

SEEDS OF CHANGE

While Some Companies Lead the Way in
Sesame Allergen Labeling, Large Gaps Remain



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CSPI

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Executive Summary

More than 300,000 people in the United States suffer from sesame allergy, which is ranked 9th in prevalence among the most commonly diagnosed food allergies, after peanuts, milk, shellfish, tree nuts, eggs, wheat, soy, and finfish (the “Big Eight”). For many people with sesame allergy, accidental exposure poses potentially deadly risks: Sesame ranks 6th or 7th among major allergens in terms of severity, and a greater fraction of adults with sesame allergy report an emergency room visit for food allergy in the past year than adults with any other major food allergy.

Despite being similar in severity and close in prevalence to the eight other major allergens, sesame is not covered by the same public health protections as allergens in the Big Eight. While federal law requires that the Big Eight allergens be declared on packaging using common names, sesame ingredients can be hidden as “spices” or “natural flavorings,” or listed under unfamiliar names such as tahini, gingelly, or benne. Similarly, efforts to address allergen cross-contact risks have focused on the Big Eight, bypassing sesame. To address this, the Center for Science in the Public Interest (CSPI) joined allergy experts in filing a citizen petition with the Food and Drug Administration (FDA) in 2014, urging the agency to require that sesame be clearly declared in foods in the same manner as other major allergens.

In this report, we highlight the need for better sesame labeling by showing how deficiencies in food manufacturers’ current sesame disclosure policies cause confusion for consumers. We contacted 22 major food companies in order to better characterize the consumer experience in attempting to obtain clear information about sesame. Fourteen of the 22 (64 percent) have shown leadership on sesame by declaring sesame ingredients and addressing cross-contact risks. These leading companies can serve as “seeds of change” for the rest of the food industry. Unfortunately, many major food companies continue to lag behind, complying with regulatory requirements to disclose the Big Eight major allergens, but not providing clear labeling for sesame.

CSPI is not alone in calling for a reconsideration of sesame as a major allergen. In November 2016, a report by the National Academies of Sciences, Engineering, and Medicine called for an update of the list of major allergens and the reconsideration of sesame. The report stated that “[t]he prevalence of sesame seed allergy in the United States appears to be equivalent to the existing eight priority foods or food groups recognized in the United States among children.” It concluded that “evidence of the allergy prevalence and reaction severity to sesame seeds may warrant their inclusion on the priority allergen list in the United States.”¹

The European Union, Australia and New Zealand, and Canada already require that packaged food be labeled for sesame. Americans are now making clear that they are ready for similar progress. Since the CSPI petition was filed, more than 700 comments have been submitted to the docket, the vast majority in support of the petition. More than 11,000 people have also supported a petition for sesame labeling posted on Change.org, launched by a father whose 10-year-old son suffered a serious reaction from undeclared sesame in a restaurant meal.

Members of Congress have also taken action, writing letters in support of CSPI’s petition and re-introducing the Food Labeling Modernization Act (FLMA), a bill that would require sesame to be included in the list of major allergens and also make major allergen information available for the first time for non-prepackaged food sold in restaurants and grocery store delis.

The time has come for the FDA to protect consumers from this life-threatening risk. Until federal regulators take action, the grocery store will remain an unnecessarily dangerous place for the 300,000 Americans with sesame allergy.

Recommendations

The FDA should:

1. Use its authority under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (codified as 21 U.S.C. § 343(x)) to require clear labeling for sesame.
2. Develop standards and criteria, consistent with international recommendations, for determining when to add labeling requirements for other allergens, such as mustard, poppy, and other seeds.
3. Instruct FDA inspectors to identify sesame cross-contact risks by adding sesame to CPG Sec. 555.250.
4. Amend the model Food Code to recommend that restaurant workers be trained to identify sesame risks.
5. Issue regulation or guidance to industry describing best practices for allergens not otherwise specifically addressed by current regulation, including use of statements like “allergen-free.”

Congress should:

1. Accelerate FDA action by passing the Food Labeling Modernization Act (FLMA), which requires that the FDA list sesame as a major allergen and requires major allergen labeling for nonprepackaged food sold at retail.
2. Provide funding for a public relations campaign advising manufacturers, restaurants, and the public of the risks of allergy, including sesame.

Food manufacturers should:

1. Follow industry leaders by including sesame as part of each company’s allergen policy, ensuring that sesame always be accurately declared as an ingredient and addressing cross-contact risks.
2. Assess current allergen policies for inclusion of other allergens not covered by regulation.
3. Post allergen labeling policies transparently on company websites.
4. Assess current allergen policies to ensure that confusing statements like “allergen-free” are not used when uncommon allergens may be present.

Consumers should:

1. Press the FDA to label sesame, including by submitting new sesame allergy reports to the petition docket.² The strongest accounts include detailed descriptions of serious sesame reactions, the exact circumstances of exposure and potential re-exposure, and their short- and long-term health impact, as well as efforts to track down sesame in foods.
2. Promote the Change.org petition demanding that the FDA include sesame as a major allergen.³
3. Organize campaigns to directly urge food manufacturers and restaurants to adopt better policies on sesame.

I. A Call for Action on Sesame Labeling

My husband and I want our daughter to come of age in a world where she can trust the foods she eats will be safe for her. We don't want her to feel isolated in her community because of her allergy... We—meaning our government, the food establishments in our communities, and friends and families everywhere—need to take collective responsibility to provide that sense of security. Proper labeling is essential—it shows that we as a country value human life.⁴

— Frances Beach, Georgia

a. Petition to the FDA for Sesame Labeling

In 2014, CSPI joined a group of distinguished allergy experts and academics in filing a citizen petition with the FDA to require clear and consistent labeling of sesame in foods.⁵ The petition requested three actions from the agency:

1. Require Consistent Labeling for Sesame Ingredients

The CSPI petition asked the FDA to use its existing authority under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) to require clear labeling for sesame.⁶ FALCPA improves labeling for major food allergens by requiring that they be listed clearly as ingredients using their common, readily identifiable name. That prevents their being listed simply as “spices” or “natural flavors” or with an unusual name.

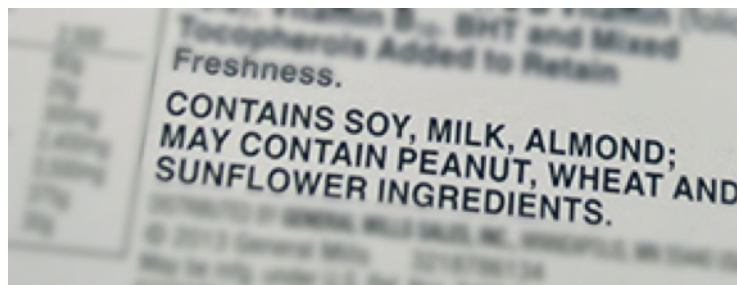
When FALCPA was enacted, it expressly covered eight “major” allergens considered to be a public health priority at the time: peanuts, milk, shellfish, tree nuts, eggs, wheat, soy, and finfish.⁷ Yet Congress anticipated that other allergens could be identified that pose similar public health risks as the Big Eight. It therefore authorized the FDA to add disclosure requirements for additional allergens through regulation, by adding a provision now codified as 21 U.S.C. § 343(x).⁸ That provision states:

(x) Nonmajor food allergen labeling requirements

Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.

This provision allows the FDA to regulate additional priority allergens in the same manner as the Big Eight, without amending the statutory definition of “major allergen.” Section 343(x) thereby gives the agency flexibility to protect more consumers in response to improved scientific understanding, shifts in allergen prevalence, and an evolving American diet.

Since the passage of FALCPA, the FDA has relied on section 343(x) only once: In 2011, the agency cited 343(x) as additional authority for granting CSPI’s 1998 citizen petition to require that the color additives cochineal extract and carmine be declared by name on the label of food and cosmetic products.⁹ Notably, cochineal and carmine are not considered major allergens in terms of prevalence, but the FDA required disclosure because these color additives had been associated with reports of severe allergic reactions, including anaphylaxis. Similarly, 343(x) could be used as authority for the FDA to require labeling of sesame even though it is not defined as a “major allergen” in FALCPA.



Federal law requires labeling for eight major allergens, but not sesame.

2. Control Sesame Cross-Contact Risks Through CPG 555.250

CSPI and the other petitioners also asked the FDA to take steps to prevent unintentional cross-contact from sesame, which can occur when products that contain sesame are manufactured on shared machinery with those that do not.

FALCPA does not address good manufacturing practices or require companies to include a “may contain” statement to identify foods that may be unintentionally contaminated with allergens through cross-contact with other foods.¹⁰

However, federal law generally requires food to be safe and not contain any unlisted ingredients, so the addition of an unintended allergen through cross-contact may render the food adulterated or misbranded. The FDA instructs its inspectors to look for cross-contact risks for major allergens in its Compliance Policy Guide (CPG) for federal inspectors, Sec. 555.250 “Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens.”¹¹ This CPG was issued in 2001 and was updated in 2005 following FALCPA’s passage. While the FDA has authority to extend the CPG to cover any allergen, the CPG currently covers only the eight major allergens addressed in FALCPA. Extending CPG Sec. 555.250 to sesame could help mitigate cross-contact risks for this allergen.

3. Improve Education for Restaurant Staff by Including Sesame in the Model Food Code

In addition to these direct regulatory steps, CSPI asked the FDA to encourage better sesame allergen practices at restaurants by including sesame as part of its allergen training recommendations in the model Food Code, and by issuing public educational materials directed at restaurants and food providers to raise awareness that sesame and sesame-based ingredients can cause severe allergic reactions.¹²

The Food Code is a reference document for state, city, and county agencies that is used in developing regulations for restaurants, grocery stores, and other food vendors. It currently contains provisions for restaurants to train workers in recognizing major food allergens and their symptoms, but this training, as with other federal mea-

tures, only currently covers the eight allergens listed in FALCPA.¹³ Including sesame in the Food Code would help raise awareness of sesame allergy at the state and local levels, encouraging better practices within the restaurant industry.

b. Growing Support for Regulatory Action

Since the CSPI petition was filed, more than 700 comments have been submitted to the docket, overwhelmingly in support of the petition. Members of Congress have also expressed support, including Senators Chris Murphy (D-CT), Richard Blumenthal (D-CT), and Ed Markey (D-MA), who wrote to the FDA in June 2015 and again in March 2018, urging the agency to require labeling for sesame under FALCPA.^{14,15}

Sesame-allergic consumers have also used online tools to voice their concerns to the FDA. An online petition on Change.org asking the FDA to require sesame labeling has garnered widespread support. The author of the petition, Brian Heller of Virginia, was prompted to act after his son experienced a serious reaction from a restaurant meal seasoned with prepackaged sauce containing undeclared sesame oil.¹⁶ As of April 5, 2018, the Change.org petition has swelled to more than 11,800 signatures.

These efforts, highlighted in the personal stories drawn from public statements that are included throughout this report, have all combined to send a clear message to the FDA that the time has come for that agency to use its existing public health authority to extend basic protections to sesame-allergic consumers, improving their lives by helping them avoid a deadly risk.

c. The Food Labeling Modernization Act

In addition to these regulatory efforts, Congress has also provided a potential solution to the sesame labeling problem. The Food Labeling Modernization Act (FLMA) was recently re-introduced in the House by Representatives Frank Pallone, Jr. and Rosa DeLauro (H.R. 5425), and in the Senate by Senators Richard Blumenthal, Sheldon Whitehouse, and Ed Markey (bill number pending). The FLMA would require the FDA to promulgate regulations requiring

labeling for sesame as a major allergen, and would require new major allergen labeling for nonprepackaged foods, so that allergens can be properly identified in foods sold at restaurants and grocery store delis.

II. Living with Sesame Allergy

I remember high fiving my husband after we gave our ten-month-old peanut butter and he had no reaction. Yes! We cleared all allergies or so we thought. ... One day we gave him hummus and our world changed forever. He started getting red, then we saw hives, and his left eye started to swell. He started scratching his neck, and I started screaming for my husband to look at him. He comes over, taking his time, saying "nobody is allergic to hummus." We had no idea that this was even a possibility.¹⁷

— Irina Lerman, New Jersey

a. US and International Priority Allergen Lists

Many Americans fail to recognize that sesame reaction is a serious concern until they learn of a friend or family member who is allergic to sesame. The lack of public awareness of sesame allergy is mirrored in a lack of attention by US policymakers, whose efforts to address allergen risks have long been focused primarily on the list of eight priority allergens currently covered under federal law. These eight are in turn drawn from an international list established in 1999 by the Codex Alimentarius Commission (CAC), relying largely on data from limited pediatric prevalence studies collected earlier.¹⁸ As noted above, the Big Eight have long served as a touchstone for US policymakers, defining the scope of most rules governing allergen ingredient disclosures, control of cross-contact risks, and even advice on training to restaurant employees.

As the study of allergy has improved, it has become clear that the original list of eight priority allergens requires an update. In November 2016, the National Academies of Sciences, Engineering, and Medicine issued a report urging a re-assessment of the 1999 CAC list. Specifically, the report stated that “[a]lthough the list of eight priority allergenic foods or food groups established by the CAC remains valid in general, the list has not been reviewed since 1999 and it should be reconsidered now and periodically thereafter.”¹⁹

The 2016 report also specifically identified sesame as a focus area, stating that “[t]he prevalence of sesame seed allergy in the United States appears to be equivalent to the existing eight priority foods or food groups recognized in the United States among children.”²⁰ It concluded that “evidence of the allergy prevalence and reaction severity to sesame seeds may warrant their inclusion on the priority allergen list in the United States.”²¹

The European Union,²² Australia and New Zealand,²³ and Canada²⁴ have already taken action to require that prepackaged food be labeled for sesame. Some countries also have a systematic process for updating their allergen policies in accordance with scientific recommendations. For example, when Canada updated its regulations in 2010 to include mustard seed among priority allergens, it also adopted systematic criteria for adding new food ingredients to its national list of priority food allergens.^{25,26} These criteria include evidence of causation, severity, and prevalence as key considerations for categorizing new priority allergens.

b. Sesame Allergy Prevalence in the United States

The prevalence and severity of sesame allergy justify its inclusion among priority allergens in the United States. While earlier sesame allergy prevalence estimates have been available from other countries,²⁷ the first published report on sesame allergy prevalence in the United States did not appear until 2010. That report, which came from a nationwide, cross-sectional random telephone survey conducted by Sicherer et al in 2008, estimated a self-reported prevalence of sesame allergy of 0.1 percent of children and adults.²⁸

More recently, Gupta et al conducted a cross-sectional nationwide survey in 2015-2016 drawing data from more than 50,000 households. The results of that study, presented to the American College of Allergy, Asthma, and Immunology in 2017, show sesame ranked 9th in prevalence in the United States among reported childhood allergens, placing it just behind peanuts, milk, shellfish, tree nuts, eggs, wheat, soy, and finfish.²⁹ Dr. Gupta also recently submitted additional, unpublished data from that survey to the FDA, covering both children and adults and offering greater detail on the prevalence of sesame allergy in relation to other major food allergies. (See Figs 1 & 2.)

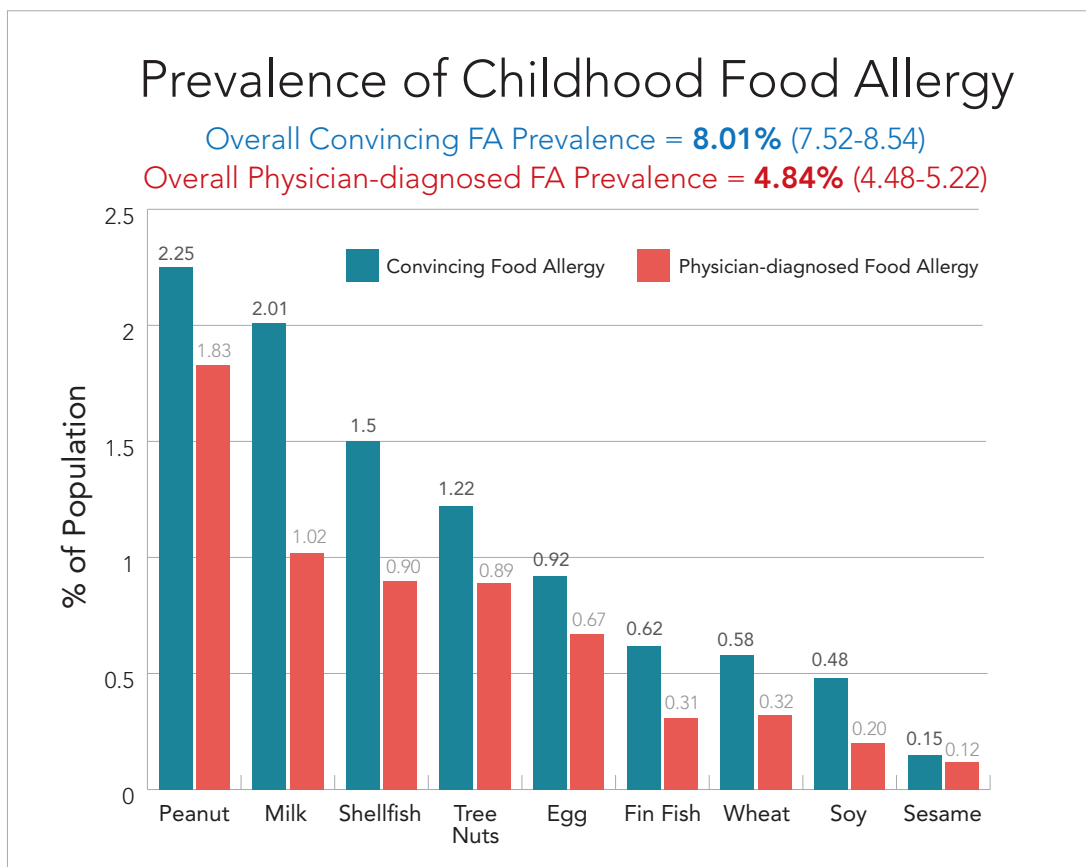


Fig 1

Source: Unpublished Data Submitted to the FDA by Ruchi S. Gupta, MD, April 2, 2018.

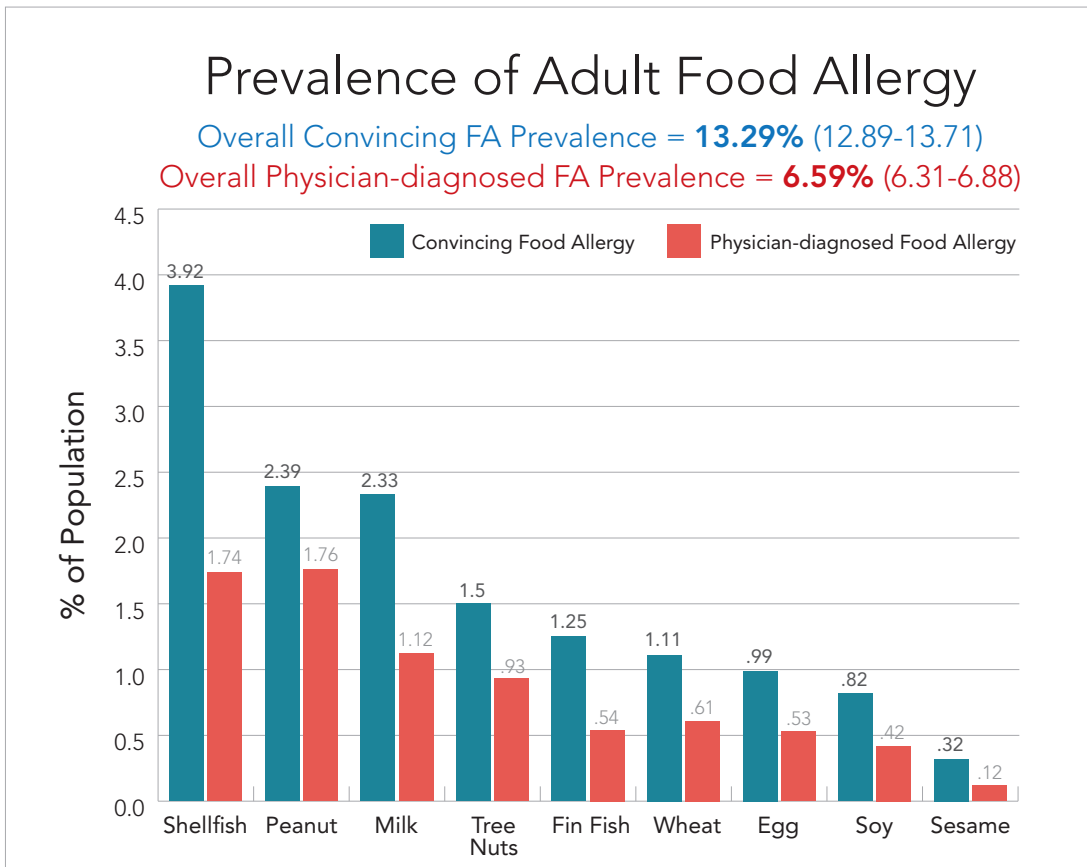


Fig 2

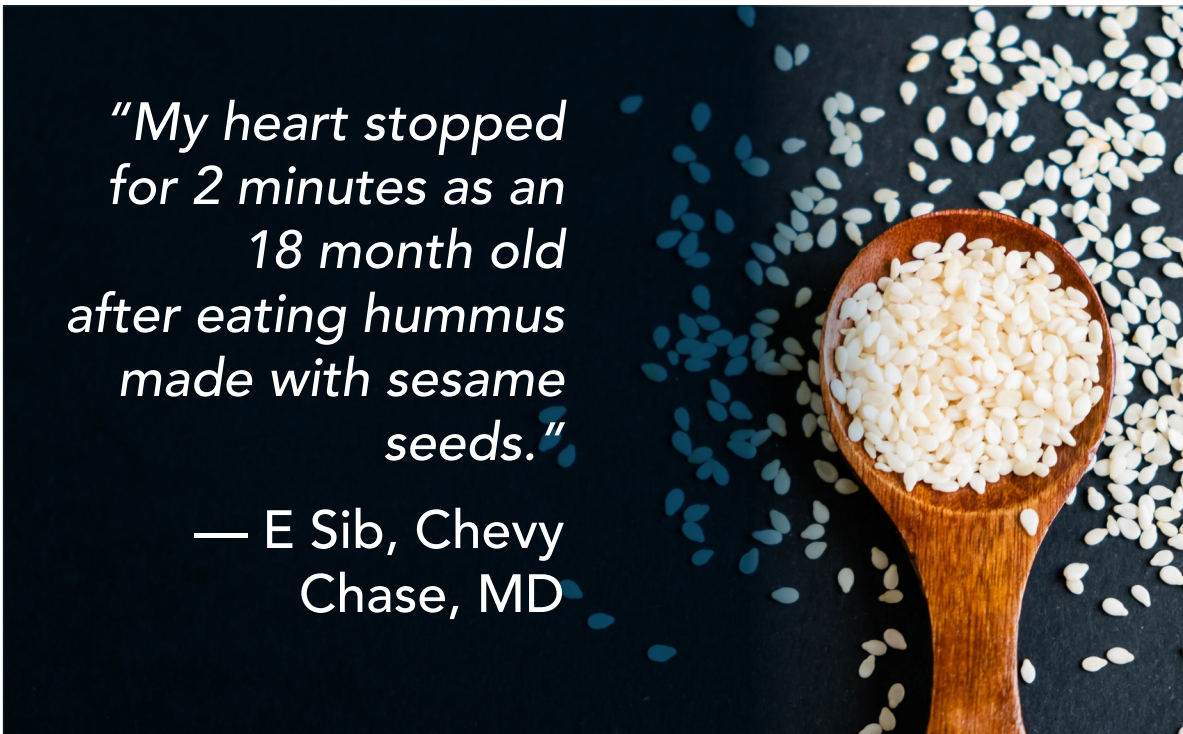
Source: Unpublished Data Submitted to the FDA by Ruchi S. Gupta, MD, April 2, 2018.

c. Sesame Allergy Severity in the United States

The 2016 National Academies of Sciences, Engineering, and Medicine report also identified severity as a key factor to be considered in deciding whether to include sesame on the priority list of food allergens.³⁰ Sesame reactions can range in severity from a relatively mild rash or itching to severe anaphylaxis involving multiple organ systems. The reaction can lead to swelling in the face, throat, or mouth, difficulty breathing, nausea, and vomiting.^{31,32} If untreated, anaphylaxis from sesame can result in unconsciousness and even death.³³

*“My heart stopped
for 2 minutes as an
18 month old
after eating hummus
made with sesame
seeds.”*

— E Sib, Chevy
Chase, MD



A substantial number of people with sesame allergy are at risk of severe allergic reactions. Data from the 2015-16 cross-sectional survey by Gupta et al, referenced above, indicate that 38.8 percent of sesame-allergic children and 44.7 percent of sesame-allergic adults in the United States have experienced a severe allergic reaction from sesame, defined as a reaction involving multiple organ systems. These results rank sesame 6th (for adults) and 7th (for children) among major allergens in terms of severity of reaction. (See Figs 3 & 4.)³⁴

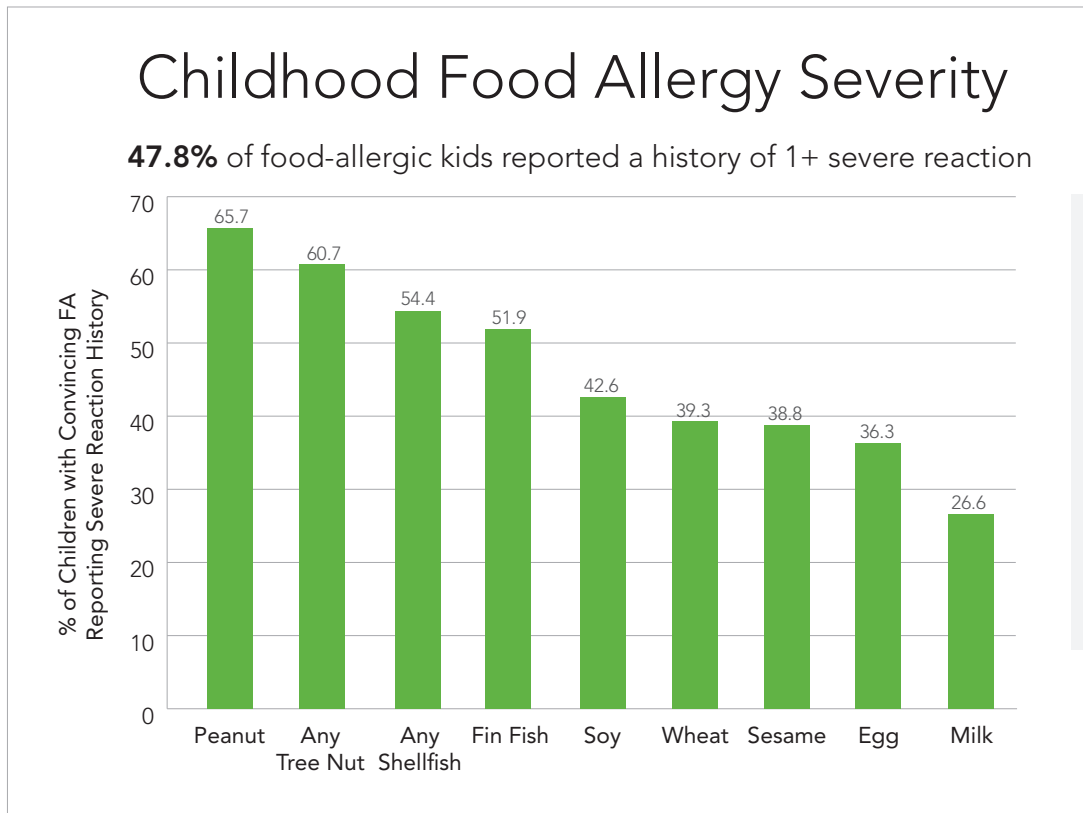


Fig 3

Source: Unpublished Data Submitted to the FDA by Ruchi S. Gupta, MD, April 2, 2018.

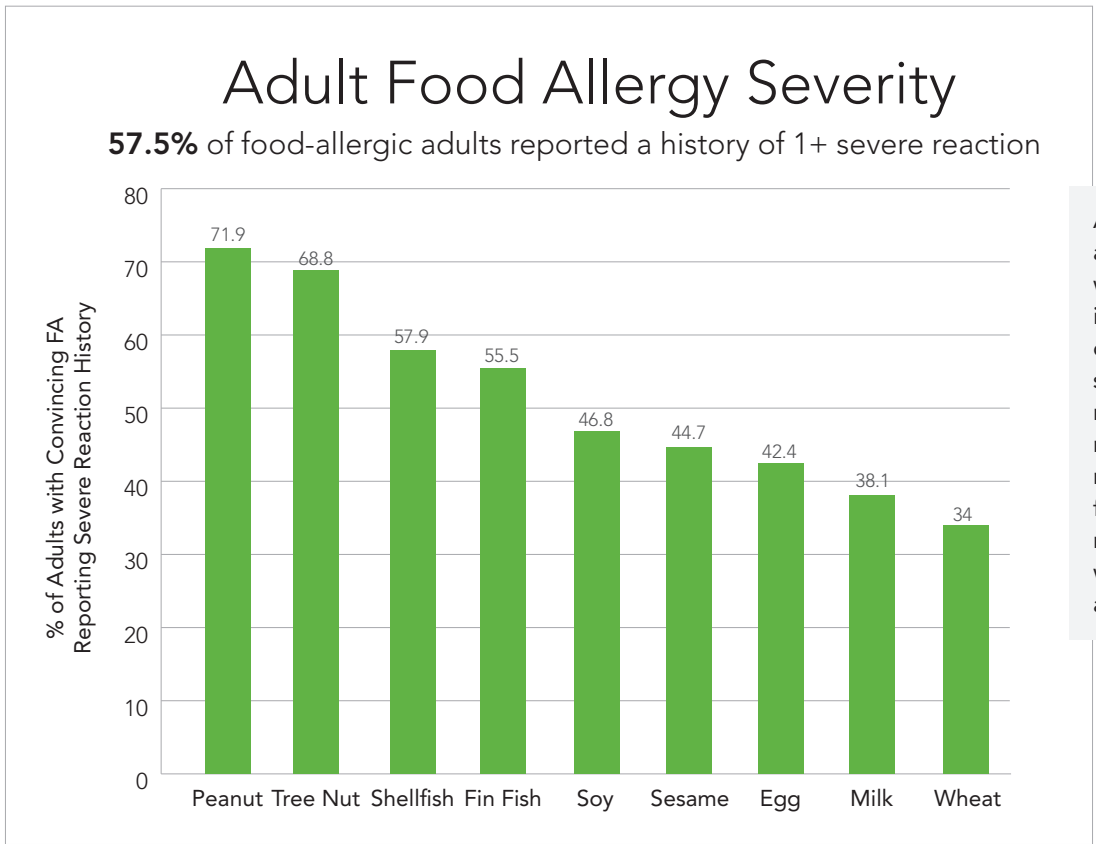


Fig 4

Source: Unpublished Data Submitted to the FDA by Ruchi S. Gupta, MD, April 2, 2018.

Difficulty avoiding accidental exposure to sesame may further increase the frequency of severe reactions for sesame-allergic individuals. The Gupta et al survey found that 33 percent of sesame-allergic adults reported one or more emergency department (ED) visits related to food allergy in the past year (*see* Fig 5), a greater fraction than any other allergen in the survey (rank not presented in figures). By contrast, among all adults with food allergy surveyed, only 9 percent had experienced an ED visit in the past year.

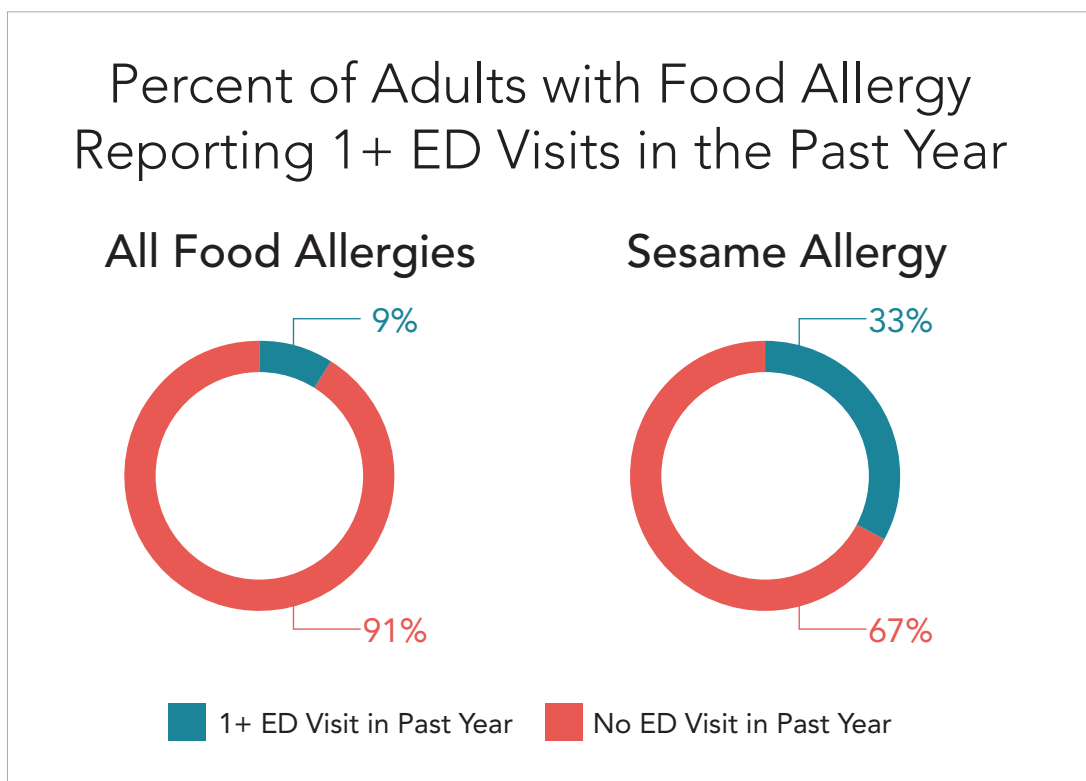


Fig 5

Source: Unpublished Data Submitted to the FDA by Ruchi S. Gupta, MD, April 2, 2018.

Although there may be other explanations for these findings, this suggests that the rate of recent ED visits for sesame is well above the food allergen average, possibly indicating that sesame-allergic adults have greater difficulty avoiding accidental exposure to sesame than adults with other major allergies that are subject to better labeling requirements.

Children with sesame allergy also may be more likely to report an emergency department visit in the past year than children with food allergy overall. In the Gupta et al survey, 34 percent of sesame-allergic children and 19 percent of all children with food allergy had experienced an emergency department visit in the past year. (See Fig 6.) However, because emergency department visits were more common for children with several other major food allergies, children with sesame allergy had only the 4th highest rate of ED visits in the past year among food allergies surveyed (rank not presented in figures).³⁵

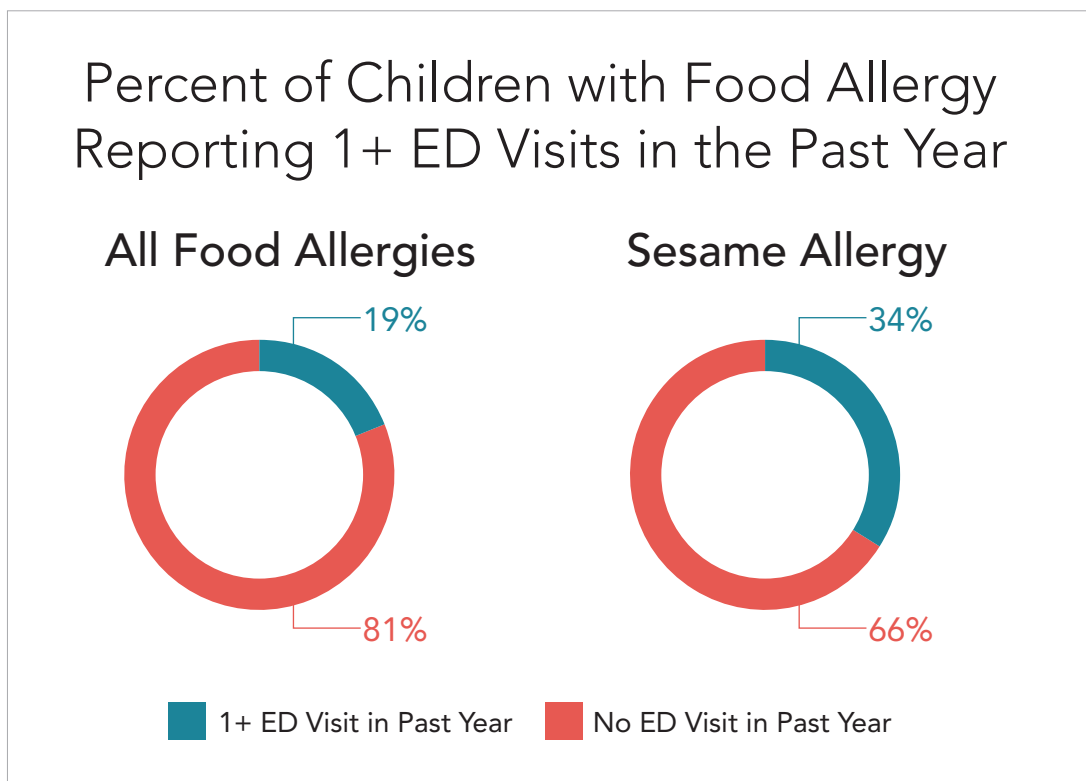


Fig 6

Source: Unpublished Data Submitted to the FDA by Ruchi S. Gupta, MD, April 2, 2018.

A severe reaction to sesame can be a harrowing experience. Numerous consumers have described their own serious reactions to sesame in urging the FDA to label sesame through public comments to the CSPI petition or the petition on Change.org.

CONSUMERS DESCRIBE SERIOUS REACTIONS TO SESAME

In my son's 14 months of life, we have already lost count of how many anaphylactic/multi-system reactions he has had. For example, we gave him a tiny piece (one quarter of a small sliver) of store-bought sausage that had "spices" on the label, and he had an anaphylactic reaction with repeated vomiting and hives all over his body. We had to administer an epipen and benadryl and rush him to the ER where we spent most of the rest of the day monitoring his breathing and swelling...

— Maggie Quinn³⁶

My adult daughter has had two anaphylaxis episodes in two months time. The first occurred at home, the second in a restaurant. She did not know she had such an allergy. In both cases she had to be rushed to the ER.

— Martha Albright, Eaton, OH³⁷

The impact of a severe sesame reaction reaches beyond physical effects. It can have far-reaching mental and behavioral health implications. These effects are particularly troubling for children, who may struggle to understand the experience. Consumer Frances Beach of Georgia, whose public statement to the FDA is also quoted above, described the emotional toll that sesame reactions have taken on her daughter:

My seven-year-old daughter has a severe sesame allergy. Her last exposure was this past April 2017 when she ate pita bread for a Holy Thursday meal in her classroom. Her teacher fell victim to product packaging and decided to buy the pita bread that advertised to be "allergen free." She did not know that sesame does not have to be labeled like other allergens. This pita bread contained sesame oil.

My daughter threw up about 15 minutes after eating the bread. ... Since she required two doses of epinephrine, she had to be monitored overnight in the pediatric [intensive care unit]. Fortunately, she was released the next day. However, her fear of another exposure grew. My daughter stopped eating as normal. During her annual check-up, she had a net gain of one pound from the previous year's check-up, which put her at the 5th percentile [body mass index]. She started having anxiety attacks when she was in new situations because she thought she would be exposed to an allergen. She also started exhibiting strong [obsessive-compulsive] behaviors. We are currently in therapy, and with the grace of God, my daughter is dealing with her fears and anxieties with great courage. She is eating normally again, and she is courageously dealing with situations when friends and classmates eat foods she is allergic to. Her underlying anxieties deal with issues of trust. A well-meaning teacher whom she adored made a mistake. We, as parents, made a mistake early on when we were first learning how to identify what foods contain sesame. What would help us restore trust with our daughter and have a more secure peace of mind is stronger labeling laws for allergens.³⁸

III. Sesame Labeling Confusion in the Food Marketplace

The mainstay of treatment for food allergy, as any medical text will tell you, is avoidance of the triggering food. This can be particularly difficult for sesame, as even tiny amounts of sesame protein can trigger a reaction. Adverse effects have been documented from as little as 1 milligram of sesame protein, an amount found in just two sesame seeds.³⁹

Consumers must avoid not only sesame seeds but also sesame oil, flour, paste, and other derivatives, which may contain allergy-triggering sesame proteins and can appear in unexpected places. Sesame ingredients have been found in tomato sauce, beef jerky, and even candy.



Sesame in unusual places: these products all contain sesame ingredients.
Source: Label Insight.

Yet, as noted above, exclusion of sesame from the “Big Eight” list of major allergens in the United States means that sesame need not be declared if it is listed as a “spice” or “natural flavor” in a food product.⁴⁰ And while other major allergens must be listed clearly under a common name, food manufacturers may declare sesame ingredients under an unusual name, such as “tahini,” “gingelly oil,” “til oil,” “sesamol,” “sesamolina,” or “benne.”⁴¹



Ingredients

ALMOND MILK (WATER, ALMONDS), LIQUID SUGAR (SUGAR, WATER), CORN SYRUP, COCONUT OIL, ALMONDS, CORN SYRUP SOLIDS, SUGAR, PEA PROTEIN, SUNFLOWER LECITHIN, NATURAL FLAVOR (SESAME, COCONUT), CORN STARCH, MOLASSES, SALT, SEA SALT, GUAR GUM, LOCUST BEAN GUM, BAKING SODA, CARAMEL COLOR, CARRAGEENAN, DRY MALT EXTRACT (BARLEY), SOY LECITHIN.

Allergy Information: MAY CONTAIN OTHER TREE NUTS.

Showing sesame included as a “natural flavor” in this ice cream helps protect sesame-allergic customers from potential harm.

Source: www.benjerry.com

These labeling decisions have real consequences for consumers, causing confusion and frustration in addition to putting them at risk. Consumer Jenny Gutman of Hamilton, Ohio, shared her own frustration in trying to track down information about sesame after her son had a severe reaction to “spices” in a prepackaged food:

My son has a severe sesame seed allergy, which has caused him to spend the night in the ICU. I called Classico, a manufacturer of many spaghetti sauces to confirm that “spices” in the ingredients list didn’t mean sesame seed. They told me that it was “proprietary” and they won’t tell me if it’s sesame or not.⁴²

Other consumers have also expressed extreme frustration at the difficulty of getting clear answers from food companies about sesame in products. As consumer Mary Roberts of Virginia told the FDA in comments on the CSPI petition:

I have to call companies weekly, at minimum, to inquire about the safety of product after product; for example, the other day I called Whole Foods 365 brands to ask about their labeling for sesame, and all they could tell me was that they do not label for it... Another food company I recently contacted about a "natural flavor" in their product told me the recipe was "proprietary," and they could not tell me if sesame was present because of that.⁴³

Another consumer, Barry Kleiman, described similar fatigue:

We have twin 15-year-old boys and have been dealing with this life-threatening allergy since they were 2 years old. It is scary that sesame can be hidden in products under words like "spices," "natural flavoring," etc. We have to call about each and every product that we buy to find out if it is safe for our boys to consume. Even if we have called previously, companies can change what they make in their facility. ... This situation makes it necessary to call each and every time we buy a product.⁴⁴

Ironically, sesame-allergic consumers also experience added challenges from the fact that other major allergens are now increasingly labeled. As noted in a personal account in the last section, statements like "allergen-free" are sometimes included on foods that are free from peanuts, tree nuts, milk, eggs, and other major allergens, even where the manufacturer has not assessed risks from sesame and other allergens not covered by regulatory requirements.

In addition to these issues with intentionally added ingredients, cross-contact with sesame products can result in dangerous unintentional contamination, posing additional risks. Many companies with strong allergen policies now address these risks by under-

standing where and when cross-contact can occur, cleaning to mitigate risks when possible, and labeling products when known risks are unavoidable. Unfortunately, these policies often exclude sesame.

Consumer Christopher Wells of Virginia recently reported to the FDA how an accidental exposure to sesame from unintentional cross-contact between bakery items resulted in a trip to the hospital:

On a fall day last year, I found myself, as I often do, sorting through the racks of bread and rolls at the grocery store, looking for an Italian style bun that did not have sesame on the label. Finally, I found one. I purchased it, went home, and started cooking. An hour later I was at the hospital. ... [T]he rolls I had purchased had sesame seeds embedded underneath them...⁴⁵

If the cross-contact involves ground sesame, scanning for such tiny seeds is no help. Dora Straus of Chappaqua, NY, recounts her shock after she learned of an entirely hidden cross-contact risk only after her son experienced a terrifying reaction:

About a year ago, I bought a bag of breadcrumbs... and used it to coat some chicken. The label on the breadcrumbs packaging did not contain any mention of the word sesame, just flour and other ingredients. After my son ate the chicken ... he had a severe allergic reaction involving hives, nausea and vomiting. ... I called the breadcrumb company and ... the representative replied that yes, when they grind up the breads to make the breadcrumbs, they sometimes use breads that have been coated with sesame seeds so it was highly likely that sesame was in the breadcrumbs I had purchased.⁴⁶

IV. Consumers Seek Information on Sesame Labeling

While the FDA has so far failed to respond to CSPI's petition, some food industry leaders have recognized the deadly risks of sesame and have begun to protect their customers. Unfortunately, significant gaps remain, leaving a confusing patchwork for consumers.

a. Consumer Inquiry into Company-Wide Allergen Declaration Practices

As noted above, consumers with sesame allergy must spend countless hours contacting food companies to obtain clear information about sesame risks for different products, often to find that that information is not available even on request. To better characterize this experience, we identified and contacted major food companies to inquire about their allergen declaration policies.

The companies were selected from the 2017 Grocery Headquarters State of the Industry Almanac as leading in sales for food categories likely to contain sesame ingredients (e.g., snack bars, bread, crackers, etc.) (*See Appendix for a complete list.*) We visited the companies' websites to look for information about sesame allergen labeling, contacted them via email/webform made available to the public for general inquiries, and followed up by phone if they did not respond to our written questions. We asked (or verified online) whether sesame is declared as an allergen for their brands, and verified that the companies addressed sesame cross-contact risks as part of their allergen policies.

Two companies, Ruiz Foods and Storck USA, did not respond to emails and provided no public phone number for consumer inquiries. We excluded both from our study.

Of the 22 companies that did provide answers to our questions, 14 (64 percent) indicated that they carried at least one brand that always declares sesame when it is present as an ingredient, and never hide it as a "spice" or "natural flavoring." (*See Table 1.*) This included Nestlé, which declares sesame as an allergen for DiGiorno but not for Nestlé Toll House. (Because each Nestlé brand had to be contacted separately and there were over a dozen brands, we did not

assess additional Nestlé brands.) We also included Russell Stover and McKee Foods among the 14, because in each case a representative informed us by phone that sesame is not currently used in any of that company’s products, including as a spice or natural flavoring.

These 14 companies that declare sesame also indicated that sesame cross-contact risks were addressed, either because they had taken steps to control sesame cross-contact risks when present (e.g., by thoroughly cleaning machinery between products or verifying that sesame was absent from a facility) or because they labeled individual foods with a “may contain” or similar statement when sesame cross-contact risks could not be avoided.

Table 1: Sesame Allergy Declaration Practices among Major Food Manufacturers

Manufacturer	Is Sesame Declared as an Allergen?
Amy’s Kitchen	Yes
Campbell’s Soup	Yes
Conagra	Yes
General Mills	Yes
Hormel	Yes
Kraft-Heinz	Yes
McCormick	Yes
McKee Foods	Yes*
Mondelez International	Yes*
Nestlé	Yes for DiGiorno, no for Nestlé Toll House (other brands not assessed)
Russell Stover	Yes
Snyder’s-Lance	Yes
Unilever	Yes
Utz	Yes
Barcel USA	No*
Goya Foods	Unclear
Hershey	No
Kellogg	No
Lactalis	Unclear
Mars	No
PepsiCo (Frito-Lay)	No
Schwan Food	No*

*Response given by phone

The information reported in this table is subject to change and may contain inaccuracies. Consumers with sesame allergy should contact food manufacturers directly for information about sesame in products.

Among the 14 companies that declare sesame as an allergen, General Mills and Utz stood out for their leadership by posting their allergen policies publicly on their websites with a clear statement that sesame is always declared.^{47,48} (The other companies only provided information for sesame upon request.) This type of public effort simplifies the process for consumers, allowing them to easily trust that the labels for foods made by a company will declare sesame, without the added headache of contacting the company to ask for its current allergen policy.

By contrast, 8 companies (36 percent) failed to clearly indicate that sesame was always declared as an allergen. Six of them (Barcel, Hershey, Kellogg, Mars, PepsiCo, and Schwan) confirmed that their labels do not always clearly declare sesame as an ingredient. Some indicated that their allergen programs were strictly limited to compliance with federal requirements. For example, Kellogg offered the following explanation for its non-disclosure of sesame:

*[S]esame is **NOT** one of the top 8 allergies in the US, but it is considered a top food allergy in Canada and other nations. Sesame seed and sesame oil, if used, will be labeled as an ingredient. Sesame can be used in our flavors, and therefore won't be listed separately as we do not label for non-top 8 allergens. We label and manage for the Top 8 Allergens and provide all required product information according to Federal Regulations.⁴⁹*

Two companies (Goya and Lactalis) provided non-responsive answers that did not clearly describe their policies for sesame. Goya provided a written response that described labeling practices for the top eight allergens, but failed to mention sesame. (A representative was unable to provide additional information when we contacted the company by phone.) Lactalis stated that milk is the only allergen present in its products. However, when we called to confirm, a representative from the company could not verify that the Lactalis American Group had assessed its “natural flavors” and “spices” to confirm that sesame was not present as an allergen.

b. Consumer Inquiry into Sesame in Individual Products

For the eight companies that did not have universal sesame disclosure policies, we determined whether consumers could nevertheless obtain information about specific products in cases where sesame was included as a “natural flavor” or “spice.”

We searched the websites of the companies that had failed to provide a clear sesame disclosure policy, identifying one product from each company that contained an ambiguous ingredient (“natural flavor” or “spice”) but that did not declare the presence of sesame. We contacted the company in each case to ask whether sesame was a part of that ingredient, as well as to ask about the potential for cross-contact risks.

In one case—Schwan Food Chicken Lo Mein Skillet Meal—a company representative verified that the “natural flavor” in the product did, in fact, contain undeclared sesame. (*See* Table 2.)

In addition, Goya Foods and PepsiCo verified that sesame was not included as part of the ambiguous ingredient (spices, natural flavor). The companies could not verify that the product was free of cross-contact risks.

Table 2. Sesame Information Available for Specific Products

Company	Product	Ambiguous Ingredient	Does the Ambiguous Ingredient Contain Sesame?	Any Cross-Contact Risk for Sesame?
Barcel USA	Mini Takis Fuego	Natural Flavor	Unclear*	Yes*
Goya Foods	Chiles Rellenos	Spices	No	Unclear*
Hershey	Cookie Layer Crunch Bar	Natural Flavor	Unclear*	Unclear*
Kellogg	Special K Chocolate Caramel Protein Meal Bars	Natural Flavor	Unclear	Unclear
Lactalis	Stonyfield Low Fat Wild Berry Smoothie	Natural Flavor	Unclear	Unclear
Mars	Snickers and Hazelnut	Natural Flavor	Unclear*	Unclear*
PepsiCo	Quaker Protein Instant Oatmeal	Natural Flavor	No	Unclear
Schwan Food	Chicken Lo Mein Skillet Meal	Natural Flavor	Yes*	n/a

*Response given by phone

The information reported in this table is subject to change and may contain inaccuracies. Consumers with sesame allergy should contact food manufacturers directly for information about sesame in products.

In the remaining cases, we were not able to get a clear response, either because the company representative would not or could not say whether sesame was present, or because he or she provided us with an answer that was hard to interpret. In some cases, the representative indicated that the information was proprietary to a third party. For example, Stonyfield, a Lactalis brand, told us by email that “the recipes of the natural flavorings in our products are proprietary to the company that makes them, and as a result we don’t have a complete listing of their components.”⁵⁰

Conclusion

The time has come for public health policymakers, elected officials, the food industry, and consumers to take action on sesame. Increasing understanding of sesame allergy has contributed to a growing scientific consensus and public support for reconsideration of sesame as a priority food allergen in the United States. The allergen is similar in prevalence and severity to other major allergens, and is associated with a higher rate of emergency department visits. People with sesame allergy should therefore be offered similar regulatory protections as those who are allergic to the “Big Eight” allergens.

Yet great confusion persists in the food marketplace. While some progressive companies have paved the way for change by taking steps to protect sesame-allergic consumers from harm, many companies continue to lag, providing only the allergen information required by regulation. This unacceptably exposes consumers with sesame allergy to life-threatening risk.

CSPI therefore urges the FDA, Congress, the food industry, and the public to support American families with food allergies by adopting the recommendations outlined at the start of this report.

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Methods

Company-Wide Disclosure (Table 1):

Manufacturer Selection: We included the top 2 vendors in each of the following categories from the 2017 Grocery Headquarters State of the Industry Almanac. These categories were selected because they contain foods identified by Food Allergy Research and Education (FARE) as potentially containing sesame.⁵¹

- Ready-to-eat cereal
- Breakfast/cereal/snack bars
- Hot cereal/oatmeal
- Pretzels
- Tortilla/tostada chips
- Hard candy/package and roll candy
- Non-chocolate chew candy
- Condensed wet soup
- Dry soup
- Granola bars
- Frozen pizza
- Refrigerated bacon
- All other crackers
- Chocolate candy snack size
- Chocolate candy box/bag/bar (all sizes)
- Spice/seasoning
- Cookies
- Cheese snacks
- Multi-serve frozen dinners/entrees
- Single-serve frozen dinners/entrees
- Frozen handheld entrees.

To determine the sesame disclosure policy of each company, we first reviewed the company website for public statements on allergen declarations. If the company had no online public declaration policy on sesame, or if its online statement was unclear, we followed up via the company's generic webform, email address, or online chat interface intended for general customer inquiries. We sought to determine if the company systematically disclosed the presence of sesame and, for those that did not, whether there was any risk for cross-contact.

In February, March, and April of 2018, we contacted 24 companies; 22 responded. The remaining two companies, Ruiz Foods and Storck USA, did not respond in writing and did not make a telephone contact available on their websites; they were excluded from the study.

All written responses are on file with the author. We considered a response to be unclear if the company representative responded that he or she did not know the answer to the question, or if we could not interpret the answer that was provided.

We considered sesame to be declared as an allergen if the company indicated that sesame was always named in the ingredients list for at least one of its brands, even if it was a component of a spice or natural flavoring. If a company indicated that it categorized for some brands, but not others, we reported this information in Table 1.

We considered a company to have controlled for or declared sesame cross-contact risks if the representative verified that 1) the company took steps to clean out equipment between products or did not process products with sesame in any of its facilities or 2) products were labeled with a "may contain" or similar statement where cross-contact risks could not be controlled. Note that all responses were based on company self-reports.

Product-Specific Follow-Up (Table 2):

For the 11 companies that indicated that they did not always declare sesame on their labels during our initial inquiry, we followed up to see if additional information was available for specific products on request.

We selected one product with an ambiguous ingredient (“spice” or “natural flavor”) from each website. In doing so, we attempted to focus on food categories described above that are likely to contain sesame. For each of these products, we contacted the company by email and/or phone to ask whether sesame was included as part of the ambiguous ingredient. We also asked about any potential for sesame to be present through cross-contact with other products during production.

All written responses are on file with the author. We considered a response to be unclear if the company representative responded that he or she did not know the answer to the question, or if we could not interpret the answer that was provided.

We considered a company to have controlled for or declared sesame cross-contact risks for a particular product if the company verified that 1) the product was not manufactured on shared equipment with sesame, 2) the company took steps to clean out equipment between products, or 3) products were labeled with a “may contain” or similar statement where cross-contact risks could not be controlled.



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