FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOODSAFETY| APPLIED NUTRITION

August 12, 2023

Christine Sylvis, Chair
Conference for Food Protection
30 Ellicott Court
Martinsville, Indiana 46151-1331

Dear Ms. Sylvis:

Thank you for your letter of June 12, 2023, transmitting the recommendations made by the Conference for Food Protection (CFP) at its 2023 Biennial Meeting in Houston, Texas. The Food and Drug Administration (FDA or "we") 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 2023 Biennial Meeting was productive, with a total of 117 issues deliberated. FDA appreciates the efforts of all participants in the 2023 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 2023 recommendations for changes to the Food Code or requests for other action by FDA.

Part 1 -2023 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 (Food Code) or the Annexes. As explained more fully below, FDA **conceptually agrees** with 17 recommendations and **partially concurs** with 5 recommendations. For 3 recommendations, FDA either **non-concurs or will consider** the recommendation before deciding whether a Food Code modification is warranted.

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FDA <u>conceptually</u> agrees with 17 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:

2023-I-017*	**Amend Food Code 3-301.11-Double Handwashing and Nail Brush Usage**
2023-I-018	**Chemical Sanitizing test strips Expiration Date**
2023-I-026	**Add Off-Site Warewashing Facilities for Multi Use Articles to Food Code**
2023-I-032*	**Reducing Cross Contamination Risk from Use of Reusable Wiping Cloths**
2023-II-039	**FDC Issue 2-Amend 2022 FDA Food Code to add food defense rule under 2-102**
2023-II-040	**FDC Issue 3-Amend FDA Food Code, Annex 2, Sect. 4 Food Defense references**
2023-II-043	**FSMS #2 Amend Food Code – Define Managerial Control and FSMS**
2023-II-048	**DFSSC 3 -Amend Food Code Annexes to include Reference to Guidance Document**
2023-II-051	**Allergen Committee 3 Amend Annex 2 "Reference" Section of the Food Code**
2023-III-003	**IUMGC 3-Amend Food Code**
2023-III-006	**RSHSC 3 – Amend Food Code Annexes to Reference Approved Document**
2023-III-011	**SURCC 3 - Amend Food Code to Include Reusable Container Definition**
2023-III-012	**SURCC 4 – Amend Food Code Language to include Reuse of Containers**
2023-III-016	**DC 4 – Amend Food Code Annex on Hand Antiseptics**
2022-III-017	**DC 5 – Amend Food Code Annex – Use of Disinfectants During Clean-up of V&D**
2023-III-023	**Revise definition of Reduced Oxygen Packaging specific to packaging type**
2023-III-030	**Amend Food Code -Add Laboratory Methods for Reinstating Ill Food Workers**

Please note that FDA agrees in concept with these 17 recommendations but may not agree with 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.

FDA partially concurs* with 5 of the 25 recommendations in Part 1 of your letter:

2023-III-008	**RSHSC 5 – Including Rice Acidification Parameters in Food Code**
2023-III-015	**DC 3 – Amend Food Code to Address Use of Disinfectants**
2023-III-026	**Add new defined term "Impermeable" to clarify cook-chill processes**
2023-III-027	**Amend Food Code to Include Definition of "Preservation"**
2023-III-031	**Amend Food Code – Considerations for Bulk Refillable Hand Soap Dispensers**

*FDA agrees conceptually with parts of these 5 recommendations, but not with the full recommendations, as described below.

2023-III-008 RSHSC 5 – Including Rice Acidification Parameters in Food Code

This recommendation requests that a letter be sent to FDA requesting the most recent version of the Food Code be amended to include specific requirements to follow for rice acidification, including critical control point, critical limit, and corrective action parameters consistent with the parameters in the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization" (attached as a content document to Issue titled: Report - Retail Sushi HACCP Standardization Committee).

FDA **partially concurs** with this recommendation because we believe adding more explanatory language about the acidification process in the codified sections and Annexes would be beneficial and would expand upon the existing language. FDA anticipates doing so in the Supplement to the 2022 Food Code.

FDA does **not concur** with amending the Food Code to address commodity specific acidification measures by including specific requirements to follow for rice acidification consistent with the parameters in the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization." Rather, we develop policy in the Food Code according to an established retail food policy framework that views the problem, the cause of the problem, identifies and considers solutions, and considers the consequences. This process means that we would look at not just one document, but several as we develop Food Code language.

2023-III-015 DC 3 – Amend Food Code to Address Use of Disinfectants

This recommendation requests FDA to amend the most recent edition of the Food Code to add a new defined term "disinfection" add the terms "disinfection" and "disinfectants" within the current definition of "poisonous and toxic material;" and add a new Part 4-8 DISINFECTION OF EQUIPMENT AND UTENSILS. Suggested language for Part 4-8 was provided in the recommendation.

FDA **partially concurs** with this recommendation. The Food Code provisions are designed to be consistent with federal food laws and regulations and subsequent to the April 2023 CFP meeting, EPA announced the availability of a Draft Guidance for the Evaluation of Products for Claims Against Viruses (88 Fed. Reg. 45417 (July 17, 2023)) that may impact the CFP recommendations for the Food Code and FDA's response.

FDA will review the CFP recommendations and the EPA Draft Guidance in light of EPA's actions and, in consult with EPA, assess whether the CFP-recommended Food Code language will align with the EPA changes for products making claims against viruses.

2023-III-026 Add new defined term "Impermeable" to clarify cook-chill processes

This recommendation requests two changes to the Food Code:

1) that FDA rapidly work with partners to develop the science to support the definition of oxygen impermeable packaging for the purpose of use in ROP applications in retail food and that a letter be sent to FDA requesting the current Food Code be amended as follows:

1-201.10 (B) Reduced Oxygen Packaging.
(2) "**Reduced oxygen packaging"** includes:

(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable bags that are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotrophic pathogens; or [. . .]

2) The recommendation also requests the current Food Code be amended where the word, "impermeable" is located in Chapter 2 Management and Personnel, Chapter 7 Poisonous or Toxic Materials, and in related Annexes, to have the word "impermeable" be replaced with the word "waterproof."

FDA notes that the recommended language change in CH 1 shown above, states the same language as in the existing definition in subparagraph 1-201.10(B)(2)(d). FDA reached out to the CFP to verify the language with the CFP Executive Director to determine if there was a typo or not. The response was that there was not an intent of the Council to include a change in the ROP definition, based on Council discussions. Therefore, the FDA decision is to not make a change in the ROP definition in response to recommendations on Issue 2023-III-026.

FDA **partially concurs** with this recommendation. FDA agrees there is a need for action around the science of ROP. FDA will be reviewing options for providing more information around the science on use of "oxygen impermeable packaging" for the purpose of its use in ROP. We will be meeting with science partners to find a best path forward for developing and communicating this information.

FDA reviewed the history and intent of the Food Code in using "impermeable" in various locations throughout the Food Code. We acknowledge that other words have been used through the years, for example, in 1993 Chapter 2 –"durable cover," Chapter 3 "moisture resistant;" in 1995 Chapter 2 – "impermeable cover," Chapter 3 "moisture-impermeable," "impermeable bandage;" in 2022 – Chapter 2 and 3 "impermeable."

While the Food Code has evolved in its use of the term "impermeable," FDA does **not concur** with changing the term "impermeable" to "waterproof" throughout the Food Code because "impermeable" encompasses the concept of not allowing a liquid or gas to go through. We recognize that many of the multiple definitions for "impermeable" appear as having the same meaning as "waterproof;" however, substituting the term "waterproof" for impermeable does not achieve the Food Code's intent. "Impermeable" is more inclusive of other liquids and gas and, unlike the term "waterproof," is not limited to water alone.

2023-III-027 Amend Food Code to Include Definition of "Preservation"

This recommendation requests for FDA to amend the current Food Code as follows:

1-201.10 Statement of Application and Listing of Terms. (B) Terms Defined. As used in this Code, each of the term listed in ¶ 1-201.10(B) shall have the meaning stated below.

"Food-Preservation" means formulating, processing and/or packaging a TIME/TEMPERATURE

CONTROL FOR SAFETY FOOD in a manner which extends shelf life of the refrigerated READY-TO-EAT FOOD product beyond seven days as allowed under 3-501.17, or which renders the final product a non-TIME/TEMPERATURE CONTROL FOR SAFETY FOOD.
FDA **partially concurs*** with this recommendation in that we will expand the Food Code by adding to the Public Health Reasons in Annex 3 rather than by adding a definition.

FDA does **not concur** with the addition of the recommended definition and questions the merit of defining "preservation" because there are multiple definitions of "preservation" that are suitable for the intended activities described in Section 3-502.11. For example, Chapter V of the Institute of Food Technologists (IFT) report, *Effect of Preservation Technologies on Microbial Inactivation in Foods* [See https://ift.onlinelibrary.wiley.com/doi/10.1111/j.1541-4337.2003.tb00050.x] states, "Traditionally, the popular preservation technologies for the reduction of microbial contamination of food, and pathogens in particular, have been the manipulation of the water activity and/or pH, heat treatments, the addition of chemical preservatives, and the control of storage temperature of foods."

Webster's dictionary, 2023 [See online: https://www.merriam-webster.com/dictionary/preservation] states:

- preservation means the preparation of food for future use (as by canning, pickling, or freezing) to prevent spoilage. An example is the use of salt in the preservation of meat
- the activity or process of keeping something valued alive, intact, or free from damage or decay.

Further, it appears the issue could be related to establishments claiming certain products do not need to abide by the date marking requirements because they have undergone a "preservation" treatment. Whether the food is preserved or not, an establishment would have to provide scientific evidence (e.g., a challenge study) to support why the product should not be subject to date marking requirements.

FDA will instead expand the language in the public health reasons in Annex 3 for Section 3-502.11 to speak to various preservation techniques.

2023-III-031 Amend Food Code – Considerations for Bulk Refillable Hand Soap Dispensers

The Conference recommends...: That a letter be sent to the FDA requesting the amendment of The FDA Food Code section 6-301.11 (Handwashing Cleanser, Availability) as follows:

6-301.11 Handwashing Cleanser, Availability.

(A) Each HANDWASHING SINK or group of 2 adjacent HANDWASHING SINKS shall be provided with a supply of hand cleaning liquid, powder, or bar soap.[Pf]

(B) If a hand cleaning liquid is used it must be undiluted or diluted to the manufacturer's instructions. The hand cleaning liquid itself and its associated dispenser must be free from filth, visible debris, or any other sign of gross contamination.

FDA **partially concurs** with this recommendation because we see merit in adding this information to strengthen the public health reasons in Annex 3 for this section, but not to add a new paragraph (B) to the codified text.

FDA does **not concur** with adding a new paragraph (B) to section 6-301.11(Handwashing Cleanser, Availability) into the codified text because FDA feels that there are provisions already in the Food Code to address the concern. The Food Code presents requirements by principle rather than by subject. For example, equipment requirements are presented under headings such as Materials, Design and Construction, Numbers and Capacities, Location and Installation, and Maintenance and Operation rather than by refrigerators, sinks, and thermometers. In this way provisions need be stated only once rather than repeated for each piece or category of equipment. Where there are special requirements for certain equipment, the requirement is delineated under the appropriate principle (e.g., Design and Construction) and listed separately in the index.

The Food Code currently has cleaning criteria, frequency of cleaning, construction, and design for NonFood-contact Surfaces. A bulk refillable soap dispenser is considered a NonFood-contact Surface. Applicable sections are:

> **4-101.19** Nonfood-Contact Surfaces. NonFOOD-CONTACT SURFACES of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning shall be constructed of a CORROSION-RESISTANT, nonabsorbent, and SMOOTH material. **(Materials for Construction and Repair Multiuse)**
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> **4-202.16** Nonfood-Contact Surfaces. NonFOOD-CONTACT SURFACES shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance. **(Design and Construction Cleanability)**
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> **4-601.11(C)** Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils (C) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be kept free of an accumulation of dust, dirt, FOOD residue, and other debris.
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> **4-602.13** Nonfood-Contact Surfaces. NonFOOD-CONTACT SURFACES of EQUIPMENT shall be cleaned at a frequency necessary to preclude accumulation of soil residues. **(Frequency)**

For the following 3 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:

> **2023-I-003 Gloves Used as a Single-Use Disposable Utensils**
> **2023-I-025 Amend Food Code to include Procedures for Clean-Up of Vomit & Diarrhea**
> **2023-III-025 Amend Food Code to Clarify Fish Thawing Requirements**

2023-I-003 Gloves Used as a Single-Use Disposable Utensils

This recommendation requests FDA to amend Annex 7, Guide 3-B, (Instructions for Marking the Food Establishment Inspection Report, Part C, # 8 IN/OUT Hands clean and properly washed) to include language that allows for scenarios for food employees to forego handwashing after or between glove changes if gloves are used as a single-use disposable utensil and no activities resulting in hand contamination were observed.

FDA does **not concur** with the recommendation to add the proposed language to Guide 3-B Instructions for Marking the Food Establishment Inspection Report. We believe that addressing hand washing criteria and glove use in the Guide 3-B, Instructions for Marking the Food Establishment Inspection Report is inappropriate without consideration to the associated codified Food Code provisions. In addition, the recommended language to the Marking Instructions is in direct conflict with the Food Code provisions on when to wash hands in ¶¶2-301.14(F)(G).

Handwashing is paramount to reducing the overall risk for transmission of foodborne pathogens such as norovirus. With norovirus being the leading cause of foodborne illness, it is not prudent for FDA to change the Food Code to allow for lesser handwashing. Lessening the times when hands are washed is counter-intuitive to achieving control of transmission of foodborne pathogens by food employees.

FDA developed a quantitative risk assessment [https://www.fda.gov/food/cfsan-risk-safety-assessments/risk-assessment-norovirus-transmission-food-establishments] to examine the risk of norovirus transmission from infected food employees to ready-to-eat (RTE) food and to consumers during food preparation, and to evaluate the impact of various control measures.

This risk assessment identified major areas of improvement to prevent norovirus transmission in these settings, including avoiding the transfer of norovirus from the hands of food employees to food through proper hand hygiene and the prevention of barehand contact with RTE food.

A key finding of the study was that improving compliance with other interventions described in the Food Code, especially those regarding handwashing, no bare hand contact with RTE foods, glove usage, and cleaning and sanitizing of food-contact surfaces was also found to reduce norovirus transmission in food establishments.

Therefore, FDA does **not concur** with the recommendation to add the proposed language to Guide 3-B Instructions for Marking the Food Establishment Inspection Report. Incidentally, the terminology used in the recommendation is inconsistent with Food Code defined terms, i.e. there is no Food Code term "Single-Use Disposable Utensil." There are terms for "Single-Use Articles" and "Utensil."

2023-I-025 Amend Food Code to include Procedures for Clean-Up of Vomit & Diarrhea

This recommendation requests that FDA amend Section 2-501.11, Clean-up of Vomiting and Diarrheal Events, to designate that the food establishment should have procedures for clean-up of vomitus and diarrheal events and the procedures shall address specific actions the food employee must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter and shall include at least 3 designated items.

This issue's text is to match verbiage in CFP Issue 2023-III-017.
Please note: Procedurally, CFP Issue 2023-I-025 was reassigned from Council I to Council III. Council III did not combine Issues 2023-I-025 and 2023-III-017. However, the recommendation for Issue 2023-I-025 is to match verbiage with Issue 2023-III-017.

FDA believes it is important to have a written plan that addresses specific actions to minimize spread of contamination and exposure when a vomitus or diarrheal event occurs. FDA does **not concur, however,** with the aforementioned recommendation because it deviates from the original intent of this section to have a written plan in place for the clean-up of vomiting and diarrheal events for employees to follow, with the flexibility to include in this written plan parameters, procedures, training, etc., to the extent needed within any particular food establishment. The recommended language to the codified section of the Food Code suggests decreased flexibility for food establishments designing plans specific to their needs and can possibly narrow the scope of the intended procedures.

When CFP first addressed this topic in 2010 in Issue 2010-III-023, FDA, at the time, indicated what should be considered when developing a written plan. FDA maintains that the items listed in Annex 3, §2-501.11 should be addressed in a written plan and the list is not exhaustive. Providing items in Annex 3 that should be considered when developing a written plan provides flexibility for food establishments to design and develop plans for their specific needs.

In addition to the many resources available to the industry to assist in the development of written plans, FDA will continue to provide information helpful to the industry and our regulatory partners in the way of factsheets, checklists and sample plans.

2023-III-025 Amend Food Code to Clarify Fish Thawing Requirements

This recommendation requests a letter be sent to FDA requesting the most recent version of the FDA Food Code Section 3-501.13(E) be amended within the Code Section to clarify the statement "removed from the reduced oxygen environment," with this clarification to allow the package to be opened without the product being removed as long as no additional *C. botulinum* risk exists.

FDA does **not concur** with this recommendation because the recommendation requests to allow the package to be opened without the product being removed as long as no additional *C. botulinum* risk exists. FDA advises for reduced oxygen packaged (ROP) fish to be <u>completely</u> removed from the ROP packaging entirely, so that the ROP environment is eliminated and to not puncture holes or slits on the packaging to thaw fish as that may not ensure that the hazard of *C. botulinum* growth and toxin formation will be eliminated.

Since 2006, when the CFP first deliberated issues that address ROP fish/thawing of fish, FDA remains committed to providing code language that is clear on how to apply code provisions during food establishment inspections. In the 2013 Food Code, FDA incorporated paragraph 3-501.13(E), and we acknowledge that the updated code provision language was not as clear as it could have been on its intent for how to implement the code section. This could lead to interpreting the Food Code in a manner different from FDA's intent. The intent of Food Code section 3-501.13 is for reduced oxygen packaged fish to be <u>completely</u> removed from the ROP packaging entirely, so that the ROP environment is eliminated as explained in the public health reasons in Annex 3.

The public health reasons in Annex 3 from 2013 to 2022 states, "As an added safeguard to prevent the possibility of *C. botulinum* toxin formation, the Food Code requires that any frozen ROP fish that does not have barriers to growth of *C. botulinum* in addition to refrigeration be completely removed from the ROP environment or package prior to thawing. This is to discourage the practice of thawing frozen ROP fish and holding it at 41ºF or less for a prolonged time period and/or selling it as a refrigerated product." Since Annex 3 already includes the term 'completely' when describing the thawing of reduced oxygen packaged fish and FDA's Issue 2023-III-024, sought to add "completely" to the codified text.

For seafood processors regulated under 21 CFR 123, ROP encompasses a large variety of packaging methods including vacuum packaging, modified atmosphere packaging (including high oxygen), hermetically sealed containers (with or without the removal or manipulation of gases), heat sealed plastic or laminated packaging, and packing in oil. By reducing or preventing the exchange of normal ambient oxygen with the environment in the package, a processor introduces the food safety hazard *C. botulinum*. Any oxygen present at the time of packing may be depleted by activity of spoilage bacteria resulting in an anaerobic environment, which is favorable for *C. botulinum* germination, growth, and toxin formation.

C. botulinum is a pathogen that produces a very potent toxin and consists of two groups, proteolytics and nonproteolytics. Proteolytics grow at a minimum temperature of 50°F and can break down proteins to produce gas and odor. Nonproteolytics do not break down protein, do not produce any signs of spoilage, and grow at a minimum of 38°F. Nonproteolytics are very concerning for ROP fish because they can grow under refrigeration, are frequently associated with fish, and can form toxin before spoilage by other microorganisms renders the product unacceptable to consumers.

C. botulinum toxin formation can result in consumer illness and death. *C. botulinum* produces the toxin responsible for botulism. From 2001 to 2017, 53 foodborne outbreaks of botulism occurred in the United States with a median number of confirmed cases of 19 per year. While foodborne botulism is rare, it is still of great concern because it produces severe illness and death. Symptoms include weakness, vertigo, double vision, difficulty in speaking, swallowing, and breathing, abdominal swelling, constipation, paralysis, and death. Symptoms start from 18 hours to 36 hours after consumption. Everyone is susceptible botulinum toxin the most toxic naturally occurring substance known; only a few micrograms of the toxin can cause illness in a healthy adult. Mortality is high; without the antitoxin and respiratory support, death is likely.

FDA never had an intent that the language be seen as meaning to just place holes or slits in the reduced oxygen packaging (ROP) as a way to eliminate the ROP environment. Removal from ROP will not be accomplished by cutting slits. Further, placing holes or slits in the ROP may not ensure that the hazard of *C. botulinum* growth and toxin formation will be eliminated. This is due to uncertainties in the amount of oxygen transmission allowed by holes and slits of unknown size and number that would be needed to revert the ROP environment to an oxygen content level normally found in the atmosphere (approximately 21% at sea level) which would render the packaging no longer ROP. FDA is unaware of any science supporting that inserting holes or slits into frozen packages of ROP fish would allow sufficient transmission of oxygen to all product surfaces during thawing to eliminate reduced oxygen conditions.

Additionally, when evaluating food containers for a reduced oxygen environment, it is the interaction of the oxygen permeability of the container, oxygen availability in the food matrix, and utilization of oxygen by spoilage organisms along with the shape and size of the container that should be considered. Thus, completely removing the ROP packaging would be the most prudent means of eliminating the hazard of botulinum toxin formation, the deadliest natural toxin known.

Complete removal from ROP packaging is especially important because Section 3-501.13 (E) for thawing of ROP fish refers to Section 3-501.13 (A) and (B) which include thawing fish at 41°F which is a concern discussed in Annex 3. Retail operators can completely remove the fish from the package/bag entirely and place it in a cleaned and sanitized container without the bag to protect it from cross contamination and eliminate the hazard of botulinum toxin formation.
Therefore, FDA does **not concur** with the Conference's recommendation.

Historical review:
Since 2006, the Conference has deliberated several issues that address ROP fish/thawing of fish:

> **2006-III-014** (FDA at the Biennial Meeting recommended that vacuum packed seafood be removed from the package prior to thawing. The 2006-III-014 was extracted by Assembly and rejected so the Board suggested it be dealt with in the Supplement or be reintroduced as an Issue in 2008);
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> **2008-III-020** (extracted and went to the Executive Board)
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> **2012-III-017** (asked FDA to amend the language in Section 3-501.13 Thawing, to require that frozen reduce oxygen packaged fishery products be removed from ROP during the thawing process. FDA added language in the 2013 Food Code section 3-501.13 and Annex 3 public health reasons for section 3-501.13. Annex language at that time indicated remove completely from the ROP environment or package prior to thawing.), and
>
> **2016-III-032** (requested the 2013 Food Code be amended to require reduced oxygen packaging (ROP) fish packaged at retail food establishments be accompanied by a label indicating ROP fish is to be kept frozen until further use and removed from packaging for thawing and that retail food establishments be required to remove ROP fish from packaging before thawing.).

References:

Food and Drug Administration. 2020. Food Code. *Annex 3—Public Health Reasons/Administrative Guidelines*—Chapter 3, Food. Annex 3-113. https://www.fda.gov/food/fda-food-code/food-code-2022

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Reddy, N. R., A. Paradis, M. G. Roman, H. M. Solomon, and E. J. Rhodehamel. 1996. Toxin development by *Clostridium botulinum* in modified atmosphere-packaged fresh tilapia fillets during storage. J. Food Sci. 61:632–635.

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Skinner, G. E., and J. W. Larkin. 1998. Conservative prediction of time to *Clostridium botulinum* toxin formation for use with time-temperature indicators to ensure the safety of foods. J. Food Prot. 61:1154–1160.

Part 2 - 0ther Recommendations to the Food and Drug Administration

Part 2 of the letter identified 19 recommendations that request FDA take certain actions but that do not recommend specific changes to the 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 2025 Biennial Meeting in **Denver, Colorado.**

As explained more fully below, FDA **conceptually agrees on the merits of** 16 recommendations of the 19 Part 2 recommendations. For 2 recommendations, FDA **non-concurs**, and for 1 recommendation, **FDA believes it merits further discussion** prior to considering this recommendation noted in Part 2 of your letter

FDA conceptually agrees on the merits of the following 16 of the 19 Part 2 recommendations:

2023-I-007 Bread bakers adding sesame flour to recipe rather than "may contains"

NOTE: This recommendation requests that a letter be sent to FDA requesting the acknowledgment of the practice on the part of the commercial bread industry's addition of sesame and sesame flour into bread and similar products consequence for industry to comply with FDA allergen label. FDA should work with commercial manufacturers towards additional solutions.

FDA informs the Conference that FDA has already initiated activities to address this specific recommendation. FDA has publicly acknowledged[1] that FDA is aware that some manufacturers are intentionally adding sesame to bakery products that previously did not contain sesame and are labeling the products to indicate its presence. FDA recognizes that this practice may make it more difficult for sesame-allergic consumers to find foods that are safe for them to consume-an outcome that FDA does not support. FDA is engaged with various stakeholders on this issue.

[1] FDA Constituent Update. May 16, 2023. FDA Releases Draft Compliance Policy Guide on Major Food Allergen Labeling and Cross-Contact | FDA https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-draft-compliance-policy-guide-major-food-allergen-labeling-and-cross-contact

2023-I-017* Amend Food Code 3-301.11 – Double Handwashing and Nail Brush Usage
2023-I-032* Reducing Cross Contamination Risk from Use of Reusable Wiping Cloths

2023-II-010 PSC3 Tracking Versions of Standard 2 Appendix B-1
2023-II-011 PSC4 Change Re-Standardization Frequency for stall not standardizing others
2023-II-016 Verification Audit guidelines for Standard 2 with regards to Appendix B-1
2023-II-018 PSC7 Std 3 Requirements and Self-Assessment & Verification Audit Form Edits
2023-II-019 PSC15 Incorporation of Plan Review into VNRFRPS Standard 3
2023-II-025 PSC8 Create Standard 4 Verification Instructions
2023-II-026 PSC9 Edits to Standard 5 and Definitions
2023-II-028 PSC17 Referencing Crosswalk – Requirements for Foodborne Illness Training
2023-II-029 PSC18 Requirements for Foodborne Illness Training Program Crosswalk Content
2023-II-31 PSC10 Standard 6 Establishment File Worksheet Form 3A
2023-II-032 PSC11 Draft Standard 6 Standardized Key Crosswalk to the 2017 FDA Food Code
2023-II-034 PSC12 Defining Standard 8 Verification Audit Parameters
2023-II-037 Retail Program Standards Verification Auditor Criteria

***2023-I-017 is connected to Part 1**

For the following 2 recommendations in **Part 2** of your letter**, FDA does not concur:**

2023-I-020 FBIIC2-Interpret if 2022 FDA Food Code Provides Investigation Authority
2023-III-019 Create a Committee - Sea Moss and Sea Moss Gel Committee

2023-I-020 FBIIC2-Interpret if 2022 FDA Food Code Provides Investigation Authority

This recommendation requests that FDA issue an interpretation of the Food Code clarifying that Section 8-304.11(H) coupled with Section 8-402.11 and other relevant sections provide sufficient authority for a regulatory authority to conduct a foodborne illness investigation.

The Food Code is a model code offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. States are free to adopt the Food Code in whole or in part.

FDA knows foodborne disease remains a significant public health problem in the United States and, within the authorities granted to FDA, the Agency works with the Centers for Disease Control and State health and regulatory partners to enhance the speed, effectiveness, coordination, and communication of outbreak investigations. So, in this capacity, we understand the impact of having information from the retail food establishments in a timely manner in order to inform the investigation so that the number of foodborne illness cases can be lessened, in real-time.

In terms of investigatory authority, State privacy and disclosure laws and other State laws may intersect with the Food Code to impact the provision of certain information (e.g., consumer purchase data) during a foodborne outbreak investigation. Because of this, we think that the requested interpretation or change is a privacy-related matter that is best left to States to resolve. Therefore, while we encourage state, local, tribal, and territorial partners to adopt the latest version of the Food Code, we decline to issue an interpretation that would effectively touch upon state, local, tribal, or territorial law. Therefore, FDA does **not concur** with issuing an interpretation on this matter.

Regulatory authorities derive the requisite legal authority to do inspections and conduct foodborne illness investigations from the appropriate statute/ordinance of the State, Local, Tribal, and Territorial governmental bodies. The Food Code recognizes this in Annex 1, Section 8-701.10, where it states, "The regulatory authority shall have the requisite legal authority from the appropriate statute/ordinance making authority to adopt and enforce regulations to carry out the administrative and judicial enforcement provisions of the Code that are critical to the framework of a Food Establishment regulatory program, to include the requirement or the issuance of a Permit."

2023-III-019 Title: Create a Committee - Sea Moss and Sea Moss Gel Committee

The Conference recommends, "That a letter be sent to FDA to provide immediate interpretation for the safe use of sea moss and sea moss gel that is used in retail establishments as an ingredient in food such as sourcing and consideration as TCS food."

FDA does **not concur** with this recommendation because, in general, industry has the burden of ensuring that any substance, including sea moss and sea moss gel, that is used or intended for use in food is safe and lawful for those uses before going to market. Food manufacturers should not use or market a food ingredient unless they have a basis to conclude their intended use would be safe. The common names "sea moss" and "sea moss gel" do not refer to single ingredients but to broad classes of substances derived from multiple algal species processed using a variety of techniques. The determination of safety is made on a case-by-case basis for each specific sea moss ingredient and takes into account multiple variables such as the genus and species of the algae, items specific to its sourcing such as growing location and water quality at the harvest location, and how the ingredient is used or intended for use in food. It is not practicable to issue a single broad interpretation to address all intended uses or multiple forms of the product.

If an industry member or regulator has a general question about the regulation of substances used in conventional food, they may reach out to FDA's Office of Food Additive Safety at Premarkt@fda.hhs.gov (no second "e"). If an industry member needs assistance determining whether their specific uses of a substance in food are safe, we suggest they work with a regulatory consultant or faculty at a local university who has experience evaluating the safety of substances used in food.

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

2023-III-007 RSHSC 3 4 Review and Streamlining of Retail Sushi HACCP Process

The Conference recommends, "That two letters be sent, one to the FDA and one to the Retail Food Collaborative requesting that jointly they identify a panel of experts and create a process to review HACCP Plans for chain establishments operating in multiple jurisdictions and provide a validation and approval of the HACCP Plan, and that FDA issue a written interpretation encouraging regulatory authorities to accept the HACCP Plans as approved by the panel, in an effort to standardize HACCP Plan review."

FDA believes this recommendation merits further discussion and information prior to providing a response to this recommendation. FDA understands the request for national uniformity in this critical risk area. Typically, HACCP plans are reviewed by SLTTs and FDA does not validate or approve HACCP plans. We are interested in further discussions on how to reduce inconsistencies across jurisdictions and we will meet with the Retail Regulatory Association Collaborative and CFP to consider possible solutions.

I trust that this letter provides sufficient information about FDA's current positions on the recommendations from the 2023 Biennial Meeting of the Conference for Food Protection. FDA looks forward to continuing our cooperative relationship with the Conference.

Sincerely,

Douglas W. Stearn -S

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Douglas Stearn
Deputy Director of Regulatory Affairs
Center for Food Safety and Applied Nutrition