

February 25, 2021

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***RE: Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry
[Docket No. FDA-2020-D-0530]***

Dear Dr. Mayne:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA) related to its request for comments on its recently issued “Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry” (the “draft guidance”).

Representing more than 107,000 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 is committed to accelerating improvements in global health and well-being through food and nutrition. **We support the draft guidance as an important interim step towards helping consumers avoid a food that may cause prevalent and severe allergic reactions among the population.**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

Between 700,000-1,500,000 U.S children and adults are believed to have a sesame allergy, with experts suggesting sesame allergies are becoming more prevalent, rising significantly from an estimated 500,000 cases in 2015.¹ In a study conducted between 2017 and 2019, an estimated 0.49% (95% CI, 0.40%-0.58%) of the US population reported a current sesame allergy.² Given the rising prevalence of sesame allergies and noting the severity of adverse events detailed in the draft guidance, the Academy believes it is appropriate to designate sesame as an allergen of public health importance.

Sesame currently present in bread, crackers, candy, tortilla chips, dips, oils, and other common food products may not be declared on the label; instead its presence is hidden in terms such as

¹ “Facts and Statistics.” *Food Allergy Research & Education*, 2021, www.foodallergy.org/resources/facts-and-statistics.

² Warren CM, Chadha AS, Sicherer SH, Jiang J, Gupta RS. Prevalence and Severity of Sesame Allergy in the United States. *JAMA Network Open* 2019; 2(8):e199144. doi:10.1001/jamanetworkopen.2019.9144.

“natural,” “spice,” or “flavor.” Such 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. Without accurate labels consistent with the draft guidance, individuals would need access to another method enabling them to make informed decisions about food allergens at the point of purchase, which may require a smartphone or potentially expensive tools.

Individuals in a variety of other settings will also likely benefit from the draft guidance’s recommendation for voluntary declaration. For example, staff in college and university settings can easily post information for prepared foods served cafeteria-style, whereas individual grab-and-go food packages would have the declaration on the label. In both instances, students with food allergies, intolerances, and conditions such as celiac disease can more easily eat safely on campus. In addition, implemented draft guidance recommendations would assist staff in healthcare facilities and other large-scale operations with food service components.

B. Academy Principles

The Academy adopted in 2014 the following principles for labeling initiatives to guide development of our regulatory comments and policy stances. Those principles specifically relevant to the declaration of the presence of sesame in food products and the Academy's response to the FDA's request for comments are bolded below.

- 1. Label claims should be clear and understandable to consumers; consumers' nutrition literacy is key to promoting understanding.**
- 2. The label must be truthful and not misleading.**
- 3. Content on the label should help consumers make informed decisions to build a healthy diet.**
4. Labels should help to provide understanding about the nutrient density and overall healthfulness of overall food rather than a focus on particular nutrients.
5. Label content should have consistent type and format so products can be read and consumers can make product comparisons.
6. Labeling should enhance consistency among the various government nutrition recommendations.
- 7. All claims should include labeling of accurate quantitative information about the dietary substance, including percent of Daily Value in a single serving of the products, when known, or the daily dietary intake necessary to achieve the claimed effect.**
8. Consumer research is imperative before making changes to the label.
9. The label is only a source of information, and thus sustained support for educational programs and individual counseling by registered dietitian nutritionists is essential.

The Academy of Nutrition and Dietetics supports science-based food regulations and recommendations that are applied consistently across sectors. In 2010, the Academy adopted food safety principles for federal food safety authority in the United States, including the principle that:

Food authority should be collaborative across national, state and local agencies, and between government and industry partners to foster more robust, consistent, accurate and timely communication and data sharing that leads to efficient and effective decision-making processes.³

A safe food system requires that “the presence of food allergens be properly disclosed and that allergic consumers and their caregivers be able to read and understand the relevant information on packaged food labels, so they can identify and avoid specific food allergens.”⁴ The draft guidance makes only voluntary recommendations, but it is nonetheless an effective tool for persuading manufacturers to declare the presence of sesame without being required to do so. Moreover, it buys time for the FDA to consider its options and choose a standard for determining additional priority allergens even as it establishes the standard we anticipate will be carried forward in a forthcoming regulatory action mandating disclosure of this allergen in accordance with section 403(x) of the FD&C Act. **In short, we welcome the draft guidance, which will provide immediate, meaningful information to help individuals with sesame allergies identify additional foods that may contain sesame as an ingredient or additive.**

By including the recommended additional declaration when sesame is present in spices, flavorings, colorings, or incidental additives, manufacturers can ensure consumers are aware of sesame’s presence in a food product when it would not otherwise appear in the ingredients list. This enhances consistency with other allergens and heightens consumers’ understanding of which allergens a food product contains and improves the label’s accuracy and clarity as to the presence of this prevalent allergen.

Finally, we note a limitation of existing allergen labeling rules in that they do not enable consumers readily to obtain detailed and reliable information about the amount of allergenic proteins incorporated in composite foods.⁵ Detailed information of the amount of allergenic protein can provide substantial assistance to registered dietitian nutritionists in the diagnosis and management of food allergies, specifically allowing for quantitative risk assessment in diet history and diagnosis.⁶ Recognizing this value to consumers and health professionals, we encourage the FDA and manufacturers to consider strategies for making this quantitative information available either upon request or on the product’s website.

C. Concerns

Because the draft guidance is limited to recommending each individual manufacturer implements voluntary declaration of sesame when present in spices, flavorings, colorings, or incidental additives, consumers may not feel confident that a product does not contain sesame if there is no

³Cody MM, Stretch T. Position of the Academy of Nutrition and Dietetics: food and water safety. *J Acad Nutr Diet.* 2014;114(11):1819-29.

⁴Draft Guidance at 3-4.

⁵Kok M, Compagner A, Panneman I, Sprikkelman A, Vlieg-Boerstra B. A Food, a Bite, a Sip: How Much Allergen Is in That? *Nutrients.* 2021; 13(2):587. <https://doi.org/10.3390/nu13020587>

⁶ Kok M, Compagner A, Panneman I, Sprikkelman A, Vlieg-Boerstra B. A Food, a Bite, a Sip: How Much Allergen Is in That? *Nutrients.* 2021; 13(2):587. <https://doi.org/10.3390/nu13020587>

wording on the packaging, because not every manufacturer is assured to adopt the draft guidance. We note this effect is similar to the current voluntary disclosure “made in a facility that processes other allergens.” If packaging does not disclose the product may or may not be made in a shared facility with sesame, consumers could be at risk.

To facilitate consumer understanding, we support declaration of the common name “sesame” in parentheses when it might properly be listed under another name, such as benne seed (heirloom sesame seed from Africa), gingelly or til (other names for sesame oil), halvah, sesame flour, sesame oil, sesame paste, gomasio (sesame salt), sim sim (East African name for sesame), tahini, hummus and tempeh.

D. Conclusion

The Academy appreciates the opportunity to submit comments related to the draft guidance, “Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry” 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 assistance we can in this endeavor.

Sincerely,



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