



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

August 8, 2016

Mr. Patrick Guzzle, Chair
Conference for Food Protection
30 Elliott Court
Martinsville, IN 46151-1331

Dear Mr. Guzzle:

Thank you for your letter dated May 27, 2016 in which you transmitted the recommendations made by the Conference for Food Protection (CFP) at its 2016 Biennial Meeting in Boise, Idaho. By all accounts, the 2016 Meeting was a productive one. The Food and Drug Administration (FDA) appreciates the efforts of all participants in the 2016 Meeting to develop recommendations intended to further food safety and foster cooperation between Federal, state, local, territorial and tribal agencies and our partners in industry, academia, and consumers. FDA values the opportunity to fully participate in the CFP Biennial Meetings and to provide consult to the Executive Board and the numerous CFP Committees.

In accordance with the Memorandum of Understanding between the FDA and the CFP, I am pleased to respond with FDA's current position on those recommendations that pertain to the FDA Food Code or otherwise recommend action on the part of FDA.

Part 1 – Conference Recommendations for Changes to the FDA Food Code

Your letter identified twenty-five recommendations accepted by the Assembly of Delegates to change the FDA Food Code or the Food Code Annexes.

FDA conceptually agrees with sixteen of the twenty-five final recommendations and anticipates making changes to the Food Code and its Annexes related to the following issues:

- 2016-I-007 IMC 3 – Amend Food Code 4-602.11 (E) (4) Equipment Cleaning Frequency**
- 2016-I-022 Update the definition of Vending Machines**
- 2016-I-023 Shellfish Retail Record Keeping**
- 2016-I-033 Thawing 3-501.13**
- 2016-I-035 Missing reference in 2013 FDA Food Code Section 3-501.19(A)(1)(a)**
- 2016-I-036 Clarifying Date Marking Disposition**
- 2016-I-042 Towel Drying Exception For Equipment Removed From High-Temp Dish Machines**
- 2016-II-004 Imminent Health Hazard: Modify Enforcement & PIC Duties**
- 2016-II-025 Mandatory Food Protection Manager Certification for Persons in Charge**
- 2016-III-002 LRG 2 - Approval of Listeria Retail Guidance Document**
- 2016-III-014 Bandage, Finger Cot, and Stall contamination**

- 2016-III-020 Plant Food Cooking for Hot Holding**
- 2016-III-025 Separating Raw Animal Food from Unwashed Fruits and Vegetables**
- 2016-III-027 Chemicals Used for Washing and Treating Fruits and Vegetables**
- 2016-III-032 Amend Food Code Annex – Clarifying ROP of fish requirements**
- 2016-III-035 Revise Food Code to be Consistent with FSIS Requirements and Guidance**

Please note that FDA may agree in concept but may not agree with the specific proposed wording for the Food Code changes. In these cases, FDA may exercise its option to modify the recommended text, either to provide clarity or to achieve consistency with the structure or conventions of the Food Code.

For the following recommendation, FDA partially concurs:

2016-III-017 Amend Food Code – Clarify Clean-up of Vomiting and Diarrheal Events

This recommendation requests: 1) the expansion of Annex 3 as related to Food Code section 2-501.11 “Clean-up of Vomiting and Diarrheal Events” to provide guidance for written procedures; and 2) that the 2013 Food Code be amended to include clarifying language for written procedures as provided.

FDA concurs with specifying in the Food Code that food establishments shall have written procedures for employees to follow when responding to vomiting or diarrheal events, but does not concur with the addition of clarifying language for written procedures into the codified section of the Food Code. Rather, FDA proposes to address the information in Annex 3, Public Health Reasons.

FDA recognizes that there are ongoing studies and research that include possible specific recommendations for clean-up of vomiting and diarrheal events. Therefore, it is too soon to specify minimum criteria for clean-up after vomiting and diarrheal events and is not advisable to add specific criteria until further information is obtained. Furthermore, with the potential for a variety of effective procedures to be developed, information was not provided to support for why the particular procedure should serve as the minimum regulatory requirement.

With regard to points raised in the Issue submission, FDA agrees that there is aerosolization of norovirus from vomiting and diarrheal events. FDA also agrees that it is preferable to use Environmental Protection Agency (EPA) registered disinfectants when cleaning up after vomiting and diarrheal events as the use of detergents alone may spread norovirus to other surfaces. We will take this into account in developing language for the Public Health Reasons in Annex 3.

For the following eight recommendations in Part 1 of your letter, FDA either does not concur or will need to further consider the matter and perhaps consult with the Executive Board of the Conference for Food Protection prior to deciding on whether to modify the Food Code in the recommended manner.

2016-I-026 Frozen Foods Maintained Frozen

This recommendation requests FDA to amend paragraph 3-202.11(E) and Section 3-501.11 to specify that only time/temperature controlled for safety (TCS) food that is labeled frozen and shipped frozen by a food processing plant is to be received and maintained frozen.

The food matrices established by the manufacturer include parameters for the product during its shelf life and these need to remain in place as established. Further, there can be variability in supplier and sources of the frozen food product that necessitate the product remain frozen if specified by the manufacturer. FDA does not concur with this recommendation and believes that food labeled “keep frozen” by the manufacturer should stay frozen at receipt and during storage – regardless of whether the food is TCS or non-TCS.

2016-I-045 Consolidating Chemical Storage Provisions in the Food Code

This recommendation requests FDA to consider reviewing and consolidating Sections 7-201.11 and 7-301.11 of the 2013 Food Code. We have reviewed both sections and carefully considered whether to consolidate the paragraphs. We do not concur with consolidation of these two sections as they address different aspects of toxic storage and display - Section 7-201.11 addresses storage of operational supplies and their application in a food establishment (Part 7-2 “back of the house”) and Section 7-301.11 addresses the storage and display for retail sale (Part 7-3 “front of the house”).

As written, the Code provisions clearly delineate what the recommendations are for each separate area. With regard to compliance, both provisions are addressed under the same item, #28 “Toxic substances properly identified, stored and used, held for retail sale, properly stored”, within Guide 3-B, Instructions for Marking the Food Establishment Report, in Annex 7.

2016-III-016 Employee Health Interventions – Reducing Norovirus

This recommendation requests that FDA amend the 2013 Food Code, Part 2-2 Employee Health, Subpart 2-201 *Responsibilities of Permit Holder, Person in Charge, Food Employees, and Conditional Employees* be amended to reflect the following changes:

1. Extend the exclusion period for food employees symptomatic with vomiting or diarrhea and NO diagnosis of norovirus illness from a minimum of 24 hours after becoming asymptomatic to a minimum of 48 hours after becoming asymptomatic.
2. Remove the distinction in criteria for exclusion and restriction in highly susceptible populations (HSP) and non-HSP establishments, thereby requiring exclusion until a minimum of 48 hours after becoming asymptomatic in all settings.

3. Remove the allowance to restrict a food employee that has been diagnosed with an infection from norovirus (exclusion criteria only).
4. Extend the exclusion period for a food employee who is asymptomatic and diagnosed with norovirus illness from a minimum of 24 hours to a minimum of 48 hours.

The Issue associated with this recommendation was an Issue submitted jointly by Centers for Disease Control and Prevention (CDC) and FDA. However, FDA recently concluded a quantitative risk assessment on norovirus transmission in retail food establishments and that is awaiting peer review. Because the results of the risk assessment have particular relevance to the subject matter of this proposal, FDA is deferring at this time.

While FDA will not make the change for the 2017 Food Code, FDA will continue to work with CDC, industry and other regulatory partners to:

- Increase employee health awareness and determine strategies with industry and regulatory to achieve better compliance with existing code provisions.
- Work to increase Code adoption of relevant Employee Health Code sections for the control of norovirus. We have 9 states that have adopted the 2013 Food Code and CDC's Prevention Status Report shows that the majority of states have not adopted all of the recommended 2013 Food Code provisions identified by CDC as foodborne disease related provisions: <http://www.cdc.gov/psr/national-summary/foodsafety.html>.
- Address industry and regulatory perceptions of [the need of and use of] No Bare Hand Contact (NBHC), exclusion of ill food employees, handwashing compliance, and reporting by food employees.

2016-III-023 Reheating Commercially Processed TCS Foods in a Microwave for Hot Holding

This recommendation requests FDA to modify Section 3-403.11 Reheating for Hot Holding to: 1) add in paragraph (C) that when reheating commercially processed TCS foods in a microwave for hot holding, the food must be rotated or stirred, covered and allowed to stand for two minutes after reheating and to keep the temperature allowance and 2) remove from paragraph (B) the specification that the food is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.

Paragraph 3-403.11(C) gives a temperature, but no other criteria for rotating or stirring, covering and allowing to stand for two minutes. This paragraph is for Ready-to-Eat (RTE) commercial product that is initially heated for hot holding in the food establishment. Refrigerated, commercially processed, ready-to-eat, TCS food will have received controlled thermal processing that destroys vegetative bacterial cells and a controlled cooling process

that prevents the germination of any spores present (and therefore presents a lower risk). As such, it is not necessary to specify in 3-403.11(C) that RTE commercial product are rotated or stirred, covered, and allowed to stand covered for 2 minutes after heating to 135°F for hot holding. Packaging prevents recontamination and refrigeration prevents spore germination. Because there is limited risk of contamination in these types of products, reheating such foods to the minimum hot holding temperature of 135°F is considered adequate when reheating for hot holding.

Paragraph 3-403.11(B) specifies that all parts of the food reach a temperature of at least 74°C (165°F) and that the food is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating. This paragraph addresses food that is cooked and cooled at the food establishment and reheated in a microwave. This would be inclusive of commercially prepared food that was heated for hot holding and cooled in the food establishment. For foods prepared, cooked and cooled in the food establishment, the controlled thermal processing and cooling process controls in place in a food processing plant cannot be guaranteed in retail food establishments. As such, foods may contain vegetative bacterial cells from germinated spores. Specifying in paragraph 3-403.11(B) that all parts of the food reach a temperature of at least 74°C (165°F) and that the food is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating is necessary to ensure the destruction of pathogens in foods prepared, cooked and cooled in the food establishment via microwave ovens.

2016-III-024 Separation of Packaged Products Displayed at Retail

This recommendation requests FDA to amend paragraph 3-302.11(A) of the 2013 Food Code to allow for the storage of vacuum packaged and modified atmosphere packaged or hermetically sealed packaged food to be displayed with or above foods packaged in the same manner and to change paragraph (7) to indicate “or” instead of “and”.

The Food Code does not prohibit the cross merchandising of items for customer convenience at point of sale and speaks to the separation of various foods to prevent cross contamination. Subparagraphs 3-302.11(A)(1)(a) and (b) call for the protection of food from cross contamination by separating raw animal foods during storage, preparation, holding, and display from raw ready-to-eat-food and cooked ready-to-eat-food. This separation may be achieved by the use of distance, physical barrier or any other effective means. Depending on the particular situation, packaging may be deemed by a regulatory authority as an effective means to separate raw animal foods from the other foods described in paragraph 3-302.11(A). However, not every type and method of packaging would likely be deemed effective means, nor are package integrity issues always corrected immediately.

2016-III-028 Ambient Cooling Pre-Chilled TCS Foods

This recommendation requests FDA to amend section 3-501.14 of the 2013 FDA Food Code to clearly state that pre-chilled time/temperature control for safety (TCS) foods that rise above 5 degrees C (41 degrees F) during preparation be cooled within four (4) hours to 5 degrees C (41 degrees F) or less when the product would be held for cold holding.

FDA does not concur with this recommendation. Allowing for extended preparation times where TCS foods are above 41°F during preparation for long periods and then returned to temperature control (potentially multiple times) would conflict with the provisions for Time as a Public Health Control (TPHC) in Section 3-501.19 where food taken out of temperature control may be held at ambient temperature using time alone for up to 4 hours before being served or discarded.

The 2013 Food Code allows in Section 3-501.16 an exception from the hot and cold holding time/temperature control parameters for TCS foods during preparation and does not currently specify a timeframe for which foods that rise above 41°F during preparation must be back at or below 41°F. It is recognized that the cooling of such food should be performed as rapidly as possible to avoid the possibility of pathogen growth and to meet the cold holding recommendations set forth in Section 3-501.16. It is not inevitable nor should it be understood that TCS foods removed from temperature control for preparation MUST rise above 41°F during preparation.

2016-III-029 Acidified Food Date Marking Exemption

This recommendation requests FDA to amend paragraph 3-501.17 (G), Ready-to-Eat, TCS Food, Date Marking, with the addition of a new subparagraph (8) adding “Packaged acidified food items, such as salad dressings, salsas, fruits, vegetables, etc. that have been manufactured in accordance with 21 CFR 114 Acidified Foods” to the list of commercially processed foods exempt from date marking.

FDA does not concur with this recommendation. According to 21 CFR 114 – Acidified Foods, an acidified food that is packaged by a manufacturer shall be thermally processed and have a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below. Based on the definition of TCS Food in the Food Code, food items with a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below would be classified as non-TCS and non-TCS foods don’t require date marking per section 3-501.17.

2016-III-030 Amend Food Code – Clarifying sprouting as a specialized process

This recommendation requests FDA to change paragraph 3-502.11(H), Variance Requirement, to include a clarifying language for “sprouting seeds and beans”.

The Food Code currently specifies that a variance is necessary before sprouting seeds or beans. We recognize there has been confusion regarding the difference between sprouts and microgreens with regard to specialized processing methods in the FDA Food Code and agrees that providing clarity surrounding sprouts will improve the understanding of the variance requirement for sprouting seeds or beans.

FDA will issue an interpretation in the Food Code Reference System rather than change the Code and will determine clarifying language based on the Produce Rule, Subpart M-Sprouts and in conjunction with FDA's Produce Safety Staff. As such, the requirements of Section 112.141 under Subpart M apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.

2016-III-038 Use of pre-formulated sanitizing solutions

The Council recommendation asked FDA to change Section 4-302.12, Sanitizing Solutions, Testing Devices, to provide an exception to having testing devices for pre-formulated sanitizing solutions that are ready-to-use, not diluted or mixed in the food establishment, and are sprayed directly onto food contact surfaces. The recommendation was rejected by the voting delegates, but because the Food Code does not prohibit the use of pre-formulated sanitizing solutions that are ready-to-use and not diluted or mixed without a testing device, FDA will issue an interpretation on this Code section on the FDA's Food Code Reference System.

Part 2 – Other Recommendations to the Food and Drug Administration


Part 2 of your letter identified recommendations that request FDA take certain actions but that do not recommend specific changes to the FDA Food Code. FDA conceptually agrees on the merits of the recommendations in the seventeen items below and will consider the availability of agency resources to pursue the recommended actions. FDA will strive to keep the CFP Executive Board and the Conference apprised of progress made between now and the 2018 Biennial Meeting in Richmond, Virginia.

- 2016-I-012 FRC 2 - Comprehensive Resource for Food Recovery Programs**
- 2016-I-024 Juice HACCP**
- 2016-I-028 Amend Returned Food and Re-Service of Food**
- 2016-I-034 Interpretation of Food Code Section 3-501.17 (A) & (B)**
- 2016-I-038 Raw Animal Foods – Consumer Advisory**
- 2016-I-047 Temporary Food Establishment Inspection Intervals**
- 2016-II-007 PSC 2 - Recommendations from Issue 2014 II-003**
- 2016-II-009 PSC 3 - Recommendations from Issue 2014 II-005**
- 2016-II-010 PSC 5 - Amend Retail Program Standard 7**
- 2016-II-011 Amend VNRFRPS – Standard 4 – Uniform Inspection Program (Part 1)**
- 2016-II-012 Amend VNRFRPS – Standard 4 – Uniform Inspection Program (Part 2)**
- 2016-II-013 Amend FDA VNRFRPS Standard 9 – Program Assessment**
- 2016-II-015 CFSRP 2– Reassign Charges to the Program Standards Committee**
- 2016-II-019 Clarification for Re-standardization in VNRFRPS Standard 2***
- 2016-III-006 HHC 4 - Recommendations to FDA**
- 2016-III-021 Cooking by food temperature**
- 2016-III-022 Slow Continuous Cooking of Raw Animal Foods**

* Please note that FDA agrees in concept with the recommendation in 2016-II-019, but does not agree with the specific proposed wording for the Program Standard 2 changes.

I trust that this letter provides sufficient information about our current positions on the Recommendations from the 2016 Biennial Meeting of the Conference for Food Protection. I look forward to continuing in our cooperative relationship with the Conference.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Mayne". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Susan Mayne, Ph.D.
Director
Center for Food Safety
and Applied Nutrition