

November 18, 2014

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852

## **CITIZEN PETITION**

The undersigned respectfully submit this petition pursuant to § 4(d) of the Administrative Procedures Act, 5 U.S.C. § 553(e); 21 U.S.C. §§ 321(n), 343(a), 343(x), and 371 (a); and 21 C.F.R. § 10.30. We request that the Commissioner of Food and Drugs issue a rule to require that sesame seeds and sesame products be regulated in a manner similar to a major allergen under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)<sup>1</sup> listed specifically by name (“sesame”) in ingredient lists of foods, that the agency add sesame to its list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens," to address both labeling and cross contact issues related to sesame in food manufacturing practices. An appendix includes letters from several parents of sesame-allergic children explaining why better labeling is so important for their families.

### **I. INTRODUCTION**

Food allergens are a major public health problem. The Congressional findings in the FALCPA state that, as of the FALCPA’s enactment, approximately 2% of adults and about 5% of infants and young children in the United States suffered from food allergies, and that each year roughly 30,000 individuals require emergency room treatment.<sup>2</sup>

Accurate and informative labeling is critical for allergic consumers and their families, because they must strictly avoid specific foods and ingredients to prevent potentially serious reactions. The Food and Drug Administration (FDA) has concluded that “the undeclared presence of allergens in foods is a serious public health issue.”<sup>3</sup>

---

<sup>1</sup> FALCPA amended the Federal Food, Drug, and Cosmetic Act as follows: Section 201 (qq) was added to define the term "major food allergen." The term means any of the following foods, or a food ingredient that contains protein derived from any of the following foods: milk; eggs; fish; crustacean shellfish; tree nuts; wheat; peanuts; and soybeans. Section 403(w) was added to address the labeling of foods that contain a major food allergen. Effective January 1, 2006, all food labels must clearly state if food products contain any ingredients that contain protein derived from the eight major allergenic foods. *See* Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282, Title II).

<sup>2</sup> *See* § 202(1) of FALCPA.

<sup>3</sup> 66 Fed. Reg. 38591-92 (July 25, 2001). The United States Department of Agriculture (USDA) Food

Consistent with the Agency's conclusion and previous action regulating the labeling of food allergens, we strongly believe that protecting the public's health requires the Agency to mandate declaration of sesame-containing foods on ingredient labels. Such a requirement would provide consumers suffering from sesame allergies the information they need to make informed choices about what foods they eat and to avert the potentially harmful or fatal consequences of consuming foods to which they are allergic. The public health also requires that food manufacturers follow stringent manufacturing practices to ensure that food allergens such as sesame are not inadvertently added to non-allergenic foods.

## II. REQUESTED ACTION

Under its authority in FALCP, in statute at 21 U.S.C. § 343(x),<sup>4</sup> we request that the FDA issue a rule to: 1) require sesame-based ingredients to be listed by name ("sesame") in the ingredient lists of all foods and; 2) add sesame to FDA's list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" to address both labeling and cross contact issues related to food manufacturing practices. These two common-sense measures would help to protect individuals who know they are sensitive and/or allergic to sesame.<sup>5</sup> We further request that the FDA issue public educational materials directed at restaurants and food providers to raise awareness that sesame and sesame-based ingredients can cause severe allergic reactions, and that the agency request that the model Food Code be modified to reflect the allergenic risks of sesame so that restaurant workers

---

Safety and Inspection Service (FSIS) also concluded that the failure to clearly disclose the presence of a major food allergen is a major public health concern. "Allergens – Voluntary Labeling Statements" <http://www.fsis.usda.gov/OPPDE/larc/Ingredients/Allergens.htm> (visited June 30, 2015). Per the FSIS, "there are many foods and food ingredients to which some individuals may have some degree of intolerance or possible allergic reaction. That is why complete labeling is so critically important." *Id.*

<sup>4</sup> That section provides: "(x) Nonmajor food allergen labeling requirements: Notwithstanding subsection (g), (i), or (k) of this section, 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."

<sup>5</sup> The non-profit group, Food Allergy and Research Education (FARE) reports that, in addition to sesame, sunflower and poppy seeds also have been known to cause anaphylaxis. See "Other Allergens," <http://www.foodallergy.org/allergens/other-allergens> (visited Oct. 6, 2014). Some of the signatories to a Change.org petition also indicated that they or family members have an allergic reaction to mustard seeds, in addition to sesame. See "Add sesame seeds as an allergen to US product labeling laws: require them to be disclosed on US food labels," <https://www.change.org/p/fda-add-sesame-seeds-as-an-allergen-to-us-product-labeling-laws-require-them-to-be-disclosed-on-us-food-labels> (visited Oct. 6, 2014). FDA should therefore also investigate the prevalence and severity of allergic reactions to other seeds, including sunflower, poppy, caraway, and mustard seeds, to ascertain whether new safeguards should also be established to clearly indicate presence of other seed allergens in addition to sesame.

are aware of this risk to consumers and could advise sesame-allergic consumers which foods to avoid.

### **III. STATEMENT OF FACTUAL GROUNDS**

#### **A. FDA recognizes the serious health threat posed by food allergens and thus regulates food labels to list major allergens.**

Food allergies are a serious public health threat. First, there is currently no medical treatment available to prevent allergic reactions to food. The only method to prevent an allergic reaction is strict avoidance of the offending food.<sup>6</sup> Second, the reaction to food allergens can be severe, and the health consequences of a failure to declare an allergen on food labels can be extreme, including death. FDA has utilized labeling as a means of enabling consumers to identify when a food has any amount of that substance. Third, without proper vigilance on the part of both consumers who have food allergies and those who prepare food at home, restaurants, and other food-service establishments, food-induced anaphylaxis and other serious reactions can strike at any time.

Accordingly, Congress passed the FALCPA, which amended the Federal Food, Drug, and Cosmetic Act (FDCA) to provide that any ingredient in a food regulated by the FDA that is a major allergen – defined as crustacean shellfish, egg, fish, milk, peanuts, soybeans, tree nuts, and wheat – must be listed by its ordinary name, such as “milk,” rather than or in addition to a milk-derivative such as “whey.” Per 2004 data, those eight allergens comprised 90 percent of food allergic reactions and were the food sources from which many other ingredients were derived.<sup>7</sup> The allergen labeling requirement applies to allergens that might be present in foods, including as components of flavorings, colorings, and incidental additives and was mandatory beginning in 2006.

#### **B. Sesame is an important allergen.**

Medical research, from as far back as 1950,<sup>8</sup> has demonstrated that sesame seeds can cause severe IgE antibody-mediated and cell-mediated hypersensitivity allergic reactions, including contact dermatitis, urticaria, angioedema, wheezing, dyspnea through inhalation, rhinitis, asthma, and potentially fatal anaphylaxis.<sup>9</sup> These symptoms of allergic reaction to sesame are indistinguishable from the identical symptoms catalogued as the basis for regulation by FDA of the so-called “major allergens.”<sup>10</sup> In addition, these

---

<sup>6</sup> 66 Fed. Reg. 38591-92 (July 25, 2001).

<sup>7</sup> Sec. 202 of FALCPA; Minor Use and Minor Species Animal Health Act of 2004, 108 P.L. 282, 118 Stat. 891, 906.

<sup>8</sup> Rubenstein L. *Sensitivity to sesame seed and sesame oil*. NY State J Med. 1950; 50:343-4.

<sup>9</sup> Dalal I, Goldberg M., Katz Y. *Sesame Seed Food Allergy*. Curr Allergy Asthma Rep. 2012; 12(4):339-45; Kanny G., Hauteclouque C., Moneret-Vautrin DA. *Sesame seed and sesame seed oil contain masked allergens of growing importance*. Allergy 1996; 51:952-957.

<sup>10</sup> “Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food,” Draft Report, Prepared by the Threshold Working Group for FDA, June 2005, 13.

symptoms are identical to the type of allergic reactions that caused FDA to require labeling of carmine/cochineal in 2009.<sup>11</sup>

In 1998, researchers identified nine patients with an allergic reaction to sesame, with symptoms including anaphylactic shock, angioedema, urticaria, contact dermatitis, and asthma.<sup>3</sup> In 2010, a total of 5,300 households in the United States were surveyed for allergies. The prevalence of sesame allergy was reported to be 0.1% of the population, or about 300,000 people (based on the census population estimate for July 1, 2013<sup>12</sup>).<sup>13</sup> Some researchers believe that sesame has become “an emerging cause of severe allergy in the U.S.” because of immigration and the globalization of the food supply.<sup>14</sup> In Israel, where sesame is common in the diet, sesame has been catalogued by researchers as the third-highest cause of food allergy and second-most common source of anaphylaxis responses.<sup>15</sup>

A 2001 study included 10 patients who had suffered laryngeal edema, hypotension, severe asthma, and anaphylactic shock after eating a sesame-containing food.<sup>16</sup> They were tested for sesame-specific IgE antibodies and given a skin prick test. All had high levels of IgE antibodies and positive skin prick tests. In addition, this study identified the major allergenic protein to be a  $M_r$  9000 2S albumin, though other 2S albumin proteins proved to be allergenic as well.

In 2005, researchers surveyed members of the Anaphylaxis Campaign, a United Kingdom-based charity, because they had observed an increasing number of reports of allergic reactions to sesame. They issued a physician-designed questionnaire to 400 members. Of 257 valid responses, 150 people reported 288 reactions to sesame. One in six of those people suffered severe and potentially life-threatening symptoms.<sup>17</sup>

While anecdotal, a petition started in August 2014 on Change.org by Brian Heller, a parent whose son has a serious sesame allergy, asks for the FDA to require labeling of sesame on foods and has garnered over 3,000 signatures without any substantial promotion. Many of the signatories provide personal stories of allergic reactions to sesame

---

<sup>11</sup> “Listing of Color Additives Exempt from Certification; Food, Drug and Cosmetic Labeling, Cochineal Extract and Carmine Declaration,” 74 FR 207, Jan. 5, 2009.

<sup>12</sup> U.S. Census Bureau, Population Division. Table 1. *Monthly Population Estimates for the United States: April 1, 2010 to July 1, 2013 (NA-EST2012-01)*. Released August, 1 2013.

<http://www.census.gov/popest/data/national/totals/2012/index.html>.

<sup>13</sup> Sicherer SH, Muñoz-Furlong A, Godbold JH, Sampson HA. *US prevalence of self-reported peanut, tree nut, and sesame allergy: 11-year follow-up*. *J Allergy Clin Immunol* 2010; 125 (6):1322-1326.

<sup>14</sup> Permaul P, et al. *Sesame Allergy: Role of Specific IgE and Skin Prick Testing in Predicting Food Challenge Results*. *Allergy Asthma Proc.* 2009; 30(6): 643-648. DOI: 10.2500/aap.2009.30.3294.

<sup>15</sup> “Sesame allergy: A growing Food Allergy,” March 2009.

<http://www.kidswithfoodallergies.org/resourcespre.php?id=107>.

<sup>16</sup> Pastorello EA, et al. *The major allergen of sesame seeds (Sesamum indicum) is a 2S albumin*. *J Chromatogr B Biomed Sci Appl.* 2001 May 25; 756(1-2):85-93.

<sup>17</sup> Derby, CJ, Gowland MH, Hourihane JO’B. *Sesame allergy in Britain: A questionnaire survey of members of the Anaphylaxis Campaign*. *Pediat Allergy Immunol* 2005; 16: 171-175.

DOI:10.1111.j.1399-3038.2005.00232.x

by themselves, a family member or close friend.<sup>18</sup> A sample of these may be found in an appendix to this petition.

It is noteworthy that sesame seeds and sesame products are required to be labeled in Canada,<sup>19</sup> the European Union,<sup>20</sup> and Australia/ New Zealand.<sup>21</sup> The Canadian government considers sesame to be a priority food allergen. Beginning in December 2014, European restaurants will be required to inform customers of the presence of 14 common allergens in their food, including sesame.<sup>22</sup>

### **C. FDA's current labeling requirements for sesame-containing foods does not adequately protect consumers.**

The sesame seed (*Sesamum indicum*) is an oilseed crop and edible seed that is used in many food and consumer products.<sup>23</sup> It is used in an increasing number of foods and might be listed in the ingredient list under an unfamiliar name, such as benne, benne seed, benniseed, gingelly, gingelly oil, gingelly seeds, gomasio, halvah, seed paste, seed oil, sesamol, sesamolina, sesamum indicum, sim sim, tahini, and teel or til.<sup>24</sup>

Sesame oil or pureed sesame seeds are a major ingredient in hummus, and some foods might list hummus or tahini, rather than sesame, as an ingredient. Consumers unfamiliar with those terms might not recognize that they are sesame and can cause an allergic reaction. In addition, sesame seeds can and are included in "natural flavorings" and, therefore, are not listed specifically on labels. A Web site on allergens in the UK notes that: "[o]ther common sources of sesame include: bakery products, biscuits, crackers, breadsticks, rice cakes, bagels, pies, and muesli. Some pre-packed delicatessen and processed foods contain sesame, for example: noodles, dips, soups, sausages, samosas, processed meats, veggie burgers, chutneys, salad dressings, mixed spices, spreads, and

---

<sup>18</sup> See "Add sesame seeds as an allergen to US product labeling laws: require them to be disclosed on US food labels," <https://www.change.org/p/fda-add-sesame-seeds-as-an-allergen-to-us-product-labeling-laws-require-them-to-be-disclosed-on-us-food-labels> (visited Oct. 6, 2014).

<sup>19</sup> Health Canada. Food and Drug Regulations (C.R.C., c. 870) B.01.010.1 (1). <http://gazette.gc.ca/rp-pr/p2/2011/2011-02-16/html/sor-dors28-eng.html>.

<sup>20</sup> European Food Safety Authority. Directive 2003/89/EC, OJ L 308/15, p.1-4 of 25.11.2003. [http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/fl\\_com2003-89\\_en.pdf](http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/fl_com2003-89_en.pdf).

<sup>21</sup> Australia New Zealand Food Standards Code - Standard 1.2.3 - Mandatory Warning and Advisory Statements and Declarations- F2010C00337. <http://www.comlaw.gov.au/Details/F2010C00337>.

<sup>22</sup> The Food Information Regulations 2014, SI 2014/1855.

<sup>23</sup> An Australian study examined the labeling of 1,355 products. The researchers reported that 6.3 percent of those products contained a sesame product as an ingredient and an additional 27.5 percent of those products stated on their labels that sesame may be present. Assuming that the American and Australian processed-food supplies are fairly similar, it is reasonable to conclude that a significant percentage of products on American supermarket shelves also do contain sesame, or may contain sesame, due to contamination in a facility that processes several types of nuts.

<sup>24</sup> Government of Canada. (2012). *Sesame: One of the ten priority food allergens*. [Brochure]. [http://www.hc-sc.gc.ca/fn-an/alt\\_formats/pdf/pubs/securit/sesame-eng.pdf](http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/pubs/securit/sesame-eng.pdf). CSPI researchers also searched the Gladson database of food ingredients on July 6, 2014.

confection bars.”<sup>25</sup>

This is a wide array of foods, and clearer labeling is required to protect sesame-allergic consumers. FDA should mandate labeling to include the word “sesame” in parentheses following sesame-containing or sesame-based ingredients and require inspection of facilities’ manufacturing practices to include an examination of the proper labeling of sesame and to check for appropriate measures to reduce cross contact of foods with sesame.

#### IV. STATEMENT OF LEGAL GROUNDS

##### A. FDA has statutory authority to require the labeling of products containing sesame.

FDA has clear authority under the law to issue regulations to require the label declaration of additional allergens, and that authority was strengthened and clarified thanks to FALCPA. Under 21 U.S.C. § 343(x), which provides: “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.” Accordingly, we request that the Secretary publish a rule to regulate sesame in a manner similar to a major allergen, and that labels be required to state when a produce “may contain” sesame due to cross-contamination.

Additionally, FDA may require labeling pursuant to its authority to enforce the prohibition on misbranded foods in sec. 403(a) of the FDCA. Under the FDCA’s misbranding provisions, a food is “misbranded” if its label is “false or misleading in any particular.”<sup>26</sup> To determine whether a product is misbranded, FDA must evaluate whether, *inter alia*, the label “fails to reveal facts material in the light of ... representations [made] or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates ... under such conditions of use as are customary or usual.”<sup>27</sup> Acting under its general authority, FDA can “promulgate regulations for the efficient enforcement of [the FDCA].”<sup>28</sup>

Congress has determined that the failure to use ordinary names for major allergens (including those in flavorings, colorings, and incidental additives<sup>29</sup>) is misleading to

---

<sup>25</sup> Allergy UK, “Sesame and Other Seeds,” <http://www.allergyuk.org/sesame-and-other-seeds/sesame-and-other-seeds> (visited Oct. 6, 2014).

<sup>26</sup> FDCA § 403(a) (codified at 21 U.S.C. § 343(a)).

<sup>27</sup> FDCA § 201(n) (codified at 21 U.S.C. § 321(n)).

<sup>28</sup> FDCA § 701(a) (codified at 21 U.S.C. § 371(a)).

<sup>29</sup> For meat and poultry products, the Secretary of Agriculture has the legal authority to determine whether spices, flavorings, and colorings shall be listed separately or designated without naming each one. Section 1(n)(9) of the FMIA and section 4(h)(9) of the PPIA, 21 U.S.C. 601(n)(9) and 453(h)(9). The Secretary can use this legal authority to require that flavorings or colorings containing a major allergen be separately identified.

consumers when the foods are regulated by FDA. In Sec. 202(5) of the FALCPA, Congress found that some of the current terms used for an ingredient “may be unfamiliar to consumers, and many consumers may not realize the ingredient is derived from, or contains, a major food allergen; and in other cases the ingredient may be declared as a class, including spices, flavorings, and certain colorings, or are exempt from the ingredient labeling requirements, such as incidental additives.”<sup>30</sup> Specifically, further clarification of the source of a specific ingredient in a parenthetical statement in the ingredients statement on labeling, *e.g.*, “whey (from milk),” is encouraged because the more recognizable term better informs consumers.<sup>31</sup>

The statute is clear: the failure of a food label to provide material information regarding the potential adverse consequences of eating a food can cause a food to be falsely or misleadingly labeled, and therefore misbranded.

**B. The FDCA confers broad authority on FDA to effectuate the important public policy goals of the statute, including the policies behind the FALCPA.**

FDA has broad authority to promulgate regulations for the efficient enforcement of the FDCA.<sup>32</sup> This authority is well-established and is supported by the public policy of protecting consumers by promoting honest and fair dealing.<sup>33</sup>

The general purpose of the FDCA is to “protect unwary customers in vital matters of health...”<sup>34</sup> Given the Act’s broad remedial purpose, courts have construed the statute liberally.<sup>35</sup> The FDCA confers authority on FDA to enforce the provisions of the statute by regulation (21 U.S.C. § 371(a)), and this regulatory authority, too, is “broad.”<sup>36</sup> Finally, in evaluating the exercise of FDA’s regulatory authority, courts accord great deference to the Agency’s decisions, especially where they implicate the evaluation of scientific data within the Agency’s technical expertise.<sup>37</sup>

---

<sup>30</sup> See 21 U.S.C.S. § 343; FALCPA; Findings. Act Aug. 2, 2004, P.L. 108-282, Title II, § 202.

<sup>31</sup> Allergens – Voluntary Labeling Statements

<http://www.fsis.usda.gov/oppde/larc/ingredients/allergens.htm> (visited June 30, 2014).

<sup>32</sup> 21 U.S.C.S. § 371(a).

<sup>33</sup> See, *e.g.*, *A. E. Staley Mfg. Co. v. Secretary of Agriculture*, 120 F.2d 258, 260 (7th Cir. 1941).

<sup>34</sup> *United States v. 216 Cartoned Bottles, More or Less, of . . . Sudden Change*, 409 F.2d 734, 741 (2d Cir. 1969).

<sup>35</sup> *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (applying “the well-accepted principle that remedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health . . .”); *216 Cartoned Bottles*, 409 F.2d at 741 (“[T]he Act . . . must be given a liberal construction to effectuate [its] high purpose.”).

<sup>36</sup> *Cosmetic, Toiletry and Fragrance Ass’n v. Schmidt*, 409 F.Supp. 57, 64 (D.D.C. 1976) (upholding FDA Commissioner’s authority to require warning statements on aerosolized food, drug, and cosmetic products).

<sup>37</sup> *International Fabricare Inst. v. U.S. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992). See also *Community Nutrition Institute v. Young*, 476 U.S. 974, 981-82 (1986) (noting that “the FDA has been delegated broad discretion by Congress in any number of areas” and deferring to Agency expertise).



The “FALCPA was designed to improve food labeling information so that consumers who suffer from food allergies - especially children and their caregivers - will be able to recognize the presence of an ingredient that they must avoid.”<sup>38</sup> Given the severity and the apparent growing prevalence of the sesame allergy, it would be consistent with existing FDA policy regarding allergen labeling to label the presence of sesame by issuing specific sesame-labeling regulations for both foods and cosmetics, as FDA did in 2009 for carmine and cochineal.<sup>39</sup>

## **V. CONCLUSION**

The agency has already developed regulations that adequately require disclosure on labels of the eight major allergens, carmine/cochineal extract, food dyes, and certain other ingredients. The FDA should now propose regulations to protect the many thousands of Americans who are allergic to sesame.

## **VI. ENVIRONMENTAL IMPACT**

The action requested here is subject to a categorical exclusion under 21 C.F.R. §§ 25.30(k) and 25.32(p), and therefore does not require the preparation of an environmental assessment. In any event, the undersigned do not believe that the actions requested in this petition would have any environmental impact.

## **VII. ECONOMIC IMPACT**

The Commissioner has not requested a statement of the economic impact of the requested action, and therefore such a statement is not presented.

---

<sup>38</sup> U.S. Food & Drug Administration. *Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers*. Updated July 18, 2006.  
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106890.htm#q4>.

<sup>39</sup> “Listing of Color Additives Exempt from Certification; Food, Drug and Cosmetic Labeling, Cochineal Extract and Carmine Declaration,” 74 FR 207, Jan. 5, 2009.



## VIII. CERTIFICATION

The undersigned certify that, to their best knowledge and belief, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Carla M. Davis, MD  
Assistant Professor of Pediatrics  
Texas Children's Hospital  
Baylor College of Medicine  
1102 Bates Avenue, Suite 330  
Houston, TX 77030

Michael Jacobson, Ph.D.  
Executive Director  
Center for Science in the Public Interest  
Washington, DC

Hugh A. Sampson  
Kurt Hirschhorn Professor of Pediatrics  
Dean for Translational Biomedical Sciences  
Director, Conduits (Mount Sinai's CTSA Program)  
Director, Jaffe Food Allergy Institute  
Department of Pediatrics; Box 1089  
Icahn School of Medicine at Mount Sinai  
New York, New York

Wayne Shreffler, MD, PhD  
Director, Food Allergy Center  
Division Chief, Pediatric Allergy & Immunology  
Massachusetts General Hospital  
Associate Professor of Pediatrics, Harvard Medical  
School  
Boston, MA

Scott H. Sicherer, MD  
Elliot and Roslyn Jaffe Professor of Pediatrics, Allergy  
and Immunology  
Jaffe Food Allergy Institute  
Icahn School of Medicine at Mount Sinai  
New York, NY

Robert A. Wood, M.D.  
Professor of Pediatrics

Division Chief, Allergy & Immunology  
The Johns Hopkins Hospital  
Baltimore, MD

Robert S. Zeiger, MD, PhD  
Senior Investigator  
Director, Allergy Research  
Department of Allergy  
Kaiser Permanente Southern California Region  
San Diego, CA

September 10, 2014

K. P.  
Easton, Massachusetts

Our son was diagnosed with a sesame allergy when he was 10 months old after having an allergic reaction to hummus. At the time he was also diagnosed with a milk allergy. He is now almost 10 years old. Though he has outgrown the milk allergy, the labeling laws had made it easier to find safe foods for him when he was allergic. Finding safe foods for him with his sesame allergy, however, continues to be a struggle.

One incident years ago demonstrates some of our frustration. After calling a pasta sauce company to find out if sesame was a "hidden ingredient" that was not listed on the label, we were told the company was unable to give us that information. Despite telling them the inquiry was for a food allergy, they told us we needed to have a doctor's note mailed to them, then they would mail the answer to the doctor and we would have to find out from the doctor whether the product was safe for him.

We worry in particular that sesame might be included in "natural flavorings" and not disclosed specifically. The FDA should declare that sesame is a "major allergen" that would have to be disclosed on labels.

Sesame seems to be becoming a more prevalent allergen and some companies are taking note of this by voluntarily including sesame in their labeling. It would be great to be able to go grocery shopping and not have so many questions about the foods we purchase. Including sesame in the labeling law would make shopping easier and less anxious.

Beyond packaged foods, another worry is that sesame would be used in restaurant foods. If the FDA declared sesame to be a "major allergen," restaurant workers would be educated (via the model Food Code) that sesame is a potentially dangerous allergen.

September 19, 2014

S. B.  
Schertz, Texas

My daughter has multiple food allergies and we have to avoid a long list of ingredients, including sesame. Sesame is a "priority allergen" in Canada, so some imported products do label for sesame, but not nearly enough to truly help. Breads, crackers, soups, pre-packaged meals, etc., often contain sesame/sesame oil, etc., and often entire food product groups are eliminated for us, on the suspicion that they come into contact with sesame. It would be helpful to know, with more certainty, if a product is a safe option for my daughter, or not. Sesame allergy is vastly underreported and the reactions to sesame can be just as swift and severe as those for peanut.

September 21, 2014

H. W.  
Las Vegas, Nevada

My daughter was diagnosed with multiple food allergies shortly after turning 1. She'd had reactions before the confirmation of her condition but it took time to isolate her triggers. She was initially allergic to peanut, tree nut, oat, sesame, corn, milk, egg, wheat, soy, and grape. This made cooking and shopping a challenge and it still is a challenge even though she did narrow her list after outgrowing a few allergies to peanut, tree nut, oat, and sesame. Having a "mainstream" allergy mixed with a "non-top-8" allergy makes a life of constant vigilance that much more challenging. You could say "just avoid the allergens" but when companies don't have to disclose the presence of sesame or use the commonly understood name of sesame, things get tricky. 5+ years into our allergy journey I know how to pick up a product and hunt for the clues that tell me about the presence of something like sesame but even my food allergy mama sleuthing skills can't see into the mind of a manufacturer that just lists "spices" as an ingredient. "Tahini," or ground sesame paste, is another nebulous ingredient that I try to work on with my budding reader but which inhibits the ability of others to assist in keeping her safe. Which is to say that I may know that tahini equals sesame but a teacher or other parent may not know that. It really boils down to disclosure for our family - sesame is a fairly major allergen not being labeled for. No one is asking companies to stop using sesame in their products, just to let the consumer know that it is there. The precedent set by adding to labeling requirements will open the door for more transparency and safety for consumers in the United States. How do I teach my child to be responsible about her allergies if companies that make food products aren't required to tell her the ingredients of their "spices" or that tahini lurks within. I distinctly remember buying tomato sauce and seeing that one variety had sesame. I was shocked and wondered if the absence of sesame on the other brands' labels meant it was present and they didn't feel obligated to tell anyone. The broader issue is not whether I'm going to walk out of the store with tomato sauce, it is that if we're consenting to have food production so removed from the end user, we should be heard when we ask for assistance knowing whether we can safely provide a food product to our families.

September 18, 2014

A. F.  
Great Neck, New York

My son is now 20 and seems to be able to tolerate cross-contamination with sesame; while we make every attempt to avoid it at home, I'm quite sure he is not as careful when eating out and has been fortunate to not have any problems.

However, when he was younger he was constantly having "mystery" reaction that we couldn't explain - they were to bread products that did not contain any peanuts, tree nuts or chickpeas (his other allergens), nor were they cross-contaminated with them. What they did contain was small amounts of sesame. Allergies to sesame are increasing, and it is appalling that we are behind other countries in declaring it a major allergen.

Being able to read a label on a product and trust that it contains complete, accurate information would mean the world to folks who deal with food allergies. Please help make this a reality by declaring sesame a major allergen, so we can see clearly and immediately if a particular product is safe.

September 24, 2014

S. L.  
Corvallis, Oregon

I still recall with some vividness what it was like to feed my toddler before FALCPA changed food allergen labeling. It was terrifying—every bite my child took felt like a food challenge in progress. FALCPA changed that for milk, peanut, and egg allergens. Our lives improved significantly—until my child was diagnosed with a sesame allergy at age four. I was horrified to discover that many of the products and companies that I'd learned to rely upon for information about my child's other allergens—were completely unreliable with respect to sesame. Some were not even particularly helpful when I spent hours phoning to determine whether or not products were sharing production space with sesame (or nuts). It was as if I'd rolled back the clock to a time before FALCPA existed. Imagine my horror when I realized, reading research articles, that the typical eliciting dose for sesame was like those of the super-potent seed storage proteins in nuts and peanuts—as low as a few micrograms. This was very sobering, as we already knew just how little it took to elicit life-threatening anaphylaxis with peanut or other tree nuts for our child. Not being able to trust food labels is one of the most socially and emotionally isolating experiences that I have had as a parent—it is difficult to explain to others, and impossible to just “let go” of such a profound and real danger. It was easier to live a reclusive and isolated existence than to explain and explain the limitations of food labeling to others. We could trust no one—not childcare providers, not friends, not family—because it was just too complicated.

When my child's sesame allergy resolved several years later, I vowed that I would do what I could so that other parents need not experience the overwhelming burden of never truly knowing whether or not a food label is accurate enough to trust. This is why I am writing in support of the effort to expand mandatory food allergen labeling to include sesame as a priority allergen. In my opinion as a parent, as a scientist, and as an online food allergy support group administrator, this is long overdue.



September 19, 2014

K. P.

Mount Laurel, New Jersey

My daughter was diagnosed with a potentially life-threatening sesame allergy when she was 14 months old. Our allergist told us to strictly avoid all sesame, and I tried to follow his advice, but I soon learned that this was much more difficult than originally anticipated. I had never realized how complicated food labels were with terms like "natural flavors", "spices", "colors", and other complex ingredient names which left me confused as to whether the food product might contain sesame. Even products with simple and clear ingredients sometimes contained a stray sesame seed from cross-contact. There was no assurance of safety even with most single ingredient food products so cooking from scratch generally reduced the allergen risk for my daughter, but did not eliminate it. When other food allergy moms were teaching their child to carefully read food labels, I was teaching mine that we cannot depend on food labels to determine if a product is safe.

When I reached out to food manufacturers for help in determining whether their products contained sesame, some were helpful, but many were not. Here are some of the general types of things that I was told:

- That information is proprietary.
- We follow all of the current allergen laws and regulations which only require us to list the "top 8 major food allergens."
- It is probably better if your daughter does not eat any of our products.
- Sesame is not an actual ingredient in that product, but we do not follow allergen control measures for sesame and there might be some cross-contact risk.
- We do not keep track of that information.

The overriding unspoken message that I heard was that we were on our own, that my daughter should eat at her own risk. It was so hard seeing the disappointment in her eyes when she wanted to eat a product that probably would have been fine for her, but I had to tell her no for lack of definitive information. There were only a couple of companies like General Mills and Kraft that went that extra consumer safety step and voluntarily treated sesame as an allergen for labeling purposes.

My daughter is now seven and we have noted some positive changes as more companies have started to label for intentionally added sesame (although not usually for cross-contact risk). We are also fortunate that she is currently able to tolerate small amounts of sesame without reaction. Even though this issue does not affect our family as much anymore, I still feel very strongly that the allergen sesame should be formally regulated and its labeling standardized as it is an extremely potent allergen that is becoming increasingly common in the United States. Every time, with every food product, sesame-allergic (just like soy-allergic or peanut-allergic) families need to be able to depend on the food label to clearly indicate whether sesame is an ingredient and whether there is cross-contact risk. It is time to address this public health safety gap.

**Change.org Petition:** <https://www.change.org/p/fda-add-sesame-seeds-as-an-allergen-to-us-product-labeling-laws-require-them-to-be-disclosed-on-us-food-labels>

*Text of petition by Brian Heller:*

Sesame seeds were estimated to be the number 9 top allergen in the US. By law, only the top 8 allergens need to be disclosed on food labels in the US.

This needs to change ASAP and sesame seeds need to be added to our food labeling laws, requiring disclosure on our food labels, just like we do for nuts.

[If you agree with this petition, please don't merely sign it, but please also share it on social media. Thanks!]

It is estimated that about half a million people in the US have severe sesame allergies. If you include poppy seeds, sunflower seeds and other similar seeds (like we do with "tree nuts" as a category), the numbers are much higher. The US lags behind other countries which already require sesame disclosure on food labels, including Canada, and most countries in Europe, Israel, Australia, New Zealand, and many others. UK study determined that, of people allergic to sesame, one in six (17%) had suffered potentially life threatening symptoms, including 65% of severe reactions on the first known exposure!

The logic used to cut off the list after the "top 8" allergens was because one old study found that 90% of all food allergies in the US were covered by the top 8 allergens at the time. This logic needs to be revised now for many reasons, including without limitation:

(1) This study is severely outdated. It was released in 2004, using data collected even before that time. Sesame seed allergies are growing, estimated with over half a million affected people in the US alone, not counting poppy seeds, mustard seed, caraway seeds, sunflower seeds, and other seeds (much like we treat "tree nuts" as a broad category). For comparison, there are roughly 3 million people in the US allergic to peanuts or one or more tree nuts. The number of peanut and tree nut allergies in the US literally tripled in just 10 years, so it is reasonable to assume that a 2004 study can be vastly outdated about other allergens, like sesame, as well.

(2) Seed allergies can be severe, leading to anaphylaxis, while the number 10-15 allergens typically cause much less severe reactions. Some people argue that if you add the number 9 allergen, then people affected with the number 10 allergen will argue that their #10 allergen should be added, and so on, causing a never ending "slippery slope". But many of these other allergens merely cause stomach discomfort and are *not life threatening*. Seed allergies can be life threatening. Thus, it makes sense to "draw the line" at number 9 (if not later), but not stop at number 8, since allergen #9 can lead to life threatening reactions. A UK study in 2005 determined that of people allergic to sesame, one in six (17%) had suffered potentially life threatening symptoms, including 65% of severe reactions on the first known exposure!

(3) Sesame allergies are even more prevalent worldwide, and other countries (such as Canada, most countries in Europe, Israel, Australia and New Zealand) already require

disclosure of sesame in their food labeling laws. Sesame is the #3 allergen in Israel (above peanuts!), #3 in Canada (right on our border!), #4 in Australia, and one of the top few allergens throughout Europe and in New Zealand. In Canada, the top 11 need to be disclosed, including both sesame seeds at number 3 and mustard seed at number 11. Canada is also working on standardizing "may contain" or cross contamination disclosures, with even more strict requirements than what we have currently in the US, even for nuts. We lag behind other countries, and it is time for us to become a world leader again, especially on this important safety issue.

(4) Very, very low doses of sesame can cause serious reactions, including death. These can be from levels as low as might be expected in mere cross contamination from the same facility.

It is time to add sesame (supposedly the #9 food allergen in the US according to an old study, now likely even higher), to the list of food allergens that must be disclosed on all US food labels, even when merely made in a factory with, or in a facility containing, sesame seeds or sesame oil, etc.

This issue is personal for me. My son recently had to be rushed to the ER in an ambulance after just a couple bites of a meal from a restaurant, even though the restaurant assured us there was no sesame in his meal. We later found out that the restaurant did not add any sesame to the meal, but they used a premade packaged sauce that had sesame oil.

Silence on a label does not mean a product is safe - and many people with severe allergies do not know this, and rely on that silence. Most prepackaged breads, buns, rolls, bagels, and other baked goods do not say anything about sesame on the label. Many people with sesame allergies are unaware of the law and assume that this means they are safe to eat and sesame free. But they are not. By law, any cross contamination of sesame currently does not need to be disclosed. If you call any of the major bread manufacturers or packaging plants, they will almost all tell you that they use the exact same equipment to process and/or pack sesame and non-sesame versions of their products. But they do not disclose this because they do not have to. I have spoken with many employees at several of these companies and they all tell me the sesame seeds are pervasive and the machines are impossible to clean. The seeds get everywhere (even in the employees' shoes!), and there are often stray seeds on the non-sesame breads. It only takes a fraction of a seed to be life threatening. So a person with a sesame allergy can have a life threatening reaction from eating a non-sesame seed bun that is not properly labeled!

I don't want my son to die from eating a hot dog bun. As a parent of a child with serious, potentially anaphylactic allergies, I need to know if the buns or breads I'm buying were made on shared equipment with sesame seeds.

As one mom said in the comments below (paraphrasing) "while other parents are teaching their kids to carefully read food labels, I have to teach my kids with allergies that they cannot trust our food labels." This is a sad but true statement in the USA.

I recommend that:

- (1) Sesame be added to the list of FDA regulated allergens, required to be disclosed on packaged food labels,
- (2) Disclosure of cross contact / cross contamination should become mandatory, not voluntary, and
- (3) There should be more stringent regulation on restaurants with regard to food allergen disclosures and practices.

To: FDA

Add Sesame Seeds as an allergen to US Product labeling laws (Require them to be disclosed on US food labels)

Sincerely,  
[Your name]

###

*Selected excerpts from signatures and comments on the petition:*

[Jennifer Gonzalez](#) CANTON, MI

My son is severely allergic to sesame, it can close his throat in under 6 minutes. US manufacturers should be required by law to disclose the existence of sesame, as well as potential cross contamination risks, to save lives. Lumping it under "spices" or "natural flavor" is not good enough, and most manufacturers have no clue whether their factory even processes sesame. Their excuse? It's not a top 8 allergen so we don't monitor. That is simply not acceptable when there are human lives on the line.

[Frederic Wilson](#) AUSTIN, TX

I have an anaphylactic reaction to sesame. I have had to be intubated and treated in the ICU after only one bite of food containing sesame. Many companies list "spices" in their ingredients list instead of sesame. When I call and ask if sesame is included in "spices," I am told that this is "proprietary information."

[Barbara Wells](#) OXFORD, MS

My grandson had a near fatal reaction to sesame oil in a hummus dip. He could die from exposure to sesame. Passing this law could save his life.

[Heather Conley](#) BENTONVILLE, AR

My son has a very severe sesame allergy. In fact, he has almost died from ingesting sesame.

[Joy Marie Powell](#) BYRON CENTER, MI

Our son had his first full-blown anaphylactic reaction requiring ER visit after eating hummus at daycare (at 26 months old). Skin and blood tests confirmed this life-threatening allergy. Please help change labeling laws to decrease his risk of repeat

reactions to an unlabeled product or undeclared ingredient ("spices").

[Nick Forte](#) TROY, MI

My Daughter has a severe Sesame Seed allergy and is allergic to seeds and oils. We find it incredibly challenging as it is not consistently disclosed on product labels and she's had several reactions as a result of sesame not being disclosed!

[Patricia Rescigno](#) MILFORD, DE

My grandchild suffers with life threatening food allergies that include sesame. It would be nice to be able to read the label and know whether or the product is safe. As of right now, every manufacturer has to be contacted by email or phone to find out whether or not a product could be cross contaminated with sesame. We have had to stop using products like Heinz ketchup because they won't divulge what is in their "spices."

[Kathleen Helbling](#) MCDONALD, PA

Studies have shown a high volume of people that have a tree nut allergy also will have a sesame seed allergy. My 6 year old son has both tree nut and sesame seed allergy. It is very difficult to find out if there is a cross contam[ina]tion when it comes to most foods. It needs to be an easier discovery.

[Swati Joshi](#) RICHMOND, UNITED STATES

My son has a sesame allergy. Ironically, it is often easier for us to determine if foods from outside the U.S. contain sesame, because other countries already label for it.