CENTER FOR Science IN THE Public Interest
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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Request for Comments Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry: Chapter 11: Food Allergen Program (Docket No. FDA-2016-D-2343)

To Whom It May Concern,

The Center for Science in the Public Interest (CSPI)[1] and the undersigned submit these comments to the United States Food and Drug Administration (FDA) on Chapter 11: Food Allergens Program of the Draft Guidance for Industry on Hazard Analysis and Risk-Based Preventive Controls for Human Food.[2]

We support the FDA objective of clarifying the means to create an effective food allergen control program but have concerns regarding the potential for thresholds of allowed allergen cross-contact as mentioned in this draft guidance and with the failure of the guidance to provide advice on consistent and accurate precautionary allergen labelling (PAL). The guidance also fails to prevent the intentional addition of allergens, a practice FDA has said it opposes,[3] which is a concerning approach that has been adopted by some members of the food industry as an alternative to implementing effective but costly preventive controls.

Nevertheless, we feel the concept of thresholds holds promise and could be incorporated constructively to improve the accuracy and consistency of PAL. Consequently, we ask that FDA remove the current draft language on thresholds in Chapter 11 and instead separately work towards creating a more comprehensive allergen labelling framework that incorporates the use of thresholds into the design of PAL and prevents the intentional addition of allergens.

I. Background

Chapter 11 is part of a broader guidance for industry on preventive controls in food production, which are mandated to be part of manufacturers' food safety systems by the Food Safety

[1] CSPI is your food and health watchdog. Since 1971, CSPI has worked to improve the public's health through better nutrition and food safety. The organization's work is supported by subscribers to its Nutrition Action Healthletter, one of the nation's leading health newsletters. CSPI is an independent organization that does not accept government donations or corporate funding.
[2] Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry Chapter 11: Food Allergen Program. U.S. Food and Drug Administration. September 26, 2023. https://www.fda.gov/media/172318/download?attachment
[3] An Update on Sesame Allergen Labeling on Food Packages. U.S. Food and Drug Administration. Updated July 27, 2023. Accessed March 14,2024. https://www.fda.gov/news-events/fda-voices/update-sesame-allergen-labeling-food-packages

Modernization Act.[4] The preventive controls outlined in Chapter 11 are geared toward controlling allergen cross-contact risks and helping mitigate the risk of undeclared allergens entering the food system from situations such as labelling errors and cross-contact.[5]

Allergen preventive controls are a critical food safety component for protecting allergic consumers, who make up a substantial portion of the public and can be severely harmed by allergens. In a recent survey[6] of U.S. adults, researchers determined that 10.8% had a convincing food allergy. Of these allergic adults, 51.1% reported experiencing at least one severe food-allergic reaction, and 38.3% reported one or more food allergy-related emergency department visits.

Because of these risks, when an undeclared major food allergen is present in a food product, FDA may consider the product to be misbranded and adulterated, leading the agency to request or require a recall.[7] Dangerous amounts of undeclared allergens in food occur all too often. Undeclared allergens represented 30-48% of incidents reported each year from 2010-2022 via FDA's reportable foods registry,[8] which is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences.[9]

Industry fears the massive costs from such recalls, which can lead to the destruction of large quantities of food. In a survey of its member companies conducted by the Grocery Manufacturers of America, published in 2011, 81% of respondents deemed the financial risk of a recall to be "significant to catastrophic."[10] Undisclosed allergens are the most common cause of recalls and have been for the past 5 years (allergens caused 43.5% of FDA food recalls in 2022).[11]

Presumably driven by a desire to prevent recalls and minimize their legal risks, as well as to mitigate health risks to consumers from exposure to undeclared allergens, many food manufacturers have begun to incorporate PAL such as "may contain x allergen." Such statements are now included on nearly 1 in 5 food labels in the United States.[12]

PAL, however, currently offers little to prevent recalls or assist consumers in identifying cross-contact risks. FDA has stated that the inclusion of PAL does not serve as a substitute for

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[4] FSMA Final Rule for Preventive Controls for Human Food. U.S. Food and Drug Administration. Updated July 13, 2023. Accessed February 7, 2024. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food

[5] Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry Chapter 11: Food Allergen Program. U.S. Food and Drug Administration. September 26, 2023. https://www.fda.gov/media/172318/download?attachment

[6] Gupta RS, Warren CM, Smith BM, et al. Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019;2(1):e185630. Published 2019 Jan 4. doi:10.1001/jamanetworkopen.2018.5630

[7] CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact. U.S. Food and Drug Administration. Updated May 16, 2023. Accessed February 7, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-draft-major-food-allergen-labeling-and-cross-contact

[8] FDA-TRACK: Reportable Food Registry Data Dashboard. U.S. Food and Drug Administration. Updated February 5, 2024. Accessed February 7, 2024. https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard

[9] Reportable Food Registry for Industry. U.S. Food and Drug Administration. Updated March 22, 2022. Accessed February 7, 2024. https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry

[10] Capturing Recall Costs, Measuring and Recovering the Losses. Grocery Manufacturers Association. October 2011. https://globalfoodsafetyresource.com/wp-content/uploads/2014/08/www.gmaonline.org_file-manager_images_gmapublications_Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf

[11] Beach C. Report finds an enormous increase in the number of food items recalled in 2022. Food Safety News. Published March 15, 2023. Accessed March 14, 2024. https://www.foodsafetynews.com/2023/03/report-finds-enormous-increase-in-number-of-food-items-recalled-in-2022/

[12] Pieretti MM, Chung D, Pacenza R, Slotkin T, Sicherer SH. Audit of manufactured products: use of allergen advisory labels and identification of labeling ambiguities. *J Allergy Clin Immunol*. 2009;124(2):337-341. doi:10.1016/j.jaci.2009.05.032

preventive controls,[13] and thus a food may be considered adulterated and misbranded by an undeclared allergen even if it bears PAL advising of such a possibility. From the consumer perspective, PAL offers a confusing diversity of statements that can be difficult to understand.[14] Furthermore, there is not a clear correlation between PAL usage and allergen levels, meaning that consumers who make purchasing decisions based on these labels may still be exposed to harmful levels of allergens while unnecessarily avoiding some safe products.[15,16] FDA has done little to bring clarity to this space, as it offers no regulation or guidance on the content of these statements, other than to require them to be truthful and non-misleading.[17]

The current approach to allergen controls also puts companies under difficult economic constraints. In some cases, the investment needed to control allergen cross-contact risks, such as re-designing facilities or production processes, is extremely high, leading some companies to conclude it cannot be mitigated via preventive controls.[18] Companies in this position are faced with two difficult choices: invest in expensive controls or face the risk of a costly recall. Unfortunately for consumers, some companies confronting these problems have opted for a third perverse and unexpected solution: adding more of the allergen to the product and then placing it in the ingredients list.[19]

In 2023, CSPI petitioned[20] FDA to address this practice of adding allergens to avoid implementing preventive controls. We documented cases of companies acknowledging that they opted to add sesame, an allergen that was added to the U.S. major food allergens list by Congress in 2019, because they asserted that they were unable to adequately control cross-contact risks for this allergen. Adding the allergen allowed the companies to declare it in the label, effectively negating the requirement to control sesame as a hazard and averting recalls if the allergen had been undeclared. We asked FDA to advise companies that they are required to mitigate identified cross-contact hazards and that adding allergen to the product to circumvent the need for controls violates this requirement. However, the agency denied our petition in relevant part in 2023, stating that such a practice is "not violative."[21] The agency stated in a separate update, however, that adding allergens for such a purpose is "a practice with an outcome we do not support."[22]

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[13] Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry. U. S. Food and Drug Administration. November 2022. https://www.fda.gov/media/117410/download

[14] Gupta R, Kanaley M, Negris O, Roach A, Bilaver L. Understanding Precautionary Allergen Labeling (PAL) Preferences Among Food Allergy Stakeholders. *J Allergy Clin Immunol Pract*. 2021;9(1):254-264.e1. doi:10.1016/j.jaip.2020.09.022

[15] Remington BC, Baumert JL, Marx DB, Taylor SL. Quantitative risk assessment of foods containing peanut advisory labeling. *Food Chem Toxicol*. 2013;62:179-187. doi:10.1016/j.fct.2013.08.030

[16] Ford LS, Taylor SL, Pacenza R, Niemann LM, Lambrecht DM, Sicherer SH. Food allergen advisory labeling and product contamination with egg, milk, and peanut. *J Allergy Clin Immunol*. 2010;126(2):384-385. doi:10.1016/j.jaci.2010.05.034

[17] Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry Chapter 11: Food Allergen Program. U.S. Food and Drug Administration. September 26, 2023. https://www.fda.gov/media/172318/download?attachment

[18] Petition to FDA to Notify Manufacturers that They Cannot Mitigate Allergen Cross-Contact Risks by Adding Sesame and other Major Allergens to Foods. Center for Science in the Public Interest. January 30, 2023. https://www.cspinet.org/sites/default/files/2023-01/Petition%20to%20Prohibit%20Allergen%20Addition.pdf

[19] Ibid.

[20] Ibid.

[21] Kavanaugh C. FDA Response to Petition to FDA to Notify Manufacturers that They Cannot Mitigate Allergen Cross-Contact Risks by Adding Sesame and other Major Allergens to Foods. July 26, 2023. https://www.cspinet.org/sites/default/files/2023-07/FDA-2023-P-0342%20-%20FDA%27s%20%20Response%20to%20the%20CSPI%20Allergen%20Labeling%20Citizen%20Petition%20-%207-26-23.pdf

[22] An Update on Sesame Allergen Labeling on Food Packages. U.S. Food and Drug Administration. Updated July 27, 2023. Accessed March 14,2024. https://www.fda.gov/news-events/fda-voices/update-sesame-allergen-labeling-food-packages

It is clear that the current system of allergen preventive controls and PAL is not working for consumers or food companies. CSPI is hopeful that a better approach is possible, one that leads to more uniform and accurate PAL labeling, reduces recalls, disincentivizes adding allergens to foods, maintains incentives to control cross-contact, and ultimately reduces the public health burden of food allergy. Accomplishing these goals requires a comprehensive approach that addresses PAL, added allergens, and preventive controls together.

II. Concerns and Recommendations for Chapter 11

While we recognize the need for change, we are concerned that Draft Chapter 11 addresses only a part of the allergen preventive controls and PAL problem and does so in a way that puts consumers at greater risk without providing clear consumer benefits. The guidance proposes to lift some of the pressure on companies to control allergen risks and determine food recalls by offering industry discretion to incorporate the concept of thresholds of allowed allergen contamination, stating that "[f]ood manufacturers/processors could evaluate such [threshold] data... in making decisions on appropriate food allergen controls."[23]

While such an approach may lighten the economic burden of allergen controls and potential recalls, we are concerned that it has the potential to put consumers at risk by offering too much discretion to manufacturers to forgo controls without grounding those changes in adequate evidence, potentially resulting in weakened protections for public health.

The approach also does not ensure that consumers are provided with consistent and accurate PAL, and it does not address the harmful industry practice of adding allergens intentionally to foods as a means of skirting regulatory requirements. (As we stated in our petition, adding a known allergen to a food that previously did not contain it does nothing to mitigate foreseeable hazards and therefore violates both the letter and spirit of the preventive controls rule.) In sum, the draft guidance's language on thresholds provides flexibility for industry but does not secure needed consumer protections in return.

Accordingly, we ask FDA to remove the language on thresholds in the final guidance, and proceed instead with exploring a more comprehensive approach to thresholds that also incorporates PAL and addresses the harmful practice of adding allergens.

The language on thresholds appears in several places in the guidance. FDA mentions "threshold dose" in the guidance[24] as part of its discussion of how to identify hazards requiring a control and in its discussion of supplier verification, stating that "published data raise the possibility that some low-level exposures to food allergens, and the presence of certain allergen-derived ingredients, may not cause allergic reactions in most consumers who have that food allergy."[25] The agency advises that "[f]ood manufacturers/processors could evaluate such data in light of their specific products, such as through risk assessments or other scientifically valid assessments,

[23] Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry Chapter 11: Food Allergen Program. U.S. Food and Drug Administration. September 26, 2023. https://www.fda.gov/media/172318/download?attachment
[24] Ibid.
[25] Ibid.

in making decisions on appropriate food allergen controls."[26] In effect, the agency raises the possibility of thresholds that might relieve companies of their preventive controls responsibilities. This suggestion also may have implications for other regulatory and quasi-regulatory decisions, such as the decision to recommend or order a recall if the allergen contamination is suspected to be below the relevant threshold.

Though the guidance explicitly discusses thresholds, it does not select any specific thresholds. Instead, it cites to a Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens[27] and a paper by Remington et al,[28] which analyze eliciting doses (ED) of allergens, or the doses at which a certain percentage of the respective allergic populations would be predicted to experience any objective allergic reaction. The Joint FAO/WHO expert consultation recommended a target threshold allergen content close to the ED05 as a "reference dose," meaning the dose at which 5% of the respective allergic population would be predicted to experience an allergic reaction.[29] Notably, the reference dose proposed in Europe was focused on applying thresholds in the management of PAL, not preventive controls, although the committee recognized that such thresholds "can have multiple dimensions in addition to consumer health, such as decisions on recall, trade rejection, as well as advice to people with food allergies and outcome measures for food immunotherapy studies."[30]

We are concerned that, as currently constructed, the guidance leaves excessive discretion to industry to experiment with thresholds in ways that could negatively impact consumer health.

First, the lack of specificity over the EDs and the "most consumers" language in the guidance leaves the door open for industry to justify any allergen threshold at or below ED50, which may result in dangerous exposures for some consumers.[31]

Second, industry can decide how to use its self-selected thresholds in preventive controls and supplier verification. This could induce manufacturers to reduce investments in preventive controls or supplier verification based on a determination that contamination risk can be maintained at an acceptable level without such activities. Industry also may also forgo recalls based on a determination that contamination is below the threshold they have selected.

Third, industry would have discretion regarding whether and how to advise consumers that it is allowing allergen contamination up to a specific threshold. This is a pressing problem, as consumers vary in risk tolerance such that more sensitive consumers will require advisory statements warning of even small risks. For example, if a manufacturer has set a threshold of the ED10 or higher and believes contamination is likely at such a level, PAL warning consumers of

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[26] Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry Chapter 11: Food Allergen Program. U.S. Food and Drug Administration. September 26, 2023. https://www.fda.gov/media/172318/download?attachment

[27] Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 2: Review and establish threshold levels in foods of the priority allergens. Virtual meeting, 15 March – 2 April 2021. Summary and Conclusions. Food and Agriculture Organization of the United Nations and World Health Organization. 2022. https://www.who.int/publications/i/item/9789240065420

[28] Remington BC, Westerhout J, Meima MY, et al. Updated population minimal eliciting dose distributions for use in risk assessment of 14 priority food allergens. *Food Chem Toxicol*. 2020;139:111259. doi:10.1016/j.fct.2020.111259

[29] Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 2: Review and establish threshold levels in foods of the priority allergens. Virtual meeting, 15 March – 2 April 2021. Summary and Conclusions. Food and Agriculture Organization of the United Nations and World Health Organization. 2022. https://www.who.int/publications/i/item/9789240065420

[30] Ibid.

[31] Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry Chapter 11: Food Allergen Program. U.S. Food and Drug Administration. September 26, 2023. https://www.fda.gov/media/172318/download?attachment

that risk may be warranted. Yet under current FDA regulations and guidance, such advisory statements would not be required (or even clearly recommended by the agency).

While we are open to considering an approach that safely incorporates thresholds into regulatory decisions (provided it also ensures clear and consistent PAL and prevents companies from adding allergens to circumvent preventive controls), we feel that incorporating thresholds into preventive controls via the current draft guidance is premature at this time considering substantial evidence and policy gaps. The WHO/FAO thresholds cited by FDA in its draft guidance were developed to inform PAL, not food safety decisions such as when to deploy a preventive control.[32] In considering these thresholds, the committee identified multiple deficiencies and/or inconsistencies in analytical methodologies and methods, including a lack of validated methods for identification and quantification of priority allergens.[33] Such deficiencies may be acceptable in the context of PAL, where no current standards exist (i.e., there is only room for improvement in the accuracy and consistency of PAL). However, we are concerned with developing policy that would allow food companies to waive preventive controls requirements for allergen contamination below a threshold, when no validated methods exist to confirm that contamination has remained below that threshold.

Consequently, we believe FDA should remove the current language on thresholds in Chapter 11, while continuing to explore threshold as part of a more comprehensive approach to the issue identified in the first section of this comment.

III. FDA Should Create a More Comprehensive PAL System

As stated above, FDA also does not require food manufacturers to utilize PAL. The Draft Chapter 11 guidance does little to address this topic and focuses on PAL primarily from the perspective of ensuring that manufacturers do not fall back on such labeling as a substitute for controlling the risk of undeclared allergens. However, the guidance does advise that such labeling must be truthful and non-misleading, and offers guidance on how to carry forward PAL from suppliers and place such statements so they are easily recognized by consumers.

While we agree that PAL is not a substitute for preventive controls, such label statements must be truthful and non-misleading, and can serve as an important risk communication tool to help inform food-allergic consumers. Manufacturers also must consider PAL in making informed food safety decisions related to preventive controls, supplier verification, and recalls, as recognized by references to PAL throughout the Chapter 11 guidance.

Given the importance of PAL, we urge FDA to create more specific recommendations on the use of PAL and standardizing practices around a specific statement or several statements that have been found to communicate risks most clearly to consumers. For example, Canada has recommended[34] the standardized "may contain x" statement and provided guidance to manufacturers in incorporating thresholds into the determination of whether to utilize PAL. FDA

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[32] Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 2: Review and establish threshold levels in foods of the priority allergens. Virtual meeting, 15 March – 2 April 2021. Summary and Conclusions. Food and Agriculture Organization of the United Nations and World Health Organization. 2022. https://www.who.int/publications/i/item/9789240065420

[33] Ibid.

[34] Allergen Management Guidelines for Food Manufacturers. Food Allergy Canada, Université Laval, Food Risk and Regulatory Excellence Platform. September 2022. https://parera.ulaval.ca/fileadmin/Fichiers/Formation_FAC/FAC_ManufacturersGuide_EN.pdf

could similarly advise on the use of PAL to indicate that allergen risk is above a certain threshold, which could be the reference dose developed by the FAO/WHO or another amount based on the agency's own review. The agency could also advise on the use of truthful and non-misleading PAL that indicate where no allergen risk is present (such as "allergen free"). These recommendations can be rooted in FDA's authority to require that label statements be truthful and non-misleading and should be based on peer-reviewed studies and consultation with stakeholders, including consumer and allergen groups and members of the food industry. If FDA feels it lacks authority to create a comprehensive PAL system, the agency should request this authority from Congress.

IV. Conclusion

Thank you for providing an opportunity to comment on the draft guidance. We emphasize the need for the agency to step back from the passing mention of thresholds in this guidance and instead to consider thresholds and their diverse implications more comprehensively.

Sincerely,

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