



August 21, 2018

David Lawrence, Chair
Conference for Food Protection
30 Ellicott Court
Martinsville, IN 46151-1331

Dear Mr. Lawrence:

Thank you for your letter of May 21, 2018, transmitting the recommendations made by the Conference for Food Protection (CFP) at its 2018 Biennial Meeting in Richmond, Virginia. The Food and Drug Administration (FDA) values the opportunity to fully participate in the CFP Biennial Meetings and to provide input to the Executive Board and the numerous CFP Committees.

The 2018 Biennial Meeting was productive, with a total of 93 Issues deliberated. FDA appreciates the efforts of all participants in the 2018 Meeting to develop recommendations intended to further food safety and foster cooperation among Federal, State, local, territorial, and tribal agencies and our partners in industry, academia, and consumer groups.

In accordance with the Memorandum of Understanding between FDA and the CFP, I am pleased to respond with FDA's current positions on the 2018 recommendations for changes to the FDA Food Code or requests for other action by FDA.

Part 1 – 2018 Conference Recommendations for Changes to the FDA Food Code

Your letter identified 25 recommendations by the Assembly of Delegates to change the FDA Food Code or the Annexes. As explained more fully below, FDA **conceptually agrees** with 14 recommendations and **partially concurs** with two recommendations. For nine recommendations, FDA either **non-concurs or will consider** the recommendation before deciding whether a Food Code modification is warranted.

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FDA conceptually agrees with 14 of the 25 recommendations in Part 1 of your letter and anticipates making changes to the Food Code and its Annexes related to the following Issues:

2018-I-003	<i>UFE 3 - Amend Food Establishment Definition and Exemption for Person in Charge (PIC)</i>
2018-I-009	<i>Clarification of the Term Easily Cleanable</i>
2018-I-013	<i>Amend Food Code – Update Definition for “Mechanically Tenderized”</i>
2018-I-018	<i>Amend Food Code – 3-502.12 Reduced Oxygen Packaging Without a Variance</i>
2018-I-019	<i>Amend Food Code – 8-201.14 Contents of a HACCP Plan</i>
2018-I-021	<i>Amend Food Code – Food Establishment Requirement to Retain Variance</i>
2018-I-026	<i>Amend Food Code – Add Time/Date together as a method of Date Marking</i>
2018-I-029	<i>Amend Food Code – FSIS Chicken Liver Compliance Guide in Annex</i>
2018-III-005	<i>MOFSC 3 – Amend Food Code to add Guidance Document for Mail Order Food</i>
2018-III-016	<i>Amend Food Code – Chill/Sous Vide Option for ROP Bags to 41°F</i>
2018-III-018	<i>Amend Food Code – Clarify 3-301.11(D) for Single Ingredient Food</i>
2018-III-019	<i>Amend Food Code – Room Temp. Non-TCS Food becoming TCS, then held using TPHC</i>
2018-III-020	<i>Amend Food Code – Reheating RTE Food to be held using TPHC</i>
2018-III-026	<i>Amend Food Code – Remove Chemically Treated Towellette from 5-203.11</i>

Please note that FDA agrees in concept with these 14 recommendations but may not agree with specific proposed wording for the FDA 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.

FDA partially concurs with the following two recommendations in Part I of your letter:

2018-I-007	<i>Amend Food Code – Standards for Food Equipment Certification</i>
2018-I-023	<i>Amend Food Code – Separation of Packaged Products Displayed at Retail</i>

FDA agrees conceptually with parts of these two recommendations, but not with the full recommendations, as described below.

2018-I-007	<i>Amend Food Code – Standards for Food Equipment Certification</i>
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This recommendation requests that FDA amend Section 4-205.10, Food Equipment, Certification and Classification, to add new language “to the corresponding American National

Standard listed in Annex 8” and to create a new Annex 8 that would provide a listing of the relevant American National Standards.

The non-debitable statement in 4-205.10 of the Food Code is intended to recognize that commercial food equipment that has been appropriately certified for sanitation is deemed to comply with Parts 4-1 and 4-2 of the Food Code. Limiting this recognition to equipment that has been certified or classified by an American National Standards Institute (ANSI)-accredited certification program helps to ensure that the certification procedures used by the certification body are adequate. FDA agrees that the use of an appropriate equipment standard as the basis for equipment certification is an important element of a reputable equipment certification program. FDA also recognizes that third-party equipment certification bodies accredited by ANSI are not mandated to only certify equipment to American National Standards and that certification to other standards is permitted under ANSI policies. FDA is still considering whether and how the text in 4-205.10 should be modified to convey that the blanket recognition of certified equipment is limited to equipment that has been certified to an appropriate American National Standard.

FDA agrees that establishing a list of recognized American National Standards for food equipment would inform third party certification programs of the appropriate standards to use when certifying equipment. However, providing a reference list can be executed in various ways such that it is easily accessible to the user without creating a new Annex to the Food Code. FDA is considering development of an informational fact sheet listing all the applicable American National Standards for Food Equipment and posting it on the resources portion of the FDA Retail Food Protection website, in addition to including it as a reference in existing Annex 2, References for Section 4-205.10 Food Equipment, Certification and Classification. FDA believes that this alternative action meets the intent of the desired recommendation without adding a new Annex to the Food Code.

2018-I-023 *Amend Food Code – Separation of Packaged Products Displayed at Retail*

This recommendation requests that FDA add a new Sub-Paragraph 3-302.11(E), Packaged and Unpackaged Food – Separation, Packaging and Segregation, that would allow for the use of “commercially processed and packaged food that is vacuum packaged, modified atmosphere packaged or hermetically sealed to prevent the entry of microbes and other contaminants such as chemicals, physical barriers or other effective means to be displayed with or above foods packaged in the same manner and package integrity is maintained.”

Currently, the Food Code does not prohibit the cross-merchandising of items for customer convenience at point of sale. FDA recognizes that separation, as specified in Subparagraphs 3-302.11(A)(1), may be achieved by using distance, physical barriers, or any other effective means. Depending on the 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. If the recommended solution is added to the Food Code, it can open the door for a listing of all possible types of packaging that could be used as a barrier. The Food Code does not list all acceptable means within the provision as there are multiple ways in which one could be in compliance with this provision. FDA believes that this issue may not lend itself to a Food Code change but FDA will develop an interpretation to be posted on the Food Code Reference System that discusses the intent of prevention from cross contamination within this provision.

For the following nine recommendations in Part 1 of the letter, FDA either **does not concur** or **will consider**, needing more time to further consider the matter or perhaps consult with the CFP Executive Board before deciding on whether a modification of the Food Code is warranted:

- 2018-I-024** *Amend Food Code – Food Safety Regulations for Food Donations*
- 2018-I-031** *Amend Food Code – Storage in Toilet Rooms*
- 2018-I-032** *Amend Food Code – Use Limitation of Untreated Wood for Cooking Surface*
- 2018-II-005** *Amend Food Code for Demonstration of Knowledge*
- 2018-II-006** *Amend Food Code 2-103.11 Person in Charge*
- 2018-III-008** *SPCC 3 – HACCP Template for ROP of Raw Meat, Cheese, Frozen Meat*
- 2018-III-009** *SPCC 4 – HACCP Template for Curing as a Single Special Process*
- 2018-III-010** *SPCC 5 – HACCP Template for Sushi Rice Acidification*
- 2018-III-028** *Amend Food Code – Mechanical Warewashing Temperature per Manufacturer Label*

2018-I-024 Amend Food Code – Food Safety Regulations for Food Donations

This recommendation requests that FDA modify the Food Code definition of “Food Establishment” in Paragraph 1-201.10 (B) to acknowledge that Food Establishments, as defined in the Food Code, commonly relinquish possession of food to “food banks and food recovery programs and organizations” in addition to relinquishing food to a consumer.

FDA agrees that the current Food Code definition of “food establishment” does not specifically acknowledge that the relinquishing of food to food rescue and food recovery organizations is a common practice of many retail and foodservice operations. However, FDA does not believe that the current definition of Food Establishment excludes an establishment that donates food to a food recovery/rescue organization from the definition of a “food establishment” nor does it render any Food Code provision inapplicable to such establishments.

FDA is considering this modification to the Food Code definition to ensure it is adequately aligned with similar definitions used in other FDA documents, including, but not limited to the

terms “Restaurant” and “Retail Food Establishment” as defined in Title 21, Subpart Sec 1.227 of the Code of Federal Regulations. Further, the Conference for Food Protection has reestablished the Food Recovery committee to consider and recommend other changes to the Food Code and CFP Guidance documents to better address food donation practices. Such recommendations could end up making modifications to the definition unnecessary. Therefore, FDA believes it would be premature to make the recommended change to the Food Code definition of “Food Establishment” without the benefit of such deliberations and **does not concur**.

2018-I-031 Amend Food Code – Storage in Toilet Rooms

This recommendation requests FDA amend Paragraph 3-305.12(B), Food Storage, Prohibited Areas, Sub-Paragraph 4-401.11(A)(2) Equipment, Clothes Washers and Dryers and Storage Cabinets, Contamination Prevention and Sub-paragraph 4-903.12(A)(2) Prohibitions, by revising the current ‘Core’ risk designation to a Priority Foundation risk designation.

Risk designations within the Food Code are categorized by three naming conventions: Priority item, Priority foundation item, and Core item.

- Priority item (P) refers to a provision in the Food code for which the application contributes directly to the elimination, prevention or reduction to an acceptable level, of hazards associated with foodborne illness or injury and for which there is no other provision that more directly controls the hazard. Priority items are those with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, or handwashing.
- Priority foundation item (Pf) refers to a provision in the Food Code whose application supports, facilitates or enables one or more Priority items. Priority foundation items are those that require 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, necessary equipment, HACCP plans, documentation, or record keeping and labeling.
- Core item refers to a provision in the Food Code that is not designated as a Priority or Priority foundation item. Core items are those that usually relate to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities, structures, equipment designs, or general maintenance.

This Issue recommends that the “storage” provisions specifically related to “toilet rooms” be re-designated as a Priority foundation item. By code convention, to designate a provision as a Priority foundation item, it must be a provision for which its application supports, facilitates or

enables one or more Priority items. It remains unclear, for each provision indicated for updating, what Priority item(s) would be directly supported. This issue lacked justification to indicate which Priority items these changes would support and also lacked any supporting risk evaluation to support the recommended code changes. One operational practice to prevent contamination of food is to avoid placement or storage of food and non-food items in toilet rooms. While placement of food and non-food items in toilet rooms is a practice to be avoided, it is not a practice that meets the Priority foundation item definition as a practice that gains control of a Code provision designated as a Priority item. Currently, FDA **does not concur** with the recommended change to modify the risk designations for the three provisions dealing with storage.

2018-I-032 Amend Food Code – Use Limitation of Untreated Wood for Cooking Surface

This recommendation requests FDA amend Section 4-101.17, Wood Use Limitation, to include a new paragraph (E) which would allow for the use of “untreated cedar wood planks that are intended to be a food contact surface and used as a single-use cooking utensil and may subsequently be used as a serving food contact surface.”

Currently, this provision does not allow the use of wood and wood wicker as a food contact surface, but does provide exceptions for wood that is hard maple or equivalently hard, close-grained, and used for: cutting boards, blocks, bakers’ tables, utensils (ex. rolling pins, doughnut dowels, salad bowls and chopsticks) and wooden paddles used in confectionary operations, wood shipping containers of whole, uncut, raw fruits and vegetables, and nuts in shell. The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used.

Cedar wood contains biologically active compounds and its use as a high temperature cooking surface may impart significant levels of these compounds to food. FDA is not aware of evidence indicating the use of cedar as a cooking surface as a safety issue, but the FDA Office of Food Additive Safety (OFAS) has not reviewed the safety of this use. Moreover, OFAS is not aware that any generally recognized as safe (GRAS) determinations have been made on the use of cedar wood as a cooking surface. Due to the lack of safety information for this intended use, FDA has neither 1) a safety assessment that would provide a basis for a safety concern, nor 2) information to establish a reasonable certainty of no harm as a result of the proposed use such that the public health would be protected if a provision that allows untreated wood planks, such as cedar, for use as a cooking food contact surface is added to the Food Code.

FDA advises the submitters of the proposed allowance for untreated wood planks for grilling and baking, and/or other interested parties, to provide FDA with safety information about the intended use of wood planks such as cedar as a cooking surface in contact with food. If the

submitters of the proposal believe untreated wood planks, such as cedar, are GRAS as a surface for grilling and baking food, we recommend they contact OFAS with a request for a pre-submission consultation for a GRAS Notification. GRAS status can be established through scientific procedures and/or experience based on common use in food prior to 1958.

Based on these concerns, FDA **does not concur** with the recommended change to allow for use of untreated cedar wood planks as a food contact surface.

2018-II-005 Amend Food Code for Demonstration of Knowledge

This recommendation requests FDA amend Paragraph 2-102.11(C), Demonstration, to remove the language, “as they relate to the specific food operation,” and add in new language, “or correctly demonstrating food safety knowledge as related to specific food operation through the use of job aids and/or other practical means as verified during the current inspection,” so that the section reads as below with underlined text added and ~~strikeout~~ text deleted:

Knowledge 2-102.11 Demonstration.

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. 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;^{Pf}
- (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;^{Pf} or
- (C) Responding correctly to the inspector's questions ~~as they relate to the specific-FOOD operation~~ or correctly demonstrating food safety knowledge as related to specific food operation through the use of job aids and/or other practical means as verified during the current inspection. The areas of knowledge include: . . .

FDA **does not concur** with this CFP recommendation. The intent of Section 2-102.11 is to ensure the PIC demonstrates food safety knowledge related to foodborne disease prevention, application of the HACCP principles, and the requirements with this Code as it relates to the specific food operation.

- Removal of the wording, “as they relate to the specific food operation,” is inconsistent with the intention of the section to ensure the PIC demonstrates the food safety

knowledge necessary to prevent foodborne illness as it relates to the specific food operation.

- Adding language that allows a PIC to simply demonstrate adherence to any job aid is inadequate to ensure the PIC demonstrates knowledge of foodborne disease prevention, application of the HACCP principles and the requirements within this Code.
- The addition of the recommended language, “or other practical means as verified during the current inspection,” would be problematic for regulatory enforcement as the meaning is not specified and supportive language was not provided as to the intent of how this language should be applied during operation.

2018-II-006 Amend Food Code 2-103.11 Person in Charge

This recommendation requests FDA amend Section 2-103.11, Person in Charge, to add in the language, “as they relate to the specific food operation,” after the opening statement so that it would read as below with underlined text added:

Duties 2-103.11 Person in Charge.

The PERSON IN CHARGE shall ensure, as they relate to the specific food operation, that:

The provisions of the Food Code should be understood as only being applicable as they relate to the specific food operation. A food establishment should not be marked out of compliance for a process or action that they do not perform. If one or more of the paragraphs does not pertain to the operation, the PIC cannot be marked out of compliance based solely on the absence of that duty/action in the establishment. Currently, FDA **does not concur** with amending Section 2-103.11 to include the recommended language.

2018-III-008, III-009, and III-010 SPCC 3 – HACCP Templates for ROP, Curing and Sushi Rice

The recommendations from Issues 2018-III-008 thru III-010 request FDA amend Annex 2 References by adding as a reference the following three Conference for Food Protection templates: Single Hazard Special Process HACCP Template for ROP of Raw Meat, Cheese, Frozen Fish; Single Hazard Special Process HACCP Template for Curing as a Single Special Process; and Single Hazard Special Process HACCP Template for Sushi Rice Acidification.

Upon review, FDA has concerns on the need to add CFP-specific templates for HACCP plans when there are many widely available HACCP plan templates and examples that can be used.

FDA believes that there is still much work that is needed to strengthen the current templates and encourages piloting the current draft templates to ensure that it is a protocol that warrants national uniformity prior to including it into the Annexes as a reference. Currently, FDA **does not concur** with including these templates as a reference into Annex 2 Reference of the Food Code.

2018-III-028 Amend Food Code – Mechanical Warewashing Temperature per Manufacturer Label

This recommendation requests FDA amend Paragraph 4-501.110(B) to read: The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than 49°C (120°F) or the temperature specified on the cleaning agents manufacturer's label instructions.^{Pf}

FDA is aware of technological advances leading to cleaning agents that can be effective at lower temperatures than specified within the Food Code. However, not all cleaning agents list specific use temperatures on their product labeling. If a data plate on a commercial warewashing machine does not specify a minimum wash solution temperature and instead refers the operator to the label instructions of the cleaning agent, then operators and regulatory authorities will be faced with uncertainty about the appropriate use of cleaning agents that do not specify a minimum use temperature on their label.

Further, the current NSF/ANSI Standard for commercial warewashing machines assesses equipment performance at a standard wash water temperature that accounts for the variability of specific chemical agents that may be used. FDA has concerns that the recommended language from CFP would, in effect, make the performance testing of spray-type mechanical warewashing machines dependent upon the label of the wash solution chemical. Before agreeing to modify the Food Code as suggested, FDA will need to consider in greater detail the impact that such a change would have on NSF/ANSI Standard 3 and the performance methods used to evaluate the efficacy of mechanical warewashing equipment.

Currently NSF/ANSI Standard 3, which establishes minimum public health and sanitation requirements for the materials, design, construction, and performance of commercial warewashing machines and their related components, requires that the manufacturer's specification for the minimum wash water temperature of chemical sanitizing machines shall be 120°F (49°C) or greater. The Standard also requires that the manufacturer of a chemical sanitizing machine specify the minimum wash water temperature on the machine data plate.

As the recommended language from CFP would add a level of uncertainty based on the specific chemical used and its impact on performance evaluation methods, FDA **does not concur** with the recommendation to amend Paragraph 4-501.110(B) at this time. FDA intends to engage in

discussions with NSF International to examine potential concerns associated with modifying NSF/ANSI Standard 3 to allow the minimum wash water temperature in chemical sanitizing machines to align with the temperature specified on the manufacturer label instructions of the cleaning agent being used by the operator. FDA **will consider** and will report back to the Conference in advance of the 2020 biennial meeting of the CFP.

Part 2 – Other Recommendations to the Food and Drug Administration

Part 2 of the letter identified 6 recommendations that request FDA take certain actions but that do not recommend specific changes to the FDA Food Code. FDA will consider the availability of agency resources to pursue the recommended actions and strive to keep the CFP Executive Board and the Conference apprised of progress made between now and the 2020 Biennial Meeting in Denver, Colorado.

FDA conceptually agrees on the merits of the following 4 of the 6 Part 2 recommendations:

- 2018-I-012** Harmonize Labeling for Mechanically Tenderized Beef
- 2018-II-014** PSC 2 – Improvements to Voluntary National Retail Food Regulatory Program Standards (VNRFRPS)*
- 2018-II-015** PSC 4 – Amend VNRFRPS Standard 3, Inspections Based on HACCP Principles
- 2018-III-021** Cooking/Heating Commercially Processed Not RTE Food

*Please note that FDA agrees in concept with the five-part recommendation within 2018-II-014, but at this time does not concur with the proposed recommendation for part 4c that requests the creation of hyperlinks throughout the VNRFRPS manual to the Clearinghouse Q/A's. The requested addition of hyperlinks to the Clearinghouse document would require the entire document to be fully interactive, and its current format is not compatible with that requirement. FDA strives to modernize these documents and make them easily accessible on an electronic portal and is exploring new technology to enable this capability, but cannot ensure completion by the next biennial meeting.

For the following Part 2 recommendation, FDA partially concurs*:

- 2018-II-016** PSC 5 – Amend VNRFRPS Standard 6, Compliance and Enforcement

FDA **agrees conceptually** with part of the recommendation, but not with the full recommendation.

- 2018-II-016** PSC 5 – Amend VNRFRPS Standard 6, Compliance and Enforcement

This recommendation requests FDA amend Standard 6, Compliance and Enforcement to: 1) add a reference and web link to a “Standardized Key Crosswalk to Code” that allows jurisdictions to make comparisons of risk factors to the FDA Food Code and 2) allow jurisdictions to assess the effectiveness of their compliance and enforcement program using an alternative sampling method that provides the same level of statistical confidence as the prescribed method in Standard 6, Compliance and Enforcement.

Upon review, FDA conceptually agrees with the CFP Part 1 request to add a reference and web link to a “Standardized Key Crosswalk to the Code.” FDA has several concerns, however, with the recommendation in Part 2 that would allow jurisdictions to use alternative sampling methods to assess their compliance and enforcement program. While FDA supports jurisdictions exploring alternative methods to achieve conformance with the Standards, FDA believes that further discussion and vetting of this alternative approach is needed within the CFP Program Standards Committee. FDA welcomes further discussion about the recommended model and the associated work it brings such as the criteria, or possible training needs of auditors, to evaluate such alternative methods. At this time, FDA **does not concur** with part 2 of the recommendations within 2018-II-016.

For the following recommendation, FDA believes it merits further discussion prior to considering this recommendation noted in Part 2 of your letter.

2018-II-029 Creation of a Retail Food Regulatory Program Alliance

This recommendation requests that FDA recognize and support a “Retail Food Regulatory Program Alliance” and provide funding for the development of this Alliance to assure it meets the objective of advancing conformance with the VNRFRPS. It is difficult for FDA to commit to the creation of a Retail Food Regulatory Program Alliance, as currently proposed under CFP Issue 2018-II-029, without additional information and specifics. The additional information and specifics FDA seeks include but are not limited to:

- The clearly defined need to establish this Alliance as well as expected outcomes;
- The proposed purpose, goals, priorities, and strategic vision of the Alliance;
- The prospective organizational structure, hierarchy, and membership of the Alliance;
- The projected funding needs, mechanisms, and cycles of the Alliance;
- The anticipated activities, deliverables, metrics, and oversight of the Alliance;
- An evaluation of the potential impact on existing funding vehicles and agreements (e.g. MOUs, cooperative agreements, partnership agreements, etc.) with FDA; and

- The elaboration of the Alliance's role with the Voluntary National Retail Food Regulatory Program Standards and impact on existing CFP processes.

FDA welcomes a discussion with the CFP and its stakeholders about the proposed Alliance.

I hope that this letter provides sufficient information about FDA's current positions on the recommendations from the 2018 Biennial Meeting of the Conference for Food Protection. FDA looks forward to continuing in our cooperative relationship with the Conference.

Sincerely,

A handwritten signature in black ink that reads "Susan Mayne". The signature is fluid and cursive, with the first name "Susan" and last name "Mayne" clearly distinguishable.

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