



January 30, 2023

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
submitted via [regulations.gov](https://www.regulations.gov)

Re: Docket FDA-2022-D-0099, Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry

To Whom It May Concern:

On behalf of the Asthma and Allergy Foundation of America (AAFA) and the undersigned organizations, thank you for the opportunity to provide comments on the FDA’s draft questions and answers document regarding allergen labeling requirements.

The proposed language includes guidance related to the addition of sesame as a new “top allergen.” We are therefore taking this opportunity to express our concerns regarding how manufacturers have responded to this policy change. Our organizations appreciate the FDA’s ongoing work addressing food allergies and ask the FDA to develop a solution that meets the needs of children and adults with sesame allergy, as well as initiating a broader move towards more meaningful use of precautionary allergen labeling (PAL) statements. Our concerns are detailed below.

Background: Addition of sesame as a top allergen

Approximately one in ten children and adults in the U.S have food allergies.^{1,2} The FDA's promulgation and enforcement of labeling requirements, along with food allergen preventive controls and good manufacturing practices, help protect the health and lives of people with food allergies. Under the Food Allergen Labeling and Consumer Protection Act (FALCPA), the agency has implemented guidance to industry mandating clear labeling of the "top eight" food allergens – milk, egg, fish, shellfish, peanuts, tree nuts, soy, and wheat – when they are ingredients of packaged food. By implementing these requirements, the FDA has allowed consumers managing these allergies to safely identify foods containing their allergens and reduce exposures, which can lead to severe anaphylactic reactions and, in rare cases, death.

The food allergy community was therefore highly supportive of the Food Allergy Safety, Treatment, Education and Research Act of 2021 (FASTER), which, among other provisions, added sesame to this list of "top" allergens which in turn requires labeling and preventive controls.³ In prevalence, sesame has become "the ninth allergen" in the U.S., with sesame allergy ranking just behind those of the eight allergens covered by FALCPA.^{4,5} Allergic reactions to sesame can be particularly severe: over a third of children and adults with sesame as their only food allergy had experienced reactions severe enough to require emergency room treatment.⁶

¹ Gupta et al., Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019 Jan 4;2(1).

² Gupta R, Warren C, Blumenstock J, Kotowska J, Mittal K, Smith B. The prevalence of childhood food allergy in the United States: An update. *Ann Allergy Asthma Immunol* (2017).

³ Faster Act of 2021 (Public Law 117-11). Available at <https://www.congress.gov/bill/117th-congress/senate-bill/578/text>

⁴ Ruchi S. Gupta, Christopher M. Warren, Bridget M. Smith, Jesse A. Blumenstock, Jialing Jiang, Matthew M. Davis, Kari C. Nadeau. "The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States."

Pediatrics Dec 2018, 142 (6) e20181235; DOI: 10.1542/peds.2018-1235

⁵ Gupta RS, Warren CM, Smith BM, et al. Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019;2(1):e185630. doi:10.1001/jamanetworkopen.2018.5630

⁶ Warren CM, Chadha AS, Sicherer SH, Jiang J, Gupta RS. Prevalence and Severity of Sesame Allergy in the United States. *JAMA Netw Open*. 2019;2(8):e199144. doi:10.1001/jamanetworkopen.2019.9144

Manufacturer response to the sesame labeling requirement

The sesame labeling requirement became effective on January 1, 2023. In late 2022, we began to hear concerning reports from our patient communities about sesame newly appearing on labels for previously safe products, including bread, rolls, and other baked goods. We are now seeing a pattern of three types of manufacturer responses to the new sesame labeling requirements:

1. Adding sesame as an ingredient. Some manufacturers have added sesame flour or seeds to products because they claim it would be too difficult to adequately clean sesame off of bakery equipment. This practice appears to have spread across the U.S. baking industry, with manufacturers of bread and rolls for school lunch providers, restaurant chains, and supermarket sales adding sesame seeds or sesame flour to their products.⁷

This practice is highly concerning for several reasons. First, consumers who purchase or eat previously-safe brands of bread and rolls without visible sesame seeds may very well assume that those products remain safe. Second, the food options available for people with sesame allergy have narrowed significantly because of these intentional additions. Third, these manufacturers seem to be rejecting out of hand the possibility of effective allergen cleaning for sesame or dedicating separate manufacturing lines for plain products, despite preventive controls being a crucial component of allergen safety across all other top allergens.

2. Adding sesame to the ingredient list *without adding sesame as an ingredient.* Some manufacturers have added sesame seeds to their ingredient list. When asked for explanations, these manufacturers have told consumers that this step was taken as a precaution in case sesame seeds are carried over accidentally in the manufacturing process. This is illegal if sesame is not an intentional ingredient and the label is not truthful, misleading, and confusing for consumers.
3. Adding an advisory label (e.g. "may contain") for sesame. Some manufacturers have not changed their recipes but are now adding a PAL statement for sesame.

⁷ JoNel Aleccia, "New label law has unintended effect: Sesame in more foods." AP News (Dec. 21, 2022). Available at <https://apnews.com/article/sesame-allergies-label-b28f8eb3dc846f2a19d87b03440848f1>

As discussed further below, we have broader concerns about the current unregulated system of PAL statements.

The role of PAL statements

We are concerned that the sesame situation has been exacerbated by the lack of a standardized system for informing consumers about the risks of potential food allergen exposure, and we urge FDA to take steps toward a clear, science-based PAL system.

Currently, PAL statements such as “may contain” or “made in a facility with” are completely voluntary and unstandardized. Because these statements are not rooted in any consistent qualitative and quantitative risk assessment standard and are voluntary, they do not convey reliable information to consumers about actual risk of allergen exposure. The absence of PAL statements in our current system is not necessarily indicative of safety.

Manufacturers’ troubling practices with regard to sesame are a clear example of why a clearer PAL system is so important. If meaningful, standardized PAL requirements were in place, manufacturers of food with potential sesame cross-contact might be more likely to implement good manufacturing practices and use accurate, risk-based PALs to inform consumers of any residual risk, rather than resort to adding sesame seeds or sesame flour to their products.

Recommendation

FDA has already stated that it “does not support” manufacturers intentionally adding sesame to products simply to mitigate their responsibilities under the Faster Act.⁸ We appreciate that statement, and are asking you to translate that position into practical next steps.

Specifically, we urge the FDA to convene allergy experts and prevention control/good manufacturing practice experts to identify a solution that prioritizes consumer health, safety, *and* consumer choice. The agency should work to address manufacturer questions and concerns about their responsibilities and liabilities related to food allergen cross-contact, and re-clarify that sesame may not be added to ingredient lists when it is not in fact an ingredient.

⁸ Aleccia, *supra*.

In addition, we encourage the FDA to initiate a process toward identifying a PAL policy that is mandatory, consistent, and evidence-based, centering the informational and health needs of consumers. For example, Australia's Voluntary Incidental Trace Allergen Labelling system, or VITAL system, relies on science-based safe reference doses for each specific allergen and provides manufacturers with clear guidance on when and how PAL statements can be used in conjunction with the program. Working towards a similarly science-based and uniform, but mandatory PAL system in the United States will greatly benefit and further protect consumers with food allergy.

Conclusion

All of the undersigned organizations stand ready to work with you on both of these goals, and we are grateful for your time and attention. If you have any questions, please contact Jenna Riemenschneider at jennar@aafa.org.

Sincerely,

Asthma and Allergy Foundation of America (AAFA)
Allergy Advocacy Association (AAA)
Allergy & Asthma Network (AAN)
American Partnership for Eosinophilic Disorders (APFED)
Campaign Urging Research for Eosinophilic Disease (CURED Nfp)
Elijah-Alavi Foundation (EAF)
Food Allergy Anaphylaxis Connection Team (FAACT)
Food Allergy Research & Education (FARE)
Food Allergy Science Initiative (FASI)
Food Equality Initiative (FEI)
FPIES Foundation
International FPIES Association (IFPIES)

With support from:

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