

December 14, 2021

Rebecca L. Vought, Chair Conference for Food Protection 30 Ellicott Court Martinsville, IN 46151-1331

Dear Ms. Vought:

Thank you for your letter dated September 29, 2021, in which you transmitted the recommendations made by the Conference for Food Protection (CFP) at its 2020 Biennial Meeting held virtually in August of 2021. The U.S. Food and Drug Administration (FDA) appreciates the efforts of all participants in the 2020 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. The 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 the FDA's current position on those recommendations that pertain to the FDA Food Code or otherwise recommend action on the part of the FDA. The CFP letter this year provided a description of the recommendation with the Issue number. Note that the FDA response herein contains the FDA response by Issue number and Issue title, following CFP convention in past letters to the FDA.

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

Your letter identified twenty-four (24) recommendations by the Assembly of Delegates to change the FDA Food Code or the Food Code Annexes.

The FDA conceptually agrees with twenty-two (22) of the twenty-four final recommendations and anticipates making changes to the Food Code and its Annexes related to the following Issues:

2020-I-005	CFP – ISSC Joint Committee on Shellfish; Amend the Food Code
2020-I-006	Amend Food Code and Annex references to 21 CFR 110 and replace with 21 CFR
	117
2020-I-007	Amend Food Code Section 1-201.10 to replace Fruits and Vegetables with term
	Plant Food
2020-I-013	Adding and other Food Contact items to Section 7-203.11
2020-I-019	Storage in Toilet Rooms

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2020-I-028 2020-I-030 2020-I-031	Amend Food Code – Permit Pet Dogs in Outdoor Dining Areas Removing the Reference to Restricted Use Pesticides in 7-202.12(B)(2) Person in Charge 2-103.11
2020-II-013	AC #3 – Amend Food Code for Major Food Allergen Training for Food
2020-II-014	Employees AC #4 – Amend Food Code for Notification of Major Food Allergens in Bulk Foods
2020-II-015	AC #5 – Amend Food Code for Written Notification of Major Food Allergens
	SHC-RPC-3 Sharing of Guidance Document for Roaster Pig Cooking
2018-III-006	DTCDC #3 Request Food Code Annex be amended to include guidance
	document
2020-III-009	PWWC – Issue 3: Amend Food Code to include Produce Wash Testing Devices
2020-III-014	PAC 5 – Amend Food Code Reference Approved Documents in FDA Food Code
	Annex 3
2020-III-019	Amend Food Code – Frozen Food Cook Requirements for HSP
2020-III-023	Amend Food Code – Clarification of allowable sanitizers in 4-501.114
2020-III-024	Amend Food Code by removing the flavor enhancers monosodium glutamate
2020-III-026	Amend 3-302.11: When raw animal products do not need separation from RTE
2020-III-027	Temperature of Water for Handwashing Sinks
2020-III-032	Manufacturer cooking instructions and disclosures
2020-III-034	Inclusion of the phrase "expelled air" in the definition of ROP

**Please note that while the FDA agrees in concept with these 22 recommendations, the agency may not agree with specific proposed wording for the FDA Food Code changes or placement of recommended changes. In these cases, the FDA may exercise its option to modify the recommended text or placement in the Food Code, either to provide clarity or to achieve consistency with the structure or conventions of the Food Code.

For the following recommendation in Part 1 of your letter, the FDA partially concurs:

2020-I-003 FRC Food Code Amendment

Issue 2020-I-003 recommends that the FDA include a new section in the Food Code addressing the distribution of food to another organization for charitable purposes, add a new defined term "food donation," and include a reference to the practice of food donations in Chapter 8.

The donation of food from food establishments to the communities they serve is a long standing and important societal practice that the FDA has and continues to support. As such, the Food Code does not prohibit food establishments from donating food.

The FDA acknowledges that while the Food Code does not prohibit the donation of food, it does not specifically state that the donation of food is permitted. This is largely due to the fact that as long as food is prepared, handled, and stored within a food establishment in accordance with the applicable provisions of the Food Code it is permitted to be offered to consumers, whether as a gift or offered for sale, regardless of the mechanism or means by which customers gain access to the food. The FDA further acknowledges there may be some benefit in, and can agree to, specifying in the Food Code that food received, stored, held, prepared, displayed, and labeled in accordance with the applicable food safety requirements contained in the Food Code may be donated to organizations or individuals.

Issue 2020-I-003 is recommending the following definition be added to the Food Code:

"FOOD DONATION: Practice by which a FOOD ESTABLISHMENT offers FOOD at no cost to an organization for distribution to, and consumption by, individuals in need. The donated FOOD is not offered for sale to the end consumer."

The FDA wants to meet the intent of the recommendation to foster the donation of food and believes the practice of donating food is acceptable and can be described without needing a definition that seems less inclusive. The FDA will continue to evaluate whether an added definition is necessary as we work through the language.

For the following recommendation in **Part 1** of your letter, **the 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.

2020-I-012 Use Limitation of Untreated Wood for Cooking Surface

This recommendation requests the FDA to amend Section 4-101.17 Wood Use Limitation to include a new paragraph (E) to allow for the use of "untreated white and western red cedar wood planks which are made from safe and clean materials as specified in \P 4-102.11(B) and with the intention to be a food contact surface may be used as a single-use cooking utensil and may subsequently be used as the serving utensil."

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); wooden paddles used in confectionary operations; and 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.

In consultation with the FDA Center for Food Safety and Applied Nutrition (CFSAN) Office of Food Additive Safety (OFAS), we concluded that the intended use of cedar planks appears to impart flavor, which would render cedar planks a food additive, not just a food contact surface as stated in the recommended solution for Food Code change. Cedar wood contains biologically active compounds and its use as a high temperature cooking surface may impart significant levels of these compounds to food. The FDA notes that if the intended use of a wood plank is to impart flavor to food, the plank would not meet the definition of a food contact substance under the Federal Food, Drug, and Cosmetic Act (FD&C Act), Section 409, and it would be considered

as a direct food additive under the FD&C Act Section 201(s) unless its use has been concluded to be generally recognized as safe (GRAS).

The FDA is not aware of evidence indicating the use of cedar as a cooking surface as a safety issue, but OFAS has not reviewed the safety of this use. Moreover, OFAS is not aware that any GRAS conclusions 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 safe use, nor 2) information to establish a reasonable certainty of no harm because of the proposed use such that the public health would be protected if a provision is added to the Food Code that allows untreated wood planks, such as cedar, for use as a cooking food contact surface.

The FDA advises the submitters of the proposed allowance for untreated wood planks for grilling and baking, and/or other interested parties, to provide the FDA with safety information about the intended use of wood planks such as cedar as a cooking surface in contact with food. The mechanism to submit safety information supporting a GRAS conclusion for the FDA's evaluation is through submission of a GRAS notice. GRAS status can be established through scientific procedures and/or experience based on common use in food prior to 1958. The general requirements applicable to GRAS status are described in 21 CFR Part 170 Subpart E. Sections 170.220 through 170.255 specifically describe the types of data and information that should be included in a GRAS notice.

If the submitters of the proposal believe that the use of untreated wood planks, such as cedar, as a surface for grilling and baking food is GRAS, we recommend they contact OFAS with a request for a pre-submission consultation prior to submission of a GRAS notice.

This Issue is tied to a Part 2 request (Other Recommendations to the FDA) for a safety assessment to be conducted by the FDA. Until safety information supporting a GRAS conclusion is submitted to FDA for evaluation, the FDA **does not concur** with the recommended change to allow for use of untreated cedar wood planks for grilling and baking food.

<u>**Part 2</u>** of your letter identified recommendations that requests the FDA take certain actions but that do not recommend specific changes to the FDA Food Code. The FDA conceptually agrees with nine (9) of the fourteen (14) recommendations below and will consider the availability of agency resources to pursue the recommended actions. The FDA will strive to keep the CFP Executive Board and the Conference apprised of progress made between now and the 2023 Biennial Meeting in Houston, Texas.</u>

- 2020-I-019 Storage in Toilet Rooms
- **2020-I-032** Whole Muscle Intact Beef Labeling
- 2020-I-035 When to Wash to Include Vaping
- 2020-II-018 PSC Issue #2 New Assessment Tool for Standard 8 Staffing Level Criteria

Issue 2020-II-018 recommends that FDA amend Standard 8 to include alternative criteria for the "staffing level" element of the requirement. The FDA acknowledges some stakeholders have raised concern that the existing staffing level criteria creates an unattainable standard for our

regulatory partners. The FDA believes the proposed model assessment tool is a promising alternative.

We also believe that this model should be compared against other optional criteria to determine the most efficient and feasible option that stakeholders deem accurate, reasonable, and attainable. Therefore, the FDA would like to continue to work with the Issue submitter, the CFP Program Standards Committee, and the CFSAN Office of Analytics and Outreach, Biostatistics & Bioinformatics Staff as this standard evolves and more audits are conducted. We are interested in engaging with potential auditors of Standard 8 to understand any challenges they may face with the alternate model and to continue discussions that engage more of our regulatory partners.

2020-II-020 PSC Issue #4 Maintenance and Posting of the Self-Assessment Tool (S/A Tool)
2020-II-027 PSC Issue #9 Amend Standard 2 to increase the time for completion of Steps 1-4
2020-II-029 CFP Model Code

The FDA welcomes the opportunity for continued collaboration and partnership with CFP. We look forward to entering purposeful discussions on ways to increase the likelihood CFP recommendations may receive the FDA concurrence. This is likely to include, but not be limited to, discussion of the overall CFP process and the inclusion of substantive reasoning and intent in both Issues submitted to the CFP for consideration as well as CFP recommendations submitted to the Agency. The FDA response letter will continue to convey the FDA's position on each CFP recommendation, and we will work to enhance communication efforts in partnership with CFP to assist with stakeholder awareness and visibility of the FDA response to the final recommendations from CFP.

2020-III-032 Amend VNRFRPS Standard 6 – Compliance and Enforcement
2020-III-035 Amend Food Code: clarify language for disinfection of food-contact surfaces

For the following recommendations in Part 2 of your letter, the FDA partially concurs:

2020-II-024 PSC Issue #6 Amend Standard 2 Appendix B-1 Format
2020-II-025 PSC Issue #7 Amend Standard 2 curriculum to replace select courses with updates
2020-II-026 PSC Issue #8 Amend Standard 2 to include addition "pre" and "post" topics

The FDA supports reformatting Appendix B-1 Curriculum into a table categorized as recommended in Issue 2020-II-024. Issue-II-024 thru 26 also call for the FDA to evaluate courses and update the listings in Standard 2 based on the suggestions from the CFP Program Standards Committee. The FDA acknowledges the need to review and revise courses listed in Standard 2 as recommended by the CFP Program Standards Committee and has already begun the process of review through the FDA Office of Training Education and Development (OTED) gap analysis process. Once this process is completed, the FDA will communicate its findings.

The staff from OTED will take this opportunity to share with the Conference its established process for aligning courses with curriculum competencies and learning paths. The staff engaged in a detailed curriculum development process through the National Curriculum Standard (NCS) resulting in the development of 26 General Education (Gen Ed) courses. Upon completion of the courses, a gap analysis was conducted comparing the Gen Ed courses with current courses listed

in Appendix B of Standard 2. The intent is to sunset one or the other and provide the most up-todate content strengthening core learner competencies. The result of the gap analysis noted major gaps between the Gen Ed courses and established courses.

To alleviate this gap, OTED has started *Gap Analysis Phase II* focused on "repairing" the competency gaps prior to releasing them for general use. The staff from OTED expect to have all 26 Gen Ed courses analyzed and repaired by the 2023 CFP meeting. As each course is "repaired" it will be released for use to support Standard 2.

The FDA will consider every suggested course by CFP, but the FDA reserves the right to ensure all recommended training courses are aligned with established curriculum competencies in order to provide the learner the knowledge, skills, and abilities needed to perform regulatory work.

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

2020-I-012 Use Limitation of Untreated Wood for Cooking Surface

This Issue calls for the FDA to conduct a safety assessment of untreated white and western red cedar for use as a cooking surface and whether it is a concern and to establish a reasonable certainty of no harm as a result of the proposed use, such that, public health would be protected. At this time, the FDA **does not concur** with this recommended solution because the FDA cannot commit to conducting a safety assessment as requested by CFP. The FDA does not initiate safety assessments for ingredients that stakeholders wish to use in food, but the FDA rather evaluates safety data submitted by stakeholders, and then responds appropriately.

Therefore, it is incumbent upon industry to provide the safety data for evaluation by the FDA through the appropriate regulatory program (e.g., the GRAS Notification Program). Through the GRAS Notification Program, GRAS conclusions are made by qualified experts outside of the government, not by the FDA. The FDA evaluates whether data and information included in GRAS notices submitted to the GRAS Notification Program provide a sufficient basis for a GRAS conclusion.

We are available to provide further information to stakeholders on the process for submitting a GRAS conclusion to the GRAS Notification Program administered by OFAS, and we can commit to ongoing communication/education efforts with CFP regarding OFAS-related issues concerning cedar planks.

For the following Issue, the FDA will need to further consider the matter and consult with the Executive Board of the Conference for Food Protection prior to deciding on the recommended solution:

2020-II-031 Standard 1 Update to Require 80% of Certain Provisions

A goal of the FDA's Retail Food Safety Program is to encourage widespread, uniform, and complete adoption of the FDA Food Code. The Food Code serves as the model regulatory foundation that jurisdictions can use to update their own food safety rules and to be consistent with national food regulatory policy. We have partnered with the Retail Food Safety Regulatory

Association Collaborative on efforts to further Food Code adoption by creating a Food Code Adoption Tool Kit and overall national adoption strategy. These are ongoing efforts. Prior to instituting such a fundamental change to this standard, we want to understand the root issues. In order to do that, we need to hear from our regulatory partners. As we do more internal deliberations on this recommendation, we will continue to work with CFP, the Issue submitter and our regulatory partners to best position ourselves in making programmatic decisions to further public health. We believe this recommendation warrants further discussion and analysis prior to proceeding on modifying the Voluntary National Retail Food Regulatory Programs Standards. The FDA will keep the CFP Executive Board informed.

I trust that this letter provides sufficient information about our current positions on the recommendations from the 2020 Biennial Meeting of the Conference for Food Protection.

I look forward to continuing our cooperative relationship with the Conference.

Sincerely,

Suran J. Mary

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