



SEP 1 2011

Ms. Sheri Morris, Chair
c/o Conference for Food Protection
1302 Silver Spur Circle
Lincoln, California 95648-2070

Dear Ms. Morris:

The Food and Drug Administration (FDA) received a letter dated June 23, 2010, from Mary Fandrey, the past Chair of the Conference for Food Protection (CFP). The letter conveyed CFP's latest recommendations related to the FDA Food Code and other issues. This response is a follow-up to the report provided by Kevin Smith to the CFP Executive Board on August 30, 2010, and is intended to provide the latest information on how FDA has addressed or plans to address the recommendations put forward by CFP.

FDA appreciates the efforts of participants in the 2010 Biennial Meeting of the CFP to develop recommendations that will further the collaborative efforts of Federal, state, local, territorial and tribal agencies and our partners in industry, academia, and consumer protection. Many of these recommendations will serve to improve the content and implementation of the Food Code, the Voluntary National Retail Food Regulatory Program Standards and other FDA documents that promote retail food safety. Part 1 of the CFP letter itemized the 2010 CFP Recommendations related to the Food Code and Part 2 contained recommendations pertaining to other FDA documents and activities. My response will follow that convention as well.

Part 1

FDA will publish on its website a Supplement to the 2009 Food Code (the Supplement) this month. The Supplement includes changes that reflect FDA's position on the sixteen Food Code-related recommendations from the 2010 Biennial Meeting. In developing the Supplement, FDA considered all the relevant CFP recommendations. The Supplement contains modifications to the 2009 Food Code that address thirteen of the sixteen recommendations made by the 2010 CFP.

In the Supplement, FDA has taken the liberty of revising the specific text suggested in many of the 2010 CFP Recommendations, including some significant modifications. The reasons for these revisions generally fall into one or more of the following categories:

- 1) text has been modified to achieve consistency with the structure or format conventions of the FDA Food Code;
- 2) text has been modified to enhance the clarity of the intent of the recommendation as understood by FDA;
- 3) text was modified to ensure consistency with other provisions of the Food Code that were not under consideration at the 2010 CFP Meeting;
- 4) text was modified to reflect an FDA position that differs in some way from what was suggested by CFP and prevents us from fully incorporating the recommendation.

Of the 2010 CFP Recommendations related to the FDA Food Code, the following are reflected, in whole or in part, in the Supplement:

2010-I-011; 2010-I-017; 2010-I-019; 2010-I-021; 2010-I-022; 2010-I-024

2010-II-021 2010-III-005; 2010-III-013; 2010-III-020; 2010-III-022; 2010-III-023; 2010-III-024

FDA believes that additional consideration must be given to the following three 2010 CFP recommendations before making any modifications to the FDA Food Code: 2010-III-006; 2010-III-007; 2010-III-015. A brief explanation of why these recommendations were not addressed in the Supplement is provided here.

2010-III-006 recommended that the Food Code no longer specify a minimum temperature for wash solutions for manual warewashing operations and that instead an operator should rely strictly on instructions provided by the manufacturer of the cleaning agent to determine the appropriate minimum temperature of the wash solution.

While FDA acknowledges that certain types of detergents may be effective in removing soils at water temperatures lower than 110°F, use instructions for detergent or cleaning agents are not required to specify a minimum water temperature. Further, employee access to use instructions may be limited. FDA believes that a standard that is widely recognized by operators and regulators is more protective of public health. It should be noted that the vote to accept this recommendation by CFP Assembly of Delegates was made by a narrow margin.

2010-III-007 recommended that the Food Code be modified to allow the wash solution applied by spray-type warewashing equipment to be at any temperature rather than the minimum temperatures currently specified in Section 4-501.11 of the Food Code provided the equipment has been evaluated and verified by a third party certifying body to a standard as meeting a sanitizing performance criteria of 5 log reduction of pathogens of public health concern. The current recognized American National Standard for commercial warewashing equipment (NSF/ANSI Standard No. 3-2010) specifies a minimum wash solution temperature that is based on the FDA Food Code. While that Standard does contain performance criteria for sanitization, those criteria and the test method used for verification were developed knowing that minimum wash water temperatures and design criteria were also specified. Before modifying the Food Code to provide for the exception recommended by CFP, assurance is needed that such a change will neither undermine the integrity of the NSF Standard nor adversely affect the ability of a food establishment to verify that a commercial dish machine is functioning properly. FDA will continue to work with the NSF Joint Committee on Food Equipment to consider what changes, if any, are needed to NSF/ANSI Standard No. 3.

2010-III-015 recommended that Section 5-202.12 of the Food Code be revised to lower the minimum water temperature that a handwashing sink be capable of providing from 100°F to 85°F. FDA recognizes that it may be appropriate to wash hands in water at temperatures lower than 100°F. However, the Food Code does not specify the temperature of the water that hands must be washed in. Instead, the current Food Code provides that water of at least 100°F must be available, in case it is preferred or necessary to remove certain soils that may be present on an employee's hands. Proper and adequate handwashing by employees is a practice that is widely recognized as important to preventing foodborne illness and one that can be difficult to ensure is routinely happening. FDA supports modifying the Food Code in ways that make it more, not less, likely that hand washing stations will be adequate to ensure that employees can effectively remove soils from their hands.

For the benefit of the CFP Executive Board and the entire CFP membership, additional discussion of the way selected 2010 CFP Recommendations were modified when incorporated into the Supplement is provided below:

2010-I-024 Management Responsibility

Currently the Food Code identifies a number of practices and operations for which a food establishment must develop a plan or set of procedures for employees to follow. The Supplement specifies that the development and implementation of all required procedures are to be among the expected duties of the person in charge of a food establishment, as specified in Section 2-103.11 of the Food Code. The supplement does not limit this duty expectation only to procedures recommended in Chapter 8 of the Food Code, as suggested by CFP. FDA looks forward to more consideration of this topic at the 2012 CFP Biennial meeting as we explore additional ways to promote the active management of food safety in food establishments.

2010-II-021 Food Protection Manager Certification

As recommended by the CFP, the Supplement requires that at least one food establishment employee with management and supervisory responsibility be a Certified Food Protection Manager (CFPM). The Supplement does not specify the particular types of establishments that should be exempt from this requirement as suggested by CFP. Instead, the Supplement acknowledges that some types of food establishments may be exempted based on the nature of the operation, but that the Regulatory Authority will need to make that determination. The Supplement does not specify, as suggested by the CFP, the conditions under which the Regulatory Authority may require the Person in Charge (as defined in the Food Code) or another specific employee to become a Certified Food Protection Manager. FDA believes that the conditions recommended by the CFP would impose unnecessary limitations on the Regulatory Authority and would not provide flexibility to consider all appropriate remedies for noncompliance with Food Code provisions. FDA plans to engage the 2012 CFP in further discussions about strategies for increasing the presence of Certified Food Protection Managers in food establishments.

2010-III-013 Bare Hand Contact for Ready-To-Eat Ingredients that are Fully Cooked After Handling

The Supplement specifies that the prohibition of bare hand contact with ready-to-eat foods does not apply to the handling of foods as they are being added as ingredients to a food that is to be cooked in the food establishment to a minimum temperature specified in the Code. FDA believes this is consistent with the intent of the CFP Recommendation and the way many jurisdictions have interpreted the

current prohibition of bare hand contact with ready-to-eat foods. The terms “fully cooked” and “reheated” were not incorporated into the Supplement as recommended by the CFP because those terms are not defined in the Food Code and their meaning may not be fully understood by users of the Code. To ensure consistent control of the hazards associated with bare hand contact with ready-to-eat foods, FDA believes that it is necessary to specify the minimum temperatures to which foods must be heated if the prohibition of bare hand contact is not to apply.

2010-III-022 Antimicrobial Treatments for Washing Fruits and Vegetables

The CFP Recommendations for modifying the Annex 3 -Public Health Reasons for Section 3-302.15 was incorporated, but was modified so as not to suggest that only one or two practices may be followed to reduce pathogens in produce wash water or on the surface of produce.

2010-III-023 Food Establishment Response Procedures to Vomiting and Diarrheal Contamination

The Supplement addresses the CFP recommendation that a food establishment have procedures for properly preparing for and responding to vomiting or diarrhea events that may unexpectedly occur in the establishment. FDA agrees that the ability to implement well-conceived response procedures can reduce the risk that customers and employees may be exposed to pathogens, whether directly or through food served or sold in the establishment.

The requirements in the new section 2.501.11 describe, in general terms, what the procedures must be designed to address. Though not specifically recommended by the CFP, the Public Health Reasons Section in Annex 3 now contains additional information that is intended to help food establishments and regulators determine what procedures are necessary to take to prevent the spread of contamination.

There is information from various other sources that can also assist in developing procedures that are suitable to different types of food establishments. FDA encourages the CFP to explore ways it can help to further the widespread use of effective response procedures.

Part 2

The 2010 Conference for Food Protection made seventeen recommendations requesting that FDA take actions unrelated to modifying the FDA Food Code. Eight of the seventeen recommendations proposed changes to the FDA Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards).

FDA published the 2011 edition of the Retail Program Standards, and in doing so, addressed each of the recommendations put forward in the following 2010 CFP recommendations: **2010-II-002; 2010-II-009; 2010-II-010; 2010-II-011; 2010-II-012; 2010-II-023; 2010-II-024; 2010-II-027.**

FDA has also addressed or continues to work on the other nine recommendations that request the agency participate in various committees or take certain actions to promote food safety at retail: **2010-I-010; 2010-I-015; 2010-I-016; 2010-II-007; 2010-II-013; 2010-II-022; 2010-II-025; 2010-II-031 and 2010-III-012.**

It should be noted that in Issue **2010-I-016**, the CFP requested that FDA post on its website answers to a series of questions posed by the CFP Criticality Implementation and Education Committee related to the Priority Designation of Food Code provisions in the 2009 Food Code. FDA believes that the majority of the questions posed are not appropriate for FDA to answer and/or go beyond what the re-designation effort was intended to address. FDA believes that the educational slide presentation developed by FDA and the CFP Committee adequately addresses those questions for which FDA direction is appropriate.

I trust the foregoing adequately addresses the recommendations made at the 2010 CFP Meeting. I look forward to continuing our cooperative relationship with the Conference.

Sincerely yours,

A handwritten signature in black ink that reads "M M Landa". The signature is written in a cursive, flowing style.

Michael M. Landa
Acting Director
Center for Food Safety
and Applied Nutrition

cc:

Mr. Kevin Smith, FDA/CFSAN

Dr. John Hicks; USDA/FSIS

Dr. Arthur Liang, CDC