

What Cos. Must Know About New Sesame Allergen Labeling

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On April 23, President Joe Biden signed into law the Food Allergy Safety, Treatment, Education and Research, or FASTER, Act, S. 578,[1] making sesame the ninth major food allergen under the Federal Food, Drug and Cosmetic Act.[2]

Effective Jan. 1, 2023, the FASTER Act requires food manufacturers to list sesame as an allergen on food labels. This act represents the first time a new allergen has been added to the list that the Food Allergen Labeling and Consumer Protection Act established as major food allergens.

In addition to the labeling mandate, the listing of sesame as a major food allergen has implications for the hazard analysis and preventive controls plans for facilities that handle sesame, under the Food Safety Modernization Act.

As background, food allergies affect approximately 7.6% of children and 10.8% of adults,[3] and sesame allergies in particular have increased in recent years.[4] Food allergies occur when a person's immune system reacts to certain proteins in food as a threat.

Recent research reports that sesame consumption can trigger severe reactions.[5] In general, allergic reactions to food can range from hives to anaphylaxis which, in certain instances, can lead to fatal respiratory effects or shock.

No cure currently exists for food allergies, and there are a limited number of approved therapeutics to prevent allergic reactions. Therefore, consumers who have food allergies must avoid allergy-triggering foods. Successful avoidance requires that food allergens be properly disclosed on food packaging.

Major Food Allergens

To facilitate consumers' ability to identify and avoid foods that contain major food allergens, in 2004, Congress passed the FALCPA, which established the list of eight major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts and soybeans.[6]



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The FALCPA amended the FDCA to require that the label of a food containing an ingredient that is, or contains protein from, a major food allergen declare the presence of the allergen in the manner described by the law. Under the FDCA, any food bearing or containing a major food allergen must declare the allergen on the label, using the allergen's common or usual name.[7]

This declaration has to be made either using a "contains" statement — e.g., "contains milk" — or in the ingredient list in parentheses following the name of the ingredient — e.g., "whey (milk)."[8] If the food's label fails to declare the major food allergen as required, the food is deemed misbranded.[9]

In addition to mandatory labeling requirements, the Food Safety Modernization Act requires food manufacturers to control for food allergens if they are identified as hazards. Under the preventive controls for human food rule, manufacturers are required to establish procedures, practices and processes that minimize or prevent allergen cross-contact during the storage, handling and use of the allergen, and that ensure the finished food product is properly labeled.[10]

Allergen cross-contact is often a concern for manufacturing facilities that make both products with and without allergens. In most circumstances, if any facility manufactures a product with a major food allergen, the manufacturer should identify allergen cross-contact as a hazard, and establish the appropriate preventive control.

Because sesame is now a major food allergen, companies handling sesame will need to reassess their hazard analysis and food safety plans, to evaluate whether additional controls are needed.

Sesame as an Allergen

In 2004, when Congress first defined a list of major food allergens, the eight listed allergens accounted for 90% of the serious food allergic reactions.[11] Since then, individuals with sesame allergies and consumer advocacy groups have pushed for sesame to be included on the major food allergen list.

Experts estimate that 0.2% of children and the same percentage of adults have a reported sesame allergy.[12] In comparison, 0.5% of children have a reported soy allergy and 0.4% of adults have a reported pistachio allergy, both of which are major food allergens.[13]

Because "major food allergen" is statutorily defined, and Congress did not create a mechanism to add another allergen to the definition, advocates needed to push Congress to make sesame a major food allergen. In recent years, advocates have also pushed the U.S. Food and Drug Administration to use its existing authorities to require some form of sesame labeling. In 2014, the Center for Science in the Public Interest, medical professionals and consumer advocacy groups filed a citizen petition asking the FDA to require sesame-based ingredients to be listed on food packaging by name.[14]

On Oct. 30, 2018, the FDA published a notice asking for information and data on the prevalence and severity of sesame allergies in the U.S. and the prevalence of foods that contain sesame, but for which sesame is not required to be disclosed as an ingredient.[15] The agency received over 4,800 comments.[16] Many of the comments cited studies on the prevalence of sesame allergies and the rising public health concerns surrounding sesame.

For example, a study cited in comments found that two-thirds of children who have a reported sesame allergy have visited an emergency room.[17] The FDA also received, through its Center for Food Safety

and Applied Nutrition's Adverse Event Reporting System, over 500 individual adverse event reports from May 2008 to December 2018 relating to sesame.[18]

The agency's review found that the most common foods linked to adverse events were hummus, tahini, halvah and baba ghanoush, and that one in four adverse events were due to the fact that sesame was undeclared as an ingredient.[19] The spotlight on sesame as an allergen led the FDA to issue a Nov. 10, 2020, draft guidance for industry, recommending voluntary labeling of sesame where it is not required to be declared as an ingredient, such as when used in flavoring or spice, or in a food declared by another name, such as tahini.[20]

As background, under Section 403(i) of the FDCA, when whole sesame seeds are used as an ingredient, they must be declared on the label. In certain circumstances, however, sesame can be declared in the ingredient list simply as "spice" or "flavor" without specifically calling out the presence of sesame on the food label.

In light of the foregoing, and the uptick in sesame allergies in the U.S. population, combined with increasing consumer concern, the FDA issued the draft guidance as a means of facilitating the disclosure of sesame in additional scenarios where such disclosure would not necessarily be required by law. The draft guidance recommended that manufacturers clearly declare sesame when used as a flavor or spice, by following those ingredients with a parenthetical, for example, "spice (sesame)," "spices (including sesame)," "flavor (sesame)" or "flavors (including sesame)."

In addition, the FDA recommended that any ingredient containing or comprised of sesame be declared with a similar parenthetical following its name — for example, "tahini (sesame)."[21]

Action on sesame labeling has not only been taking place at the federal level. In Illinois, a law was passed in 2019 mandating the declaration of sesame, which could have potentially set up a patchwork of requirements in the U.S. without a federal requirement.[22] Sesame is also already required to be declared as a food allergen in Canada, Europe, Australia and New Zealand.[23]

FASTER Act

The FASTER Act adds sesame to the major food allergen list under the FDCA, and all products that use sesame seeds or items derived therefrom must be explicitly labeled as containing sesame after Jan. 1, 2023.

In conformance with current requirements for major food allergen declarations, the presence of sesame can be declared by using a "contains" statement — e.g., "contains sesame" — or in the ingredient list by identifying sesame as an ingredient or with parentheses following the name of a sesame-containing ingredient — e.g., "tahini (sesame)."

In addition, under the FASTER Act, the FDA must to submit a report to Congress describing the ongoing activities, including the surveillance and collection of data on food allergy prevalence and severity, the development of effective food allergy diagnostics, the prevention of the onset of food allergies, the reduction of risks related to living with food allergies, and the development of new therapeutics to prevent, treat, cure and manage food allergies.[24]

The report is also required to provide recommendations for improving food allergy research, overcoming gaps in surveillance, and developing of a regulatory process — including scientific criteria

and opportunities for stakeholder engagement — for modifying the definition of "major food allergen" under the FDCA.[25]

It remains to be seen whether, in its report, the FDA will choose to address precautionary labeling — labels that state "may contain" or "manufactured in a facility that also processes" a major food allergen — or provide an update on the establishment of threshold levels for major food allergens, i.e., levels which are unlikely to cause an allergic reaction in the majority of allergic individuals, and thus exempt foods containing those levels from the FALCPA labeling requirements.

To date, adequate food allergen labeling remains a concern for many consumers. According to a 2016 FDA Reportable Food Registry report, undeclared allergens accounted for approximately 30% to 47% of reportable food registry entries from 2009 to 2014.[26]

In 2020, there were approximately 200 food allergen related recalls and alerts.[27] Key questions for the future are whether adding sesame as the ninth major food allergen will exacerbate this recall trend, and whether the passage of the FASTER Act will encourage other additions to the major food allergen definition in the near term.

Takeaways

Ensuring compliance with the FASTER Act will require companies to assess both food product labeling and food manufacturing practices. At a minimum, companies should consider taking the following steps before the act goes into effect:

- Companies should review ingredient lists for sesame or ingredients derived from sesame — e.g., tahini or hummus — or that might contain sesame that is not declared by name — e.g., natural flavors — and modify their labels as necessary, based on the allergen labeling requirements. This step may require additional information from ingredient suppliers in order to assess whether sesame is, or may be, present in any ingredient a company is using.
- Companies that handle sesame or sesame containing ingredients in their facility should reanalyze their food safety plans to list the presence of undeclared sesame in finished products as a hazard requiring a preventive control, and include preventive control procedures that ensure that finished products containing sesame are properly labeled to disclose that fact, as the FDCA requires.
- If a company manufactures products with and without sesame, the food safety plan reanalysis should additionally include:
 - Instructions for segregating sesame from other non-major food allergen ingredients, and/or a robust cleaning procedure for shared manufacturing lines after the production of a sesame-containing product;
 - Revising the company's supplier verification program to include assurances from ingredient suppliers that they have controlled for sesame. A company could review the supplier's allergen control plan to ensure it includes sesame, and ask for certificates of analysis that show sesame is not present in the supplier's ingredients;

- Verifying the controls for sesame are effective. This could mean conducting visual inspections or environmental sampling, using a preferred food allergen test such as a lateral flow or ELISA test, of manufacturing lines or food contact surfaces;
 - Implementing monitoring procedures to ensure these controls are happening; and
 - Taking corrective actions in the event of any failure of the controls.
- To prepare for FDA inspections, companies should keep comprehensive and detailed documentation of their sesame-related controls and procedures.

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[1] FASTER Act of 2021, S. 578, 117th Cong., <https://www.congress.gov/bill/117th-congress/senate-bill/578>.

[2] The White House, Bills Signed: S. 164, S. 415, S. 422, S. 578 (Apr. 23, 2021), <https://www.whitehouse.gov/briefing-room/legislation/2021/04/23/bills-signed-s-164-s-415-s-422-s-578/>.

[3] Gupta R.S., Warren C.M., Smith B.M., Blumenstock J.A., Jiang J., Davis M.M., Nadeau K.C. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. *Pediatrics*. 2018 Dec;142(6):e20181235 ("Gupta Childhood Study"). Gupta RS, Warren CM, Smith BM, et al. Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*.2019;2(1):e185630.

[4] Warren C.M., Chadha A.S., Sicherer S.H., Jiang J., Gupta R.S.. Prevalence and Severity of Sesame Allergy in the United States. *JAMA Netw Open*.2019;2(8):e199144 ("Warren Study").

[5] Gupta Childhood Study.

[6] See FDCA § 201(qq)(1).

[7] *Id.* § 403(w).

[8] *Id.*

[9] *Id.*

[10] 21 C.F.R. § 117.135(c).

[11] FDA, Guidance for Industry: Voluntary Disclosure of Sesame as an Allergen 4 (Nov.

2020), <https://www.fda.gov/media/143521/download> ("Voluntary Disclosure Guidance").

[12] Id. at 6.

[13] Id.

[14] Citizen Petition, Requests that the FDA require sesame based ingredients to be listed by name (sesame) in the ingredient lists of all foods, Docket No. FDA-2014-P-2035, <https://www.regulations.gov/docket/FDA-2014-P-2035>.

[15] FDA Notice, Sesame as an Allergen in Foods, 83 FR 54594 (Oct. 30, 2018), <https://www.federalregister.gov/documents/2018/10/30/2018-23635/sesame-as-an-allergen-in-foods>.

[16] Voluntary Disclosure Guidance at 6.

[17] Id.

[18] Id.

[19] Id. at 6-7.

[20] Id. at 7.

[21] Id. at 7.

[22] Jasper Davidoff, Illinois Requires Food Manufacturers to Label Sesame Allergen, willradio.tv.online (July 30, 2019), <https://will.illinois.edu/news/story/illinois-requires-food-manufacturers-to-label-sesame-allergen>.

[23] Warren Study.

[24] FASTER Act of 2021.

[25] Id.

[26] FDA, The Reportable Food Registry: A Five Year Overview of Targeting Inspection Resources and Identifying Patterns Of Adulteration September 8, 2009–September 7, 2014 (May 22, 2016), <https://www.fda.gov/media/97862/download>. A report on the five-year trends between 2014-2019 is expected to be released soon.

[27] Food Allergy Research And Resource Program, USA: FDA and USDA Food Recall Incidents, <https://farrp.unl.edu/reg-sit-usa> (last visited May 1, 2021).