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# **Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry**

## ***Draft Guidance***

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Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2020-D-0530 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

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# **Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry<sup>1</sup>**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## **I. Introduction**

We are issuing this guidance to provide food manufacturers with our current views on sesame as an allergen and to provide recommendations to voluntarily disclose sesame in certain circumstances where such disclosure is not currently required. The guidance is intended to help individuals who are allergic to sesame identify those foods that may contain sesame as an ingredient.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

## **II. Background**

Food allergies occur when the body's immune system reacts to certain food proteins (Ref. 1). Allergic reactions to food due to immunoglobulin E (IgE) antibodies cause the body to release inflammatory chemicals and can be particularly severe, leading to symptoms such as hives, facial swelling, vomiting, wheezing, shock, and even death. Because there is currently no cure for food allergies and approved therapeutics to avert allergic reactions are limited, allergic consumers must use avoidance to prevent allergic reactions. Successful avoidance requires, among other things, that allergic consumers and their caregivers know when allergens are present in packaged foods or in other settings, such as at retail or food service establishments. Thus, it is important that the presence of food allergens be properly disclosed and that allergic consumers and their

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<sup>1</sup> This guidance has been prepared by the Office of Nutrition and Food Labeling, Food Labeling and Standards Staff in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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caregivers be able to read and understand the relevant information on packaged food labels, so they can identify and avoid specific food allergens.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that a food (other than a raw agricultural commodity) that bears or contains a “major food allergen” declare the allergen using its “common or usual name.” A food is misbranded if it contains a major food allergen and fails to declare that major food allergen on its label using the major food allergen's common or usual name (section 403(w) of the FD&C Act). The FD&C Act defines a “major food allergen,” in part, as any of the following:

- Milk,
- Eggs,
- Fish (*e.g.*, bass, flounder, or cod),
- Crustacean shellfish (*e.g.*, crab, lobster, or shrimp),
- Tree nuts (*e.g.*, almonds, pecans, or walnuts),
- Wheat,
- Peanuts, and
- Soybeans.

See section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)).

In 2004, when Congress amended the FD&C Act to require labeling of major food allergens, these eight foods and food groups, out of more than 160 identified food allergens, accounted for 90 percent of serious food allergic reactions. Nevertheless, when drafting the food allergen-specific provisions, Congress made clear that the new statutory requirements did not alter FDA’s authority under the FD&C Act to require a label or labeling for other food allergens (21 U.S.C. 343 note). Thus, if a new food allergen emerges, we can use our existing authorities to ensure appropriate labeling. In addition to specific allergen labeling, FDA has authority to require that a food label bear the common or usual name of the food, if it has one, and the common or usual name of each ingredient if the food is made from two or more ingredients (section 403(i) of the FD&C Act). A common or usual name must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients and can either be the name established by common use or the name required by a regulation (21 CFR 102.5). Thus, the FD&C Act includes other authorities that help consumers with a food allergy or another reason for avoiding an ingredient. While there is an exception in section 403(i) for spices or flavorings, which can be declared as simply “spice” or “flavor” on the label, section 403(x) of the FD&C Act gives us authority to require the disclosure of spices, flavorings, colorings, or incidental additives, that are, or contain, allergens other than the eight major food allergens by regulation if needed.

In 2014, we received a petition from the Center for Science in the Public Interest (CSPI), several medical professionals, and two consumer advocacy groups requesting, among other things, the labeling of sesame as an allergen, even though it is not included as one of the eight major food allergens specified in the FD&C Act (see <https://www.regulations.gov/docket?D=FDA-2014-P-2035>).

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While we have not yet done so ourselves, several research groups, e.g., International Life Sciences Institute-Europe (ILSI-EU) (Ref 4-7) and countries like Canada, Australia, and New Zealand (Ref 8 and Ref 9), have developed or recommended scientific criteria that can be used to determine “priority allergens,” sometimes also referred to as “allergens of public health importance.”<sup>2</sup> Some criteria (e.g., prevalence of allergy in the population, severity of reactions experienced) are common across these different sets of criteria, while other criteria (e.g., potency of the allergen) appear more important in some sets but not others.

FDA is currently working to develop our own set of factors for evaluating which food allergens, beyond the eight major food allergens specified in the FD&C Act, should be designated as requiring additional controls, including allergen labeling. While FDA considers these factors and regulatory options regarding declaration of sesame, because of increasing concern about sesame allergies in the United States, we are providing these voluntary recommendations to manufacturers regarding what we currently believe are best practices for sesame labeling.

### **III. Discussion**

In 2017, the National Academies of Sciences, Engineering and Medicine (NASEM) issued a report entitled “Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy” (Ref 10). One recommendation in the report was that “...public health authorities in individual countries decide on a periodic basis about which allergenic foods should be included in their priority lists based on scientific and clinical evidence of regional prevalence and severity of food allergies as well as allergen potency.” The report further commented that “...evidence of the allergen prevalence and reaction severity to sesame seeds *may* warrant their inclusion on the priority allergen list in the United States” (emphasis added). FDA’s evaluation of public information, including scientific and clinical data, revealed data gaps in regional prevalence and severity of sesame allergies.

In response to these data gaps, FDA published a notice in the *Federal Register* of October 30, 2018 (83 FR 54594), inviting additional data and other information on the prevalence and severity of sesame allergies in the U.S. and the prevalence of sesame-containing foods sold in the U.S. that are not required to disclose sesame as an ingredient. The notice also asked specific questions regarding the prevalence of allergies and allergic reactions due to sesame in the U.S. and the prevalence and amounts of undeclared sesame in foods. For example, we asked for examples of products or product categories that contain sesame as a spice, flavor, color, or incidental additive. The notice also stated that we had received a citizen petition in 2014 requesting, in part, that we issue a rule to require that sesame seeds and sesame products be regulated similarly to how major food allergens are regulated under the FD&C Act. Among the various issues, the petition wanted FDA to require sesame’s disclosure by the common or usual name “sesame” in food labeling and when present in ingredients, including a spice, flavoring, coloring, or incidental additive.

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<sup>2</sup> Other countries have recognized foods other than the major food allergens, e.g. sesame, as priority allergens of public health importance for which specific product labeling of food source is required.

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We received over 4,800 comments from individual consumers and patients, as well as consumer and patient advocacy groups, medical professionals and patient caretakers, industry and trade associations, and academic institutions. Some comments submitted data and information from published studies.

Data and information received in response to the notice highlighted U.S. national prevalence data on sesame and other food allergens. In 2018, Gupta et al. published results from a nationwide survey of over 50,000 U.S. households, including 38,000 households with children (Ref 12). The authors concluded that the survey (Ref 12) showed that 0.2% of children in the U.S. were reported to have a sesame allergy, which, compared to childhood allergies to the major food allergens, ranks 9<sup>th</sup> just below soy, pistachio and wheat (each 0.5%). As part of the same nationwide survey, Gupta et al. also found a similar 0.2% prevalence of reported sesame allergy in adults, just below prevalence rates of the major food allergens pistachio (0.4%), cashew (0.5%), and soy (0.6%) (Ref 13). Gupta et al.'s study showed that two-thirds of children with reported sesame allergy experienced an emergency department visit, which is higher than reported visits for any of the major food allergens. Finally, severe reactions were reported more frequently in children with a sesame allergy than for children with allergies to the major food allergens (Ref 12). While we also received some data on incidence or prevalence of sesame allergy cases from several U.S. clinical centers, we note there continues to be a data gap in national prevalence data derived from clinically-based diagnosis of sesame allergy (i.e., with confirmatory testing and/or challenge). This lack of U.S. prevalence data based on clinically-confirmed cases of food allergy was also highlighted in the NASEM report and constitutes a gap in assessing the true prevalence of sesame allergy and other food allergies.

Under our statute and regulations, if whole sesame seeds are used as an ingredient, they must be declared on the label (see section 403(i) of the FD&C Act (21 U.S.C 343(i)); 21 CFR 101.4); however, under current regulations, sesame can, in some circumstances (such as when ground and used in a spice blend), be declared in an ingredient statement as simply "spice" or "flavor," so its presence may not be obvious to consumers.<sup>3</sup> Some comments to the notice highlighted the lack of consistent labeling of sesame on food and stated this was a major problem for those with a sesame allergy.

Our communications about the notice directed the public to submit adverse event reports due to sesame to the CFSAN Adverse Event Reporting System (CAERS). We received more than 500 individual adverse event reports.<sup>4</sup> The products most frequently reported as causing reactions to sesame were hummus, tahini, halvah, and baba ghanoush. While not all reports provided sufficient detail to make causal associations, FDA's review of the reports found that one in four

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<sup>3</sup> While Compliance Policy Guide (CPG) 525.750 for spices says that sesame seeds are not considered to be spices and, when used as an ingredient in foods, should be declared on the label by common or usual name, other non-seed forms of sesame may be used as spices and may not be required to label the food source.

<sup>4</sup> CSPI sent many of these reports. In their comments to the notice, CSPI described an analysis of 321 adverse reaction reports to sesame in sesame allergic consumers received from May 2008 to Dec 2018. CSPI found that 50% reported an emergency room visit or hospitalization and 37% reported reactions being treated with epinephrine. Foods found to be most commonly associated with reactions were breads, crackers, bagels, flavored rice, and hummus. Also, by CSPI's analysis, 39% of reports described adverse reactions occurring in food products where sesame was not declared in the ingredient statement or elsewhere on the product label (See <https://www.regulations.gov/document?D=FDA-2018-N-3809-0543>).

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reported reactions to products in which sesame was undeclared. A number of reports described reactions to food products in which “spice” or “flavor” was listed on the product’s label, however sesame was not declared as an ingredient. Of the reports we received, 44% of adverse reactions to sesame were described as severe and nearly 50% resulted in physician or hospital visits. Analysis of adverse event data found a robust incidence and severity of reported adverse reactions to sesame and provide additional evidence to inform FDA’s consideration of possible actions with regard to sesame.

Based on information received in the comments to the notice, the 2014 citizen petition (and comments submitted to the corresponding docket), other correspondence, as well as adverse event reports and recent publications with prevalence data, it appears that sesame allergy may be an increasing problem in the U.S. population. We continue to evaluate the emerging evidence and are working to develop factors to inform future regulatory actions related to sesame and other emerging food allergens, including possible labeling requirements. As we engage in this important work, we recommend, in the interim, that manufacturers voluntarily take steps to help consumers who are allergic or sensitive to sesame by disclosing the presence of sesame in packaged foods, even in circumstances where such disclosure would not be required (e.g., in spices and flavorings).

### **Recommendations for Voluntary Disclosure of Sesame**

The information available to FDA indicates that the reported prevalence of sesame allergies in the U.S. population appears to have increased. Furthermore, when reactions to sesame occur, they can be relatively severe and adverse event reports submitted in response to the notice reported reactions associated with products containing undeclared sesame. As explained above, sesame can be included in “flavors” and “spices” and therefore sometimes not listed specifically on labels. Thus, we recommend that manufacturers, as a voluntary matter, clearly declare sesame in the ingredient list when it is used in foods as a “flavor” or “spice”<sup>5</sup> in a parenthetical following the spice or flavor, such as, “spice (sesame),” “spices (including sesame),” “flavor (sesame)” or “flavors (including sesame).” If a term is used for a food that is or contains sesame, such as tahini, we recommend that sesame be included in a parenthesis, e.g. “tahini (sesame)” in the ingredient list. This voluntary declaration of all sources of sesame in the ingredient list will help consumers, especially those allergic to sesame, avoid foods that could cause an allergic reaction.

## **IV. References**

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at

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<sup>5</sup> When whole sesame seeds are used as an ingredient in foods, they must be listed in the ingredient list as “sesame” or “sesame seed” per FDA’s current labeling regulations (21 U.S.C 343(i), 21 CFR 101.4, also see CPG 525.750).

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the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff.

1. FDA. “Food Allergies: What You Need to Know.” March 2017. Available at <https://www.fda.gov/media/79019/download>. \*
2. Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004” (Edition 4). October 2006. Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4>. \*
3. Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications.” May 2014. Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications>. \*
4. Bjorksten, B., et al., Criteria for identifying allergenic foods of public health importance. *Regulatory Toxicology and Pharmacology*, 2008. 51: p. 42-52.
5. van Bilsen, J.H.M., et al., Evaluation of scientific criteria for identifying allergenic foods of public health importance. *Regulatory Toxicology and Pharmacology*, 2011. 60(3): p. 281-289.
6. Chung, Y.J., et al., Application of scientific criteria to food allergens of public health importance. *Regulatory Toxicology and Pharmacology*, 2012. 64(2):p 315-23.
7. Houben G, Burney P, Chan CH, Crevel R, Dubois A, Faludi R, Klein Entink R, Knulst A, Taylor S, Ronsmans S. Prioritisation of allergenic foods with respect to public health relevance: Report from an ILSI Europe Food Allergy Task Force Expert Group. *Food Chem Toxicol*. 2016;89:8-18
8. Canadian Criteria for the Establishment of new Priority Food Allergens. 2010. [https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt\\_formats/pdf/pubs/label-etiquet/crit/index-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/pubs/label-etiquet/crit/index-eng.pdf).
9. Risk assessment – Proposal P1026: Lupin as an Allergen, Food Standards Australia New Zealand, 2017. <http://www.foodstandards.govt.nz/code/proposals/Documents/P1026%20Lupin%20as%20an%20Allergen%20CFS%20SD1.pdf>.
10. National Academies of Sciences, Engineering, and Medicine. Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy. Nov 2017.
11. Sorscher, S. Center of Science in the Public Interest. Seeds of change. April 2018. <https://cspinet.org/sites/default/files/attachment/seeds-of-change-report.pdf>.



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12. Gupta RS., Warren CM, Smith BM et al. The public health impact of parent-reported childhood food allergies in the United States. *Pediatrics*. 2018 Dec; 142(6).
13. Gupta RS, Warren CM, Smith BM, Jiang J, Blumenstock JA, Davis MM, Schleimer RP, Nadeau KC. Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019;2(1):e185630.