.18 (disposition) is not recommended but inspection remarks written as observations should explain the situation with recommended corrections if that is your policy and the discussion with the PIC should address both development of a system for date marking and disposition.
What should you do now?
Scenario #3

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

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

• Some of the things you observe are part of a process so you must follow up with questions to verify whether your deductions based on observations are in fact correct. Examples include:
  • Whether the cooling method for the Spanish rice was cooling it in 6” deep pans or was it spread in sheet pans for example and then transferred to the deep pan.
  • Also check whether the steam table is capable of reheating the Spanish rice to 165°F within 2 hrs when it is not pre-heated and the thermostat is broken.

• Once the Priority Item violations are identified (cooking with a sore throat and fever in a nursing home facility that serves highly susceptible populations and reheating using a method that will not reach the required temperature within the required time period – THIS MUST BE VERIFIED BEFORE IT IS MARKED AS A VIOLATION)
What should you do now?
Scenario #3

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

- Immediately correct P items, then Pf items, then C items
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

• The two Priority Items include
  • excluding the cook with a sore throat and fever (she/he should report these symptoms to the PIC and the PIC should then in turn exclude the cook from work in a facility that serves HSP or only restrict in a facility that serves a normal population)
  • Verifying that the Spanish rice is reheated to 165°F before serving. Since there are only 45 minutes before serving and the steam table was just turned on and may not be in good repair (broken thermostat), reheating criteria may not be met. Make a note to check before serving or point out that the reheating method being used may not meet reheating parameters so another method (microwave oven, steamer, etc.) might be more effective.

• The two Priority Foundation Items are:
  • No thermometer to check product temperatures such as refrigeration and reheating
  • Apparent method of cooling the Spanish rice (6” deep in containers put into the cooler) is unlikely to meet the cooling parameters. Verify with the PIC or the individual who prepared the rice and put it in the cooler the exact time and method that the rice was cooled. It is possible the rice was prepared and spread in thin layers on sheet pans, put into the cooler and then transferred to a deep container and covered to save storage space in the cooler. You did not observe a P Item violation (cooling) but there may be a Pf cooling methods violation based on their answer.
  • If you are unable to stay long enough to verify the effectiveness of either the cooling method or reheating method, you can still make the observation but no mark on the inspection report that methods used were unlikely to comply with Code requirements. Recommendations for meeting the criteria should be discussed with the PIC.
What should you do now?
Scenario #4

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

• The same process of identifying and ranking the violations must be done in this scenario.
• First, identify the Priority Item violations which are most likely to directly result in foodborne illness or injury because they need immediate correction.
What should I do now?
Scenario #4

First, identify & rank violations according to risk level:

- **Priority Items**
  - Mixing slaw with bare hands – 3-301.11(B)
  - No sanitizer used in 3-compartment sink – 4-701.11(C)(1)

- **Priority Foundation Items**
  - No soap at handwashing sink – 6-301.11
  - Pans stored with dried food – 4-601.11(A)
  - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11(A)
  - Many flies, not using some method of fly control – 6-501.11(C)

- **Core Items**
  - Cases of meat on floor – 3-305.11(A)(3)
  - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11

Immediately correct P items, then Pf items, then C items
Then, remind or retrain responsible individuals
Finally, monitor those activities in the future

• The two P Item violations that have the highest risk of causing foodborne illness are mixing slaw with bare hands (bare hand contact with RTE food) and not using a final sanitizing rinse (hot water or chemical) in the 3 compartment sink utensil washing procedure.

• The Pf Item violations are:
  - No soap at hand sink (6-301.11) to assist the handwashing procedure be more effective. They still have the opportunity to go to another hand sink with soap or get soap from supplies for handwashing when it is necessary. If the observation was actually washing hands with no soap, then it would be a P Item violation, 2-301.12(B)(2).
  - The procedure for receiving frozen food (“Keep Frozen”) should be to verify it is frozen upon receipt (mark 3-202.11(E), if not, and to place it immediately in the freezer for storage (not leave it out on the floor to thaw after delivery 3-501.11(A)). It is unlikely that the product is intentionally being thawed at room temperature on the floor, therefore 3-501.13(A) is not the correct mark. Ask the PIC what time the delivery was made to the facility.
  - No procedure or control measures were being used (pesticide application, fly bait, fly “zapper”, etc.) to control excess flies numbers of flies in the establishment. The corrective action is to not prop the door open (a self-closer is implied in the scenario, check for it) or install a screen door for ventilation (both are design/construction – Core Items). Then they must apply control measures to get rid of the flies. Flies indirectly contribute to spread of foodborne pathogens by walking or vomiting on food or food contact surfaces and transferring pathogens from their bodies.
How to Use the Annexes

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

• The three Annexes attached to these training slides are not requirements of the Food Code.
• Rather, they are provided to help you as you carry out your food safety activities, whether you are a regulator, industry representative or trainer
• One Annex helps you identify common food safety hazards that must be controlled to prevent foodborne illness or injury.
• Another Annex provides some hints to help you communicate better.
• The third Annex helps you make your education and training more effective at changing behavior that results in poor food safety practices.
How to Use the Annexes

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

How can regulators, operators and trainers effectively change behavior?
Effective Behavior Change

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

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

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

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

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

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

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

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

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

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

What are some communication techniques to help convey our messages of food safety?
Food Workers as Oral Culture Learners

- Effective communication is necessary to get your message across
- Inspectors and QA staff are usually print culture learners
  - They read for primary information
  - They have linear, analytical thoughts, are task oriented and able to strategize
- Food workers are often oral culture learners
  - Most workers like to give and receive information verbally
  - Workers are less likely to follow rules made by someone they do not know or trust
Oral Culture Learners

- Verbal information, repeated regularly and reinforced with signs, posters, handouts is an effective way to communicate
  - Fewer words and more pictures is better
- Storytelling is an important method of getting information for oral culture communicators
- Many owner/managers think employees should read food safety rules to learn
  - This thinking reveals a lack of understanding of how oral culture communicators learn and process information
Effective Communication

- Communication has to be 2-way to be effective
  - Explain/demonstrate the issue and have it explained/demonstrated back to you
  - Hands on training reinforces explanation
  - Feedback that they are “doing it right” is important
- Oral culture communicators require interaction to internalize knowledge and change behavior
- Active listening skills help pinpoint misunderstanding or lack of understanding
  - There is no other way to know if their communication was effective or even heard
  - This promotes joint problem solving
Communication by Behavior

- Effective communication shapes behavior
- We want to change unsafe food behavior and attitudes that disregard food safety processes
- 80-90% of what we communicate is by non-verbal behavior rather than by what we say
- Doing and correctly practicing the behavior internalizes the information communicated
- It is important for regulators, operators and trainers to consider different methods and their appropriateness to communicate risk and change poor behavior.
Communication by Behavior

- Correct behavior is often not modeled by management
  - “Do as I say, not as I do” doesn’t work
  - Role models (managers, co-workers, inspectors) are important
- Correct behavior is often not a priority
  - “If it’s not important to you, it’s not important to me”
Use Plain Language

- Use “I,” “you” and “we” and avoid “it”
- Use short sentences, limit subjects to one per sentence
- Use vertical lists with parallel construction
- Avoid technical and legal jargon or “big words”
- Use terms listeners or employees are familiar with
- Make factual statements and avoid subjective statements that imply judgment
Communication

- Pertinence to job duties
  - People learn if they understand the importance of their job behavior
  - Communication is best understood when it is personal
    - Related to assigned job duties
    - Described with vivid, real-life examples
    - Connected to their own family, health and well being
Communication

- General statements may not be considered relevant to the job – be specific
  - Why is something important?
  - What is the right way to do it?
  - Can the right way be demonstrated?
- Provide options/examples that are specific to that job
  - Use easily available equipment, utensils or materials
  - Give employees a choice and ask which one they prefer
  - Ask employees to try it out
What doesn’t work well?

- Presenting all training in written form such as signs, pamphlets, on-line computer training, handout materials
- Using examples that aren’t related to their job duties
- Using negative reinforcement (by itself)
- Saying something only once
- Using unfamiliar language or terminology
Annex C

What are common food safety hazards?
Each provision in the Food Code is intended to prevent, eliminate, reduce to an acceptable level or control hazards that could directly or indirectly contribute to a foodborne illness or injury.

A hazard is a biological, chemical or physical property or agent that may cause an unacceptable consumer health risk.

A hazard must be identified as the first step in conducting a risk assessment.
Biological Hazards

- Biological hazards consist of microbiological pathogens, including:
  - Spore-forming bacteria
  - Vegetative bacteria
  - Viruses
  - Parasites
- Most yeast and molds are spoilage organisms and do not cause illness or injury
New Foodborne Pathogens
Identified Since 1977

More than 70 foodborne pathogens are known with the following added to the list since 1977:

- Campylobacter jejuni
- Campylobacter fetus ssp. Fetus
- Cryptosporidium parvum
- Cyclospora cayetanensis
- Shiga-toxin producing E. coli
- Listeria monocytogenes
- Noroviruses
- Salmonella Enteritidis
- Vibrio vulnificus
- Vibrio cholerae 0139
- Yersinia enterocolitica
- Vibrio parahaemolyticus
- Salmonella Typhimurium DT 104
- Salmonella Typhimurium DT 104
- Spongiform encephalopathy prions
Controls for Biological Hazards

Provisions in the Food Code control biological hazards by eliminating, preventing, and/or reducing to acceptable levels or holding numbers unchanged by:

- Cooking, pasteurization
- Retorting
- pH/acidity
- Water activity
- Competing organisms
- Bacteriocins, nicin
- Preservatives
- Hot holding
- Cooling
- Refrigeration
- Sanitizers
- Fermentation
- Irradiation
- High pressure
- Nitrites, nitrates
Spore-Forming Bacteria

- *Clostridium botulinum, Clostridium perfringens, Bacillus cereus*
- Spores are able to survive cooking & other adverse conditions
- Spores do not multiply in this form so require no nutrients, water, etc. to survive
- Spores germinate & start to multiply when conditions are right – best control at this stage to prevent growth
- Retort processing (high temp & pressure) is necessary to destroy spores
- Toxins form after germination when the spore is actively growing
Vegetative Bacteria

- The growth phase of spore-forming and non spore-forming bacteria
- Nutrients, water and adequate environmental conditions (pH, $a_w$, temperature, etc.) are necessary for growth
- May form toxins in food or in the body
- Susceptible to cooking and many other environmental factors on a case-by-case basis
- Controlled by refrigeration although some vegetative bacteria can multiply slowly at refrigeration temperatures (e.g., *Listeria*, non-proteolytic *Clostridium botulinum*)
Viruses

- Viruses are pathogens which cannot multiply outside of a living cell
- Norovirus, hepatitis A and rotavirus are the most common foodborne viruses
- Infected human beings (not animals) are the usual source
- Preventing contamination (exclude infected workers, handwashing, no hand contact) and thorough cooking control viruses
- Viruses are very heat resistant
Typical Sources of Biological Hazards

- Field and farm crops – soil, birds, other infected animals, failed septic systems, sludge and biosolids contaminate food products
- Animals – manure, slaughtering process (skin, intestinal tract), service animals, pets and petting zoos contaminate food
- Fish and seafood – marine bacteria, histamine producing bacteria and fish parasites contaminate food

Some sources of hazards are introduced to the food product while it is being grown, raised, harvested or processed, that is, outside the food establishment and only control or destruction by cooking, for example, is possible, not always prevention.
Some sources of hazards are introduced to the food at the food establishment by food employees or dirty food contact or environmental surfaces. Some provision of the Food Code can prevent, eliminate or reduce to an acceptable level hazards that cause foodborne illness or injury. The degree of risk is dependent on many things:

- on the pathogen itself (virulence, severity, etc.)
- the level of contamination (pathogen load)
- the consuming individual (, immuno-compromised, HSP or not)
Characteristics of Pathogens

- Infectivity – potential or ease of transfer, infectious dose
- Severity – virulence of the pathogen, length & severity of illness, hospitalization or death
- Spore formers/vegetative cells – ability to survive adverse conditions
- Acid resistance – susceptibility to pH
- Heat resistance – ability to survive cooking
- Biofilm formation – ability to form a protective polysaccharide covering resistant to cleaning & sanitizing
- Association with certain foods – SE with eggs, *E. coli* O157:H7 in meat, cider, etc.

• The characteristics of a pathogen can help determine the risks of causing a foodborne illness and therefore was used to assign risk levels to provisions that are intended to control those pathogens.

• The levels of infectivity, how easily the organism/hazard infects an individual vary according to:
  - Highly infective norovirus can infect through 3 different pathways (ingestion of water or food, contact with mucus membranes such as eyes, or by aerosolization/inhalation)
  - *Listeria monocytogenes* has a very low infective dose, tens to hundreds of organisms, and is therefore is highly infective.

• Severity describes the effect the hazard has on the individual:
  - Virulence means the hazard/agent is extremely harmful
  - The length, symptoms and severity of the foodborne illness often results in hospitalization and/or death.
  - Less severe illnesses or injuries are shorter, have fewer or less harmful symptoms

• The ability to form spores means the pathogens can survive adverse conditions for long periods of time including normal cooking, dry conditions, lack of oxygen/ROP, etc.

• Acid (low pH) resistance means the pathogens can survive in naturally acid food (fruit and fruit juices) or in acidified foods.

• Heat resistance – some pathogens can adapt to higher temperatures, especially when protected by fats in the food.

• Some organisms including *E. coli* O157:H7, Salmonella and *Listeria monocytogenes* can form protective biofilms, a polysaccharide matrix, that protects them in adverse conditions.
Clostridium botulinum

Minimal growth requirement for *C. botulinum*

<table>
<thead>
<tr>
<th>Property</th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Proteolytic Type A, B, F</td>
<td>Non-Proteolytic Type B, F, E</td>
</tr>
<tr>
<td>Inhibitory pH</td>
<td>4.6</td>
<td>5.0</td>
</tr>
<tr>
<td>Inhibitory NaCl</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>Minimum <em>a</em>&lt;sub&gt;w&lt;/sub&gt;</td>
<td><strong>0.94</strong></td>
<td>0.97</td>
</tr>
<tr>
<td>Temp. optimum</td>
<td>98°F</td>
<td>86°F</td>
</tr>
<tr>
<td>Temp. range</td>
<td>50 - 118°F</td>
<td>38 - 113°F</td>
</tr>
<tr>
<td>Toxin production</td>
<td>≥ 50°F</td>
<td>≥ 38°F</td>
</tr>
</tbody>
</table>

- The minimum growth parameters for *Clostridium botulinum* show why this spore former has to have such stringent controls.

- There are six human strains and several different ways to classify *C. botulinum*: by Group, whether it is proteolytic (lyses blood cells) or non-proteolytic and by name of Type.

- The characteristics and sources (part of the world, soil, aquatic, etc.) of the pathogen are used to classify them:

  - *pH* or resistance to acid – Group I/Proteolytics are much more resistant to acid environments as they can germinate and produce toxin down to pH 4.6. This is the reason why pH 4.6 was previously considered the lower range of PHF food. Non-proteolytic *C. botulinum* is more sensitive to pH, it can only grow and produce toxin down to pH 5.0.

  - *Salt concentration* – Group I/Proteolytic *C. botulinum* strains are able to grow and produce toxin in a 10% salt solution (very salty) versus 5% for non-proteolytics.

  - *Water activity* – Group I/Proteolytic strains are able to grow and produce toxin at a relatively low water activity of 0.94. Group II/Non-Proteolytic strains’ lower limit is 0.97.

  - *Temperature* – Temperature is the parameter most easily controlled with foods and the growth factor for *C. botulinum* that separates the two most easily. Group I/Proteolytic strains have an optimum growth temperature of 98°F and a lower range of 50°F (well controlled by normal refrigeration temperatures.) Group II/Non-Proteolytic strains (generally found in seafood) can multiply and produce toxin at 38°F, below normal refrigeration temperatures, therefore more difficult to control with temperature alone.
**Clostridium botulinum**

- *C. botulinum* is an obligate anaerobe, spore-former, common in soil & aquatic environments (salt and fresh water)
  - Proteolytic *C. bot* – more pH & salt resistant, more resistant to low $a_w$, only grows & produces toxin down to 50°F
  - Non-proteolytic *C. bot* – less pH & salt resistant, less able to grow at low $a_w$, can grow and produce toxin down to 38°F

- Preformed toxin is heat labile (boiling 10 min.)
- Improper canning, retorting and reduced oxygen packaging (ROP) are risks
**Clostridium perfringens**

- *C. perfringens* is an anaerobic spore-former found in humans, animals, soil and vegetation
- Cooking heat shocks spores
- Generation time can be 8 minutes starting at 122 - 127°F
- Contributing factors for illness include:
  - Slow cooling (allows germination of spores)
  - Inadequate refrigeration (allows growth of cells)
  - Inadequate reheating (allows survival of cells)
- Vegetative cells sporulate (return to spore form) in gut and release toxin
- Large numbers of cells (≥10⁵) are required to cause illness
Bacillus cereus

- *B. cereus* is an aerobic spore-former
- Spores are ubiquitous in the soil & environment
- 2 types of toxins can be formed:
  - Emetic is heat stable, formed in food
  - Diarrheal is heat labile, formed in intestine
- Slow cooling and inadequate refrigeration allow spore germination and growth to high numbers
- Toxin is not produced at temperatures < 50°F
- $10^5$ – $10^6$ cells needed to produce toxin
• Instead of looking at the clinical aspects of *Salmonella*, let’s look at its ecology, how it moves around and interacts with its environment. In other words, why it’s so successful as a foodborne pathogen.

• *Salmonella enterica* with over 2000 subtypes is normally a commensal organism in the lower intestine of animals. That means it lives peacefully with other organisms, not doing harm as a parasite might. Obviously several subtypes have gone beyond that.

• *Salmonella* also survives in birds (SE in eggs) and reptiles (reason for the prohibited sale of baby turtles).

• *Salmonella* can survive for many months under the right conditions in the environment.

• *Salmonella* also forms biofilms as a protective mechanism which makes it very difficult to remove from a surface whether it is fresh produce or a cutting board.

• Finally, *Salmonella* is relatively heat resistant.
**Escherichia coli** O157:H7

- Cattle and other animals are reservoirs
- Survives well in the environment
- Forms biofilms resistant to washing and sanitizing
- pH resistant
- Transmitted mainly through the ingestion of food contaminated with ruminant feces

- *E. Coli* is also a commensal organism in the lower gut of mammals. All of us in fact, carry *E. coli*. But as with *Salmonella*, some of them exchanged a little genetic material with their bacterial friends and we have Enterotoxigenic *E. coli*, Enterohemorrhagic *E. coli*, or Enteroinvasive *E. coli*.
- Cattle are the primary reservoirs but other animals and humans may be as well.
- It survives well in the environment for weeks or even months under the cool, wet conditions.
- It forms biofilms for protection as does *Salmonella* and *Listeria*.
- It is very pH resistant, surviving in apple cider at pH’s as low as 3.3. Many people think that fresh produce, especially fruits are protected by their low pH but this may not always be the case.
- You often see generic *E. coli* used as an indicator organism for fecal contamination. Since an indicator should have a survival rate equal to or slightly higher than the bacteria of interest. *E.coli* may not be a good indicator for *Salmonella*. 
**Escherichia coli O157:H7**

- Inadequate cooking and cross-contamination of RTE food are contributing factors
- Shiga-toxin produced in the gut is absorbed into the blood stream
- Damages small blood vessels
  - Leading to bloody diarrhea, kidney failure and death
  - Causes 90% of diarrhea and associated HUS
**Staphylococcus aureus**

- People are carriers (skin, nasal passages, infected lesions) as well as dogs, fowl, cows with infected udders
- Non spore-former produces toxin at $a_w$ too low for competing bacteria
  - Growth at $a_w = 0.83$,
  - Toxin production requires $10^6 – 10^7$ CFU/g
  - Toxin produced at $a_w = 0.88$
  - Pre-formed toxin produced in food
- Reheating destroys cells but toxin is heat stable
- Food likely to be contaminated by hand contact with RTE food and infected lesions
Listeria monocytogenes (Lm)

- *Listeria* is ubiquitous in the environment
- Lm forms biofilms resistant to washing & sanitizing in high moisture niches
- Lm multiplies slowly at refrigeration temperatures down to 32°F
- Controls include addition of listeriocides to food, short shelf life (datemarking), preventing contamination from the environment, refrigeration, cooking, adequate cleaning & sanitizing
- Fetuses (miscarriages), babies, pregnant women and the elderly are particularly susceptible – high case fatality rate
Norovirus (NOV)

- Human beings are the reservoir for NOV
- Norovirus is reported as the single most common cause of gastroenteritis in the western world
- NOV is transmitted by:
  - Fecal-oral route (through food)
  - Inhalation (breathing vomitus droplets)
  - Person-to-person (touching someone contaminated)
  - Environment to person (touching contaminated surfaces)
Norovirus

- NOV infectious dose is 1 particle (a cluster of 200-300 viruses), highly infectious
- $10^9 - 10^{10}$ particles/g feces (the size of the tip of a fingernail)
- NOV is highly resistant to disinfectants
- Projectile vomiting or diarrhea episode
  - Needs to be contained (covered)
  - Then double wash and disinfect surfaces
  - Discard protective clothing and cleaning materials
- Virus survives in environment hours to days
Hepatitis A (HAV)

- HAV is spread from human beings through:
  - Contaminated sewage in wells, seafood harvest areas, recreational waters
  - Fecal-oral route (contaminated food)
  - Person to person
- HAV is shed at $10^8$ viral particles /g feces
- Shed in feces midway through incubation period before symptoms appear
- Symptoms can last 6-9 months
- Controls are handwashing, no bare hand contact with RTE foods, exclusion with jaundice, shellfish certification & tag retention for 90 days
Parasites

- **Anisakis**
  - The motile larval stage burrows into the stomach walls
  - Infection caused by eating raw or undertreated marine fish

- **Cryptosporidium parvum**
  - Infects 45 different species besides man
  - Oocysts (infective stage) often associated with contaminated drinking & recreational water
  - Oocysts are highly resistant to disinfection
Parasites

- *Cyclospora cayentanensis*
  - Oocysts are infective
  - Often found in contaminated water

- *Giardia lamblia*
  - Reservoir is human beings & wild animals
  - Protozoan cysts & trophozoites shed in feces
  - Often associated with contaminated water or person-to-person transfer in day cares
Chemical Hazards

- A chemical hazard may be naturally occurring or may be added during processing or preparation
- Normal cleaners, sanitizers and other chemicals used in a facility may be a food hazard
- Scombrotoxin (histamine poisoning)
  - Formed by bacteria that convert histidine to histamine
  - Found in tuna, mackerel, skipjack, bonito, mahi mahi, blue fish and certain cheeses
  - Temperature abuse allows bacterial growth and histamine formation
Chemical Hazards

- Ciguatoxin
  - Found in tropical reef fish (i.e., barracuda, a predator fish)
  - Dinoflagellates and algae that produce the toxin are consumed by fish
  - Causes temperature reversal (hot ↔ cold) and other neurological symptoms, often for years
Chemical Hazards

- Tetrodotoxin
  - Certain fish (e.g., puffer fish, fugu, blow fish) produce toxin in their skin and viscera
  - Tetrodotoxin is heat stable – cooking will not destroy

- Aflatoxin
  - Mycotoxin produced in corn, nuts and other grains

- Patulin
  - Mycotoxin produced in rotten apples
  - Not destroyed by pasteurization or cooking
Chemical Hazards

- Monitoring shellfish harvest areas for certain phytoplankton prevents shellfish poisoning
- Common shellfish poisoning includes:
  - Paralytic shellfish poisoning (PSP)
    - Molluscan shellfish, lobster and crab concentrate saxitoxin from certain dinoflagellates (“red tide”)
    - From a heat stable toxin
    - Flushed from animal within weeks
Chemical Hazards

- Common shellfish poisoning includes:
  - Diarrhetic shellfish poisoning (DSP)
    - Molluscan shellfish concentrate toxins from certain dinoflagellates
    - Heat stable toxin
  - Neurotoxin shellfish poisoning (NSP)
    - Molluscan shellfish concentrate brinotoxins from algal blooms
    - Toxic to fish, birds and sea mammals too
Chemical Hazards

- Common shellfish poisoning includes:
  - Amnesic shellfish poisoning (ASP)
    - Shellfish, Dungeness crabs and anchovies concentrate domoic acid produced by a diatom
    - Produces short term memory loss
  - Toxic mushroom species – False morels, Little Brown Mushrooms, Jack-O’-Lantern, Green-Spored Lepiota, Deathcap, Death Angel
  - Toxic plant species – Belladonna, bloodroot, buckeyes, castor bean, foxglove, hemlock, holly berries, Lily of the Valley, mandrake, May apple, mistletoe, rhubarb leaves, snakerooot
Physical Hazards

- Illness and injury can result from foreign objects in food including:
  - Glass – from lights, bottles and jars, utensils, gauge covers
  - Wood – from fields, pallets, boxes, buildings
  - Stones, metal fragments – from fields, buildings, machinery, wire
  - Bone – from improper plant processing
  - Plastic – from packaging materials, pallets
  - Personal effects – jewelry, buttons, band aids, etc.
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

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.
FREQUENTLY ASKED QUESTIONS

THE RE-DESIGNATION OF FOOD CODE PROVISIONS

Introductory

1. Why have the terms “critical and “non-critical” been replaced with other terms in the Food Code?

2. What is the rationale for utilizing three designations in the Food Code, rather than two designations?

3. What are the names of the three designations and what are the definitions?

4. Who was involved in the process to change from critical/non-critical to priority, priority foundation, and core?

5. Why was the FDA Criticality Work Group formed and who was on the work group?

6. Are there any plans for a focus group study to be conducted by the Conference for Food Protection’s (CFP) Criticality Implementation and Education Committee or by FDA as was charged by the CFP?

7. What is the level of risk for each designation?

8. What are some examples of each designation?
   a. Priority Item Examples:
   b. Priority Foundation Item Examples:
   c. Core Item Examples:

9. Why is each subparagraph of the Food Code now designated?

10. Will all regulatory jurisdictions be required to adopt the new designations?
11. When will the regulatory jurisdictions be required to adopt the 2009 Food Code with these new designations in order to meet Program Standard #1?

12. Will regulatory jurisdictions be required to adopt the designations Priority, Priority Foundation and Core in order to meet Program Standard #1?

Food Safety Issues

1. How will the change to three designations (or categories) of importance improve food safety and reduce illness?

2. Are the priority foundation items a direct cause of foodborne illness?

3. Are the three designations based on scientific data and will they change if the science changes?

4. How can the three designations be used by Industry to minimize risk factors within their operation?

Regulatory Issues

1. Will the methods used to conduct inspections change because of the new designations?

2. How can regulatory inspectors use the three designation system to maximize their time during inspections?

3. How will the three designation system help prioritize the time of regulators and industry?

4. My jurisdiction is using the CFP inspection form. Will the three designation system result in a modification of the provisions listed in the risk factor and intervention code reference table? Will the Good Retail Practices code reference table be modified due the change to the three designation system?

5. Will the inspection form change due to the change to the three designation system?

6. How much time must a regulator allow a food establishment to correct violations in the following designations?
   
   a. Priority Item violations:

   b. Priority Foundation Item violations:

   c. Core Item violations:
7. What are some specific examples of the enforcement actions of the priority or priority foundation item violations?

   a. If using a risk based assessment of a food establishment in a jurisdiction that enforces 41F, would TCS food held at 45F be considered a priority foundation item or priority item violation?

   b. If using a risk based assessment of a food establishment in a jurisdiction that enforces 140F, would TCS food held at 135F be considered a priority foundation item or priority item violation?

   c. If using a risk based assessment of a food establishment and the sanitizer sink solution in a refrigerated prep room falls below 75F, is this a priority item, priority foundation item, or core item violation or no violation?

8. Is there a recommended scoring mechanism or matrix relating violations of the three designations to points?

9. Will the new designations impact risk factor and intervention baseline activities that we are following as part of our enrollment in the FDA Program Standards?

Training / Industry Issues

1. When will the new three designation system be in effect?

2. Will there be a “transition time” from the old system to the three designation system?

3. Where can I find more information about the new three designation system?

4. When will the ANSI-CFP licensed examination providers integrate the new designations into their job analysis and examinations?

5. Will FDA revise the Standardization Procedures Manual to reflect the new three designation system? Will the new designations require any changes in the standardization process?

6. Are guidelines/tools being developed to assist local and state health jurisdictions in the process of evaluating their current risk-based inspection system based on the new designations?

7. Since uniform training is a priority to assure the knowledge and implementation of the new designations, will training workshops, materials or a PowerPoint be developed for industry and regulators?

8. Will the health department provide classes so we can understand the new designations?
9. How can industry use the new designations in training front line workers?

10. Will my health department inspection look different?

11. Is the new designation system more subjective?

12. Will a list of primary changes be provided?

13. What will cause a health code violation with the new designations?

14. How long will I have to correct violations in the following designations?

   a. Priority Item violations:
   b. Priority Foundation Item violations:
   c. Core Item violations:

15. What happens if my restaurant gets multiple violations?

16. What is an example of a Priority violation that was a critical violation?

17. A display of window glass cleaner over paper towels is now listed as a critical violation by my regulatory agency. Would this practice now be designated as a Priority Item violation or a Priority Foundation Item violation? Why?
Title:

Criticality Implementation&Educational 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. Pr

(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 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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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.
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 reference 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 degrees below 140. The revision finally passed at the '08 conference. (comment: some will say that the point at which the critical limit should be measured is a core temp. This is not true. Surface temps are most likely to be abused when you are hot or cold holding....not core temps.) Note that the CCL’s change based upon the local licensing authority, and the method and means for measuring the critical limit may vary by interpretation and inspector. Further confusion abounds do to differences in equipment performance test standards critical limits and the food codes criteria. For example, the NSF/ANSI standard 7 critical limit measurement point for cold holding is 1” below the surface of the food. The food code requires all of the food to be at the stated CL or better without exempting the top 1” layer of food. Then, where is the point of measurement for hot holding critical limit relative to the code vs. NSF/ANSI Std 4? These "gaps" reduce the effectiveness of the codes risk message.

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

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Attachments:
• "The Three Tiers for Microbial Critical Limits"

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The Three Tiers for Critical limits

By Tom Johnson, JDP, Inc. tomj@jdpinc.com

Effective risk communication is crucial to reducing risk and it is a core principle of risk management.

The FDA Food Code has embraced the principles of HACCP from a process perspective, whereby throughout the code critical control points are denoted as **Priority items** (P), control points, or the control procedures needed to ensure compliance of the Priority item are referred to as **Priority foundation** (Pf), and standard sanitary operating procedures (SOP’s, which have also been called **prerequisite programs**) are referred to as **Core items**.

The above recent addition/revisions to the code were implemented in part to enhance the risk communication relative to common food product/processes. It is well known that effective risk communication requires that those in the communication loop share the same perspective and frame of reference. Because the FDA Food code is constantly evolving, the specific critical limits in today’s code are often different than those found in food rules published in older editions. This presents a moving target due to the different dates of rule adoption by the many dozens of States and the thousands of boards of health and other licensing authorities.

This jurisdiction-to-jurisdiction variability confuses food handlers, risk managers and the public yielding ineffective risk communication. When people do not understand the basis for the variability of critical limits, the integrity of the whole code suffers with a corresponding increase in risk.

Here is but one example of the above referenced critical limit confusion: *what is the critical limit for hot food holding?*

The answer: it depends where you are and what you are talking about.

Effective risk communication mandates that we cut through this fog and clearly articulate facts.

To keep our process HACCP risk communication effective, we must have a tight correlation of each stated critical limit to our intended point of reference.

There are up to three different critical limit concepts or points of reference for every pathogen related critical control point:

1. **The science based critical limit.** Lets call it the “SCL”. It is the same in Saigon as in St. Paul. If we identify all of the environmental and food characteristics that give rise to the given microbial hazard, then we can agree upon peer reviewed published data and given statistical analysis and the consensus standards process establish a single **fixed “SCL”**. With that, we’d likely say that 127.5F is the SCL for hot food holding based upon peer reviewed, published scientific research (*F. Busta, et al*).

2. **The compliance critical limit.** Lets call it the “CCL”. In Minnesota, since their administrative rule (MR4626) is based on the 1995 FDA Food Code, that minimum hot
safe food holding temp is 140F. In Maryland where they modeled code after the 2008 FDA Food code and their Title 10, subtitle 15 Chapt 03.06 states: “(7) Except as provided in §B(8)—(14) of this regulation, the internal temperature of a potentially hazardous food is kept at 41°F or less or 135°F or greater”. The downward revision to 135F was hotly debated for several CFPs with data presented in council 3 to support the scientific critical limit was at least 12 degrees below 140. The revision finally passed at the ’08 conference. (comment: some will say that the point at which the critical limit should be measured is a core temp. This is not true. Surface temps are most likely to be abused when you are hot or cold holding....not core temps.) Note that the CCL’s change based upon the local licensing authority, and the method and means for measuring the critical limit may vary by interpretation and inspector. Further confusion abounds do to differences in equipment performance test standards critical limits and the food codes criteria. For example, the NSF/ANSI standard 7 critical limit measurement point for cold holding is 1” below the surface of the food. The food code requires all of the food to be at the stated CL or better without exempting the top 1” layer of food. Then, where is the point of measurement for hot holding critical limit relative to the code vs. NSF/ANSI Std 4? These “gaps” reduce the effectiveness of the codes risk message.

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

HACCP is about RISK, not quality. That said many if not most companies integrate quality criteria into their HACCP plans, largely for convenience. Nonetheless, it is not logical to have your QCL as your CCP. You may use the local CCL for your CCP, but the SCL must be also stated so food handlers and risk manager can better understand the required interventions for the stated hazard given its scientific underpinnings.

If everyone that got certified as a food manager by one scheme or another had this fundamental differentiation as a part of their training, then they would have the foundation to understand the science based limit and the public health rationale for the compliance critical limit being different specific values.

Further, by accommodating a quality critical limit, retailers and food service operators can create a single HACCP plan (or food plan if you prefer) with dramatic improvement in the effectiveness of their plans risk communication.

Effective risk communication is fundamental to risk analysis and management. HACCP is mush without it.

Tom Johnson  CFP 2010
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 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:

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

American National Standards for Food Equipment - Clarification of Food Code

Issue you would like the Conference to consider:

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

Public Health Significance:

The rapid increase of imported foods and food equipment, and the many public health related issues associated with imported products, makes it vitally important to have products comply with American National Standards, where specific requirements for compliance are clearly spelled out. Manufacturers, exporters, importers, wholesalers, retailers, consultants and regulators at all levels understand the role and importance of American National Standards, and participate in their development and maintenance. Specification of the appropriate national standards in the Model Food Code clarifies the original intent, increases consistency of certifications, and results in increased public health protection. Having clearly defined equipment requirements is essential to increasing regulatory compliance.
Background

Equipment sanitation is a critical component of state and local regulatory food safety programs, and is an integral part of the Model Food Code. Food equipment materials, performance, design and cleanability are all critical components of the Model Food Code and are detailed in the American National Standards for Food Equipment. The purpose of the current Section 4-205.10 of the Food Code is to reference ANSI-accredited third party certifications or classifications of Food Equipment. It is implied that the certifications or classifications are to the requirements of specific American National Standards. Given the widespread adoption of the Model Food Code at the State and Local levels, it is very important that the intent of the FDA and the CFP is without question.

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

Acceptability 4-205.10 Food Equipment, Certification and Classification.

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

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

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

Recommended Solution: The Conference recommends...:

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

Acceptability 4-205.10 Food Equipment, Certification and Classification.

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

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Attachments:
• "Proposed ANNEX 8 of Food Code"
• "NEHA Letter of Support"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.
## Proposed ANNEX 8 of Food Code

### List of ANSI Food Equipment Standards

The following standards were established and adopted by the ANSI process as minimum voluntary consensus standards and are also used internationally:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
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<tr>
<td>NSF/ANSI 2</td>
<td>Food equipment</td>
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<tr>
<td>NSF/ANSI 3</td>
<td>Commercial warewashing equipment</td>
</tr>
<tr>
<td>NSF/ANSI 4</td>
<td>Commercial cooking, rethermalization, and powered hot food holding and transport equipment</td>
</tr>
<tr>
<td>NSF/ANSI 5</td>
<td>Water heaters, hot water supply boilers, and heat recovery equipment</td>
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<td>NSF/ANSI 6</td>
<td>Dispensing freezers</td>
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<td>NSF/ANSI 7</td>
<td>Commercial refrigerators and freezers</td>
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<td>NSF/ANSI 8</td>
<td>Commercial powered food preparation equipment</td>
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<tr>
<td>NSF/ANSI 12</td>
<td>Automatic ice making equipment</td>
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<tr>
<td>NSF/ANSI 13</td>
<td>Refuse processors and processing systems</td>
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<tr>
<td>NSF/ANSI 18</td>
<td>Manual food and beverage dispensing equipment</td>
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<tr>
<td>NSF/ANSI 20</td>
<td>Commercial bulk milk dispensing equipment</td>
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<td>NSF/ANSI 21</td>
<td>Thermoplastic refuse containers</td>
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<td>NSF/ANSI 25</td>
<td>Vending machines for food and beverages</td>
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<td>Detergent and chemical feeders for commercial spray-type dishwashing machines</td>
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<td>NSF/ANSI 35</td>
<td>High pressure decorative laminates (HPDL) for surfacing food service equipment</td>
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<td>NSF/ANSI 36</td>
<td>Dinnerware</td>
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<td>NSF/ANSI 37</td>
<td>Air curtains for entranceways in food and food service establishments</td>
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<td>NSF/ANSI 51</td>
<td>Food equipment materials</td>
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<td>NSF/ANSI 169</td>
<td>Special purpose food equipment and devices</td>
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<tr>
<td>ANSI/UL 2333</td>
<td>Infrared Thermometers</td>
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</tbody>
</table>
December 21, 2009

Conference for Food Protection
2792 Miramar Lane
Lincoln, CA. 95648

To Whom It May Concern:

The National Environmental Health Association (NEHA) is pleased to provide this letter of support for the 2010 CFP issue titled: *American National Standards for Food Equipment – Clarification of Food Code Intent*, which was drafted by NSF International and Underwriters Laboratories Inc.

While Section 4-205.10 of the Model Food Code identifies the need for food service equipment to be certified by an ANSI-Accredited organization, it is lacking with respect to identifying a specific standard(s) for the equipment certification. The language proposed in this issue submission identifies the appropriate national standard(s) for product certification. Addition of this language completes both the need for certification as well as the means of certification.

NEHA urges the Conference for Food Protection to accept this issue and incorporate the suggested language into the Model Food Code.

Sincerely,

Welford C. Roberts, M.S., Ph.D., R.S. / R.E.H.S., D.A.A.S.
NEHA President
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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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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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.
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.


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

**Submitter Information:**
Name: Teresa Bullock, Food Protection Program Director
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.
Title:

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

Issue you would like the Conference to consider:

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

Public Health Significance:

Grinding intact beef "in house" may spread pathogenic contamination from the exterior of an intact product throughout the resulting ground beef, or, may serve as a source of cross-contamination of grinding equipment. Further, consumers may mistakenly believe that ground beef produced "in house" in this way is fresher or safer, and thus may order such products undercooked (i.e. rare or medium rare), which is insufficient to kill pathogens.

It is thus imperative that those employees tasked with handling and grinding such meats (and those employees responsible for cleaning the grinding equipment, if different) are specially trained in both the logistics of cleaning and the importance of rigorous cleaning for the prevention of foodborne illness.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending the addition of the underlined language to Section 2-103.11 of the Model Food Code, Duties: Person in Charge:

2-103.11 Person in Charge.
(L) EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties; specifically and especially those employees who may be responsible for production and handling of "in house" ground beef, such as the grinding of PRIMAL CUTS and WHOLE MUSCLE, INTACT BEEF: and

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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.
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"

*It is the policy of the Conference for Food Protection to not accept issues that would endorse a brand name or a commercial proprietary process.*
Attachment A – Suggested Changes to 2009 Food Code - Mandatory Food Protection Manager Certification for Person in Charge

Responsibility

2-101.11 Assignment. (unchanged)

1. (A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall be the PERSON IN CHARGE or shall designate a PERSON IN CHARGE and shall ensure that a PERSON IN CHARGE is present at the FOOD ESTABLISHMENT during all hours of operation.°

2. (B) In a FOOD ESTABLISHMENT with two or more separately PERMITTED departments that are the legal responsibility of the same PERMIT HOLDER and that are located on the same PREMISES, the PERMIT HOLDER may, during specific time periods when food is not being prepared, packaged, or served, designate a single PERSON IN CHARGE who is present on the PREMISES during all hours of operation, and who is responsible for each separately PERMITTED FOOD ESTABLISHMENT on the PREMISES.°

Knowledge

2-102.11 Demonstration. (proposed changes in underline and strikeout)

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY possess knowledge of foodborne disease prevention, the application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. As it relates to the operation of the specific FOOD ESTABLISHMENT and in response to questions that may be posed by the REGULATORY AUTHORITY, the PERSON IN CHARGE shall demonstrate this knowledge by:

(A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection;°

(B) Being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM;° or

(C) Responding correctly to the inspector’s questions as they relate to the specific FOOD operation. The areas of knowledge include:

(1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE;°

(2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease;°
(3) Describing the symptoms associated with the diseases that are transmissible through food; Pf

(4) Explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food (time/temperature control for safety food) and the prevention of foodborne illness; Pf

(5) Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish; Pf

(6) Stating the required food temperatures and times for safe cooking of potentially hazardous food (time/temperature control for safety food) including meat, poultry, eggs, and fish; Pf

(7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food (time/temperature control for safety food); Pf

(8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:

   (a) Cross contamination, Pf

   (b) Hand contact with ready-to-eat foods, Pf

   (c) Handwashing, Pf and

   (d) Maintaining the food establishment in a clean condition and in good repair; Pf

(9) Describing foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction. Pf

(10) Explaining the relationship between food safety and providing equipment that is:

   (a) Sufficient in number and capacity, Pf and

   (b) Properly designed, constructed, located, installed, operated, maintained, and cleaned; Pf

(11) Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment; Pf
(12) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; Pf

(13) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW; Pf

(14) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code; Pf

(15) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the FOOD ESTABLISHMENT; Pf

(16) Explaining the responsibilities, rights, and authorities assigned by this Code to the:

(a) FOOD EMPLOYEE, Pf

(b) CONDITIONAL EMPLOYEE, Pf

(c) PERSON IN CHARGE, Pf

(d) REGULATORY AUTHORITY; Pf and

(17) Explaining how the PERSON IN CHARGE, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION OR RESTRICTION of FOOD EMPLOYEES. Pf

2-102.20 12 Food Protection Manager Certification.

A The PERSON IN CHARGE who demonstrates knowledge by being shall be a FOOD protection manager that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs is deemed to comply with ¶ 2-102.11(B).


