Unintended consequences of new US law to protect allergic consumers from sesame allergen

Number of sesame-free foods decreases while risk of accidental allergen exposure increases

A new United States law recognizing sesame as a major food allergen is having unintended consequences. Some food manufacturers and commercial bakeries that support restaurants, stock grocery shelves and supply schools are intentionally adding sesame to various products that previously did not contain it. Consequently, this decreases the number of sesame-free products available for allergic consumers and creates the risk of accidental exposure through foods they previously considered safe.

Sesame usage in food

Sesame can be found in apparent places, such as seeds on hamburger buns, but is also an ingredient in many foods such as dressings, sauces, protein bars, cereals and soups. It often has been used when a label says "natural flavors" or "natural spices" and was previously added to many foods without being named. These situations have been confusing and worrisome for consumers working to avoid sesame allergen, sometimes requiring extensive phone calls to manufacturers to determine whether products contain sesame.

The ninth major food allergen

In 2004, to protect consumers, the US Congress passed the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), identifying eight major food allergens: milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat and soybeans. At that time, those eight allergens accounted for 90 percent of food allergies and serious allergic reactions in the US.

Sesame was recognized as the ninth major food allergen when the Food Allergy Safety, Treatment, Education and Research (FASTER) Act was passed by the US Congress on April 23, 2021. The new law made all United States Food and Drug Administration (FDA) requirements for major food allergens, including those for labeling and manufacturing, applicable to sesame. An effective date of January 1, 2023 gave food manufacturers, commercial bakeries and restaurants more than 18 months to comply.

According to *Allergic Living* and *Time.com,* patient advocacy groups including Food Allergy Research & Education (FARE), the Asthma and Allergy Foundation of America (AAFA) and the American Academy of Allergy, Asthma, & Immunology (AAAAI) "worked for years to lobby for and help create the new legislation." This is "a huge victory for the food allergy community," said Jason Linde, FARE senior vice president of government and community affairs.

FDA requirements and expectations

The FDA website uses text and illustrations to show consumers that sesame is now "required to be labeled as an allergen on packaged foods, including dietary supplements." The FDA also "expects that it be specifically listed as sesame on the label it it's part of another ingredient, like 'natural flavor' or

'spice mix.'" In addition, "if a food package has a 'contains' statement and has sesame as an ingredient, sesame will now have to be included in that contains statement."

The website further explains that "consumers may also see advisory statements such as 'may contain [allergen]' or 'produced in a facility that also uses [allergen].' [However,] such statements are not required by law and can be used to address unavoidable 'cross-contact,' only if manufacturers have incorporated good manufacturing processes in their facility and have taken every precaution to avoid cross-contact that can occur when multiple foods with different allergen profiles are produced in the same facility using shared equipment or on the same production line, as the result of ineffective cleaning, or from the generation of dust or aerosols containing an allergen." The *AP News* and *Time.com* also noted these statements "do not absolve the company of requirements to prevent cross-contamination."

While the FDA's website discusses labeling of packaged foods, *Fast Company* noted that "restaurant brands must now disclose if products contain or even potentially could have come into contact with sesame."

An unexpected countereffect

In December 2022—just prior to the new law's effective date—advocates for consumers with sesame allergy began warning that the FASTER Act could have an unexpected countereffect and unintended consequences. Some food manufacturers and commercial bakeries that supply national restaurant chains, grocery stores and schools had begun intentionally adding sesame to various breads and baked goods that previously did not contain it then were naming sesame as an ingredient. Consequently, this is decreasing the number of sesame-free products available for allergic consumers and increasing the risk of accidental exposure to sesame in foods that were previously considered safe.

Linde told *Allergic Living* that "food allergy families have been expressing concern and outrage" to FARE. "The addition of sesame flour to products at restaurants and in retail will deprive many in the food allergy community of choices," he said. "It is especially problematic that suppliers to schools are adding sesame because students in the cafeteria might not be aware. A student with a sesame allergy, who has always safely eaten a hamburger from the school cafeteria, could now potentially be exposed to sesame in the bun," he continued. Food allergy advocate Stacey Saiontz has a 15-year-old son who is allergic to sesame. According to *Allergic Living*, she "finds it disappointing that more products will become off-limits due to companies adding sesame flour. 'Sadly, this means that brands that had been safe for us are no longer safe,'" she stated.

"It is critically important for food allergy consumers to continue to read every label every time and to inquire at restaurants and fast-food chains. Formerly safe foods may now contain sesame allergen," Kenneth Mendez, president and CEO of AAFA told *Allergic Living*. "During negotiations with industry members and lawmakers, there was no indication that companies might take this type of action," said Linde.

Baking industry perspectives

A rationale for the addition of sesame was provided by *Fast Company*, which explained that "sesame differs in one distinct way from eggs, peanuts, shellfish, milk and soy," all of which are other major US allergens. "The seeds are teeny tiny and hard to track, making them prone to cross-contamination. If you operate a bakery that makes sesame bagels, the odds are decent that rogue seeds will end up in your other products too."

According to the *AP News* and *Time.com,* "Food industry experts said the requirements are so stringent that many manufacturers, especially bakers, find it simpler and less expensive to add sesame to a product—and to label it—than to try to keep it away from other foods or equipment with sesame."

That action is "frustrating and scary for parents like Kristy Fitzgerald," whose daughter had a sesame allergy but has since outgrown it. According to the *AP News* and *Time.com,* Fitzgerald learned that "the Pan-O-Gold Baking Company, which supplies breads to schools, health centers and grocery stores across the Midwest, was adding small amounts of sesame to its products, including those served at her daughter's school." As she investigated through emails with Pan-O-Gold, Bob Huebner, food safety/quality assurance manager, told her that "the company was forced to add sesame to the product and the label. 'The unfortunate reality is that our equipment and bakeries are not set up for allergen cleanings that would be required to prevent sesame cross-contamination and was not an option for us.'" In response, Fitzgerald has started an online petition at www.change.org. "At some point, someone is going to feed an allergic child sesame," she

said. "It makes me think the laws need to change to show that this is not an acceptable practice."

Notifying consumers

The American Bakers Association, a trade association of more than 300 members, told the I-Team of *WLS-TV News*, Chicago, IL (an *ABC Eyewitness News* organization) that "baking companies are working with their customers, including restaurants, to transparently disclose any allergen labeling changes to help ensure consumer safety. In turn, restaurants are using their websites, apps, menus and signs in drive-through lanes to notify consumers about the addition of sesame to some foods. The Association also "reminded allergic consumers to read labels carefully."

The *WLS-TV News* website published statements it received from two restaurants, Olive Garden and Chick-fil-A. The full statement from Olive Garden said, "Following the FDA's declaration of sesame as a major allergen, our suppliers have added a minimal amount of sesame flour (less than 2%) to our breadsticks due to the potential for cross-contamination at the bakery. We have updated our allergen guide accordingly and are sharing this information with our guests. You can view our updated allergen list here."

Chick-fil-A's statement read, "Food safety and quality are our top priorities. We take great care in adhering to stringent food safety procedures. As of Dec[ember] 12, our white bun and multigrain brioche bun contain sesame flour, while our flaxseed flour flat bread and [C]hick-fil-a cool wrap have always contained sesame. Chick-Fil-A [obtains] bread from multiple suppliers across the country and due to the shared production lines in our supplier facilities and use of shared cooking and preparation areas, we cannot ensure that our menu items are sesame-free. This is an industrywide matter that led to the recipe change for our white bun and multigrain brioche bun to now include sesame as an ingredient. Customers with a sesame allergy may prefer to order a gluten-free bun, which does not contain a sesame ingredient. Bread products on the breakfast menu, including the tortilla, English muffin, mini yeast rolls and biscuit, are also free of sesame ingredients. For more details about nutrition and allergens, please visit www.chick-fil-a.com/nutrition-allergens."

In addition, Chick-fil-A told *Allergic Living* that "this is an industry-wide issue, and there are no sesame-free bread suppliers that could consistently supply Chick-fil-A's bread volumes."

"A result the FDA does not support"

To address the situation, the FDA released an emailed statement. Published by *Allergic Living*, it said, "While a practice of adding sesame and then declaring it on the label is not violative, it would make it more difficult for sesame allergic consumers to find

Options the baking industry could consider

At the International Baking Industry Exposition (IBIE) in September 2022 in Las Vegas, Nevada, US, Nathan Mirdamadi, senior food specialist for Commercial Food Sanitation, discussed managing the risks of producing baked goods made with sesame and the "very serious challenge" posed by the new law. *Commercial Baking* reported his remarks.

In baked goods, he explained, sesame is commonly used as a topping rather than an inclusion and applied to a product surface such as hamburger buns after baking. Because sesame is considered a "very fine particulate" [in the baking industry,] controlling it is like "trying to remove sand from the beach, especially when most post-oven equipment sanitation employs dry methods." He continued, saying, "then we take into consideration supply chain issues and sanitation departments struggling to find, train and retain employees. We're pushing ourselves into a corner trying to create a scenario where we can successfully remove sesame."

However, "there are options," said Mirdamadi and "knowing the right strategy will depend on the level of disruption to the operation." He also emphasized "the most important strategy is validating through sanitation" and that "the safest protocols begin proactively, not defensively."

"It could be as simple as scheduling runs with sesame as late in the process as possible or going as far as investing in equipment that's dedicated specifically to sesame. Some middle ground could be found in modifications to the existing line, such as with dedicated pans, a modified pan return or modular belt systems. You can put them on casters or wheels so you can slide it into or out of place. Another option is dedicating a depanning belt for seeded products and another for unseeded."

Further he explained "some equipment manufacturers are putting in the R&D to find solutions for sanitation, especially with belts, where those little sesame seeds can find great gathering (and hiding) places. Some manufacturers are developing a brush with vacuum attachments that can minimize the migration of seeds. Other technologies include driving belts from the edge rather than the center shaft to eliminate transfer points on the line. Then you could put some of these cleaning apparatuses directly on the [manufacturing] line for a dry [clean-in-place process] CIP that's automated. That could be [quite] impactful. In equipment overall, hygienic design has never been more important."

He also posed a larger question, saying, "the FASTER Act added a layer of complexity with the addition of sesame as the ninth top allergen. How will it all change when the tenth is added later on?"

foods that are safe for them to consume. This is a result the FDA does not support."

Advocates express concerns to the FDA

On January 30, 2023, AAFA joined with 11 other consumer and patient advocacy organizations to comment on the FDA's 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. They used the opportunity to express their concerns regarding ways in which manufacturers have responded to new law. Key segments from those comments are shown here:

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.

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 [Precautionary Allergen Labeling] PAL statement for sesame.

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. 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.

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.

FDA advises caution during transition

The FDA website advises consumers to be cautious as the new law goes into effect because they "may find food products for sale that don't list sesame as an allergen on the label."

"The law establishing this sesame labeling does not require food products that were already on their way to the store or in stock before 2023 to list sesame as an allergen on the label. Therefore, these food products do not need to be removed from the marketplace or relabeled to declare sesame as an allergen."

The FDA also noted that "because some packaged foods can have a long shelf life, [it is difficult] to say when pre-2023 stock will be replaced with food products carrying the required labels."

Further, they advised consumers to "remember that a food product's ingredients can be changed at any time," so [it is prudent] to check the label *every time* [they] buy the food product, even if [they] have eaten it before and didn't have an allergic reaction."

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.

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 [Food Protein-Induced Enterocolitis Syndrome] Foundation
- International FPIES Association (IFPIES)
- With support from: Ruchi Gupta, MD, MPH; Director, Center for Food Allergy & Asthma Research (CFAAR)

As this article goes to publication, there have been no reports regarding an FDA response to the submitted comments.

Sesame-free brands still available

To assist consumers, the FARE website lists food brands and restaurants that are not adding sesame flour to their products. The list is divided into the following categories:

- "Dedicated sesame-free facilities. These brands have confirmed their facilities are dedicated free of sesame."
- "Some facilities are dedicated sesame-free. These brands have multiple facilities with at least one facility that is dedicated sesame-free." Products made in sesame-free facilities are noted.
- "Dedicated sesame-free lines. These brands have confirmed their products are made on dedicated sesame-free lines but the facility is not dedicated sesame-free."
- "Dedicated sesame-free restaurants."

The web page also has a disclaimer that says, "This list represents a moment in time and is not inclusive of all sesame-free companies. This list is provided for general awareness, and FARE does not guarantee these companies are 100% sesame-free. FARE encourages individuals to read each label at the time of purchase and before consumption, and contact the manufacturer if they have questions."

The list was developed and shared with FARE by Spokin, a food allergy resource. They contacted more than "130 brands to confirm their sesame details, including information on facilities, lines, ingredient and label changes, and more" and noted that their "categorization is based on responses received directly from each manufacturer." The Spokin list was originally published in January 2023 and updates are planned as new information is received.

New law "still…a success"

Allergic Living noted that members of the allergy community are still finding reasons to be positive about the designation of sesame as the ninth major allergen in the US. Saiontz "is glad to avoid spending hours calling companies to find out if sesame is in many packaged foods. 'We are still very excited that sesame will be labeled," she said.

Linde also stated, "The clear information on labels for products like salad dressings, crackers, granola bars, and sauces will still make this law a success for the allergy community."

"There is a workable solution"

"AAFA is eager to work with industry members, lawyers, the FDA and the food allergy community to improve allergen labeling and prevent 'potentially harmful manufacturing practices,'" Mendez told *Allergic Living*. "We believe there is a workable solution with improved, regulated, and evidence-based

precautionary allergy labeling that would ensure the safety of people with food allergy while eliminating manufacturers need to purposefully add a known allergen to reduce liability."

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