

August 15, 2022

Robert M. Califf M.D.
Commissioner
Food and Drug Administration
c/o Dockets Management Staff (HFA-305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Submitted via www.regulations.gov

Re: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders (FDA-2021-N-0553)

Dear Dr. Califf

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments on “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders (FDA-2021-N-0553)” (the “Draft Guidance”). Representing more than 114,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and the world. Our members work with patients, researchers, physicians, policymakers and families to prevent, identify, and manage food allergies among all population groups. **We support the draft guidance as an important interim step towards helping consumers avoid a food that may cause prevalent and severe allergic reactions among the population.**

A. Background

Congress passed the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act, P.L. 117-11), making sesame the ninth major food allergen through a quickly moving legislative process that short-circuited the need to continue regulatory efforts to achieve the same result. The presence of non-major allergens can be hidden in terms such as “natural,” “spice,” or “flavor,” and this ambiguity leaves open the possibility of an individual with an allergy in a perilous position of not knowing whether it is present or not in the food, risking a severe allergic or life-threatening reaction. Special consideration should be given to Americans facing disparities impacted by social determinants of health who may have limited access to healthcare, nutrition literacy, or education resources. In some cases, the only tool available for identifying food allergens is the food label, which may fail to disclose the presence of a “non- major” allergen and consumers may be misled. This Draft Guidance is a critical first step in addressing the concerns of millions of Americans by outlining the rigorous scientific framework by which additional allergens may be labeled.

B. Diversity, Equity, and Inclusion

The Academy's Strategic Plan¹ both recognizes and encourages a shift in focus toward health equity, social determinants of health, and transparent involvement of broader constituencies, which we believe are critical to incorporate and address on a global scale as well. We earlier this year shared with the U.S. Department of Agriculture and the U.S. Department of Health and Human Services recommendations² for issues and scientific questions to be addressed during the development of the 2025-2030 Dietary Guidelines for Americans, including specific consideration to food allergens and the patterns and practices for the introduction of foods to infants and toddlers in Hispanic and Latino communities, and encourage consideration of these concerns throughout relevant stages of the framework.

C. Interoperability, Common Data Sets and Food Allergy Documentation

The Academy has long worked collaboratively with the National Institutes of Health and the Office of the National Coordinator for Health Information Technology (ONC) on efforts to promote nationwide, interoperable health information exchange, which will enhance patient care and facilitate more robust research opportunities by using common data elements and terminology. A key element of these efforts is ensuring certain nutrition-related data and the associated terminology recommended by the Academy are included in the United States Core Data for Interoperability (USCDI), which is the minimum data elements that are required to be part of an application programming interface (API) for certified electronic health records (EHRs) as required by the 21st Century Cures Act.

For the submission year 2020, the Academy worked with our Interoperability and Standards Committee (ISC) to submit a [food allergy data element](#) that achieved level 2 and became eligible for consideration for inclusion in the next version of the USCDI. If this food allergy data element were to be included, the presence of a unique, uniform data set would enable food allergies to be tracked separately from drug and other allergies and thereby provide documented, valuable data on the prevalence, evidence, and severity of food allergens among a larger number of Americans. Given the nature of the facilities where such data would be expected to be collected and the clinicians collecting it, there is an enhanced likelihood it would be specified standards of scientific rigor.

D. Generating, Sharing and Applying Knowledge and Evidence

The Academy commends the thoughtful and detailed comments to this Draft Guidance submitted by FARE (Food Allergy Research and Education), with whom we are grateful to partner on issues of mutual concern. We specifically associate ourselves with several of their requests for clarification, detail, or incorporation, restated as below:

¹ Academy of Nutrition and Dietetics Strategic Plan. eatrightPRO.org. <https://www.eatrightpro.org/-/media/eatrightpro-files/leadership/bod/strategic-plan/academy-of-nutrition-and-dietetics-strategic-plan-sep-2017.pdf?la=en&hash=D00E3FE00D1475FB416E20004DECC3C136D5D7E5>.

² Academy Comments to HHS and USDA re 2025 Proposed Scientific Questions. Academy of Nutrition and Dietetics website. Available at <https://www.eatrightpro.org/-/media/eatrightpro-files/news-center/on-the-pulse/regulatorycomments/academy-comments-to-hhs-and-usda-re-2025-proposed-scientific-questions-final.pdf?la=en&hash=FB739E541D6536D5A52E43D1CB2BE24126A806E6>. Accessed April 18, 2022.

- 1) The FDA must clarify in revision to the draft guidance that the top nine (9) food allergens (milk, egg, peanuts, tree nuts, soy, wheat, fish, crustacean shellfish, and sesame) **only can be changed via a legislative amendment** to the FD&C Act (21 U.S.C. §321 (qq) definition of “major food allergen”), as amended by FALCPA and the FASTER Act, and not through a regulatory process established by this framework.
- 2) The Academy agrees with FARE regarding the four scientific factors FDA intends to consider when evaluating the public health importance of a food allergen in the United States – evidence, prevalence, severity, and potency. Further, we agree with FDA’s assessment of the general global consistency of criteria from the Codex Alimentarius Commission, International Life Sciences Institute-Europe, and National Academies of Sciences, Engineering, and Medicine.
- 3) In addition, the Academy believes that FDA also must establish a regulatory process (as required by the FASTER Act) to implement the framework, with a review of updated scientific information to be conducted on a recurring basis. If a food ingredient meets the criteria of the framework to modify food allergens requiring labeling, FDA must be clear that it will initiate the rulemaking process. FDA’s regulatory process should allow adequate time for stakeholder engagement, particularly those from the food allergy community and board-certified food allergists and researchers to provide data on what foods qualify as a public health priority for food allergens requiring labeling.
- 4) Evidence data are generally well characterized in the published, peer-reviewed literature for known food allergens, less so for emerging food allergens.
- 5) To ensure the greatest clarity in this framework, FDA must provide more details on thresholds or benchmarks across each category of prevalence, severity, and potency.

E. Conclusion

The Academy appreciates the opportunity to submit comments related to the draft guidance, “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders” and to support the FDA’s work ensuring disclosure of allergens and promoting a safer food system for individuals with allergies. We encourage the FDA to finalize without delay regulatory action mandating the disclosure of the presence of sesame in a packaged food product, including as an ingredient in spices, flavorings, colorings, or incidental additives, by expeditiously identifying and defining an appropriate set of scientific criteria for determining priority allergens. Please contact either Jeanne Blankenship by telephone at 312-899-1730 or by email at jblankenship@eatright.org or Pepin Tuma by telephone at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information; we would welcome the opportunity to provide whatever input or assistance we can in this endeavor.

Sincerely,



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