



CITIZEN PETITION

January 30, 2023

The Hon. Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Re: Petition to FDA to Notify Manufacturers that They Cannot Mitigate Allergen Cross-Contact Risks by Adding Sesame and other Major Allergens to Foods

Dear Commissioner Califf,

The Center for Science in the Public Interest (CSPI) submits this petition under 21 U.S.C. § 350g, 5 U.S.C. § 553(e), 21 C.F.R. § 117.135, and 10 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs issue a notice to manufacturers and update its industry guidance to prevent manufacturers from intentionally adding sesame and other major allergens to products when they identify allergen cross-contact risks, a practice that violates food safety rules. This FDA action is urgently needed to prevent concerning practices that have emerged as industry moves to implement the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act, which went into effect on January 1, 2023.

Specifically, we request that the Food and Drug Administration issue a notice to manufacturers stating they cannot meet their food safety obligation to mitigate allergen cross-contact risks by, paradoxically, adding sesame or other major allergens intentionally to foods. We also ask that the FDA address this practice through its draft Allergen Questions and Answers document. Finally, we ask FDA to clarify that the ingredients and “contains” statement cannot be used to declare cross-contact risks.

CSPI, “Your Food and Health Watchdog,” is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public’s health through better nutrition and safer food. The organization does not accept government or corporate donations and is supported by foundation grants, donations, and subscribers to its magazine, *Nutrition Action*.

CSPI was the first group to urge the FDA to require sesame to be declared on food labels alongside other major allergens, petitioning the agency to require allergen labeling for sesame in 2014.¹ We were also among the groups lobbying in support of the Food Allergen Labeling and

¹ Center for Science in the Public Interest. CSPI Petition re: FDA requiring sesame to be labeled as a major allergen. November 18, 2014. <https://www.cspinet.org/resource/cspi-petition-re-fda-requiring-sesame-be-labeled-major-allergen>. Accessed January 27, 2023.

Consumer Protection Act (FALCPA) of 2004 and the FASTER Act, which required sesame to be labeled as a major food allergen.

With the implementation of the FASTER Act, many food manufacturers have begun ensuring proper labeling and implementing preventive controls to address the risk that sesame might make its way unintentionally into foods through cross-contact. Unfortunately, other manufacturers are intentionally adding sesame to products instead of implementing these preventive controls. This addition of allergens has the potential to increase risks for sesame-allergic consumers, the very opposite of what the FASTER Act intended.

CSPI has identified, and outlines in this petition, five examples of companies that have publicly admitted to intentionally adding sesame to foods in response to the new food safety and labeling requirements of the FASTER Act. Countless additional manufacturers across America have quietly begun declaring sesame at the end of their ingredients list² without explanation or comment, making the full scope of this practice difficult to assess.³

The practice of adding major allergens as a response to food safety rules is shocking, unprecedented in scope, and has the potential to undermine long-established protections for Americans with food allergies. It is also illegal, violating both the letter and intent of FDA's food safety rules, because it takes an existing hazard identified by the company (an allergen cross-contact risk) and further elevates the risk to consumers by increasing potential exposure to the food allergen.

FDA must act swiftly to curb this activity, which sets a dangerous precedent. If food manufacturers can evade food safety requirements simply by adding and then declaring trace amounts of allergens, there will be a strong economic incentive to apply this practice more generally to all major food allergens, increasing risks and decreasing safe food access for the nearly 34 million Americans estimated to have food allergies who must then avoid these foods.⁴

A. Action Requested

We request that the Commissioner take the following actions:

- 1) Issue a notice to manufacturers, similar to the agency's June 1996 "Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers,"⁵ declaring that companies cannot

² The smallest ingredients, by mass, appear last in the ingredients list.

³ While some of these new declarations may represent sesame that was previously present undeclared in the product as a component of an ingredient, such as a spice or flavor, this seems unlikely given the timing, scope of the practice, explanations by companies, and the fact that many of the products now newly declaring sesame do not include spices or flavorings.

⁴ In the United States, an estimated 7.6 percent of children and 10.8 percent of adults have food allergies. Gupta RS et. al. The public health impact of parent-reported childhood food allergies in the United States. *Pediatrics*. 2018; 142 (6): e20181235; Gupta RS, Warren CW, Smith BM, Prevalence and severity of food allergies among US adults. *JAMA Netw Open*. 2019;2(1):e185630. The US Census estimates a population of 261 million adults and 72 million children under age 18 in 2022. Estimates of the Total Resident Population and Resident Population Age 18 Years and Older for the United States, Regions, States, District of Columbia, and Puerto Rico: July 1, 2022 (SCPRC-EST2022-18+POP), U.S. Census Bureau, Population Division, December 2022.

⁵ Shank FR. Notice to manufacturers: Label declaration of allergenic substances in foods. June 10, 1996.

meet their obligation to control allergen cross-contact risks by adding major food allergens intentionally to foods.

- 2) Finalize its “Draft Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5)” (draft Allergen Questions and Answers)⁶ to likewise reflect the policy that companies cannot add major food allergens to mitigate cross-contact risks.
- 3) Clarify in guidance that while cross-contact risks can be declared voluntarily in a “may contains” advisory statement, they cannot be declared by naming the allergen in the “Contains” statement or ingredient list, as these are reserved for declaring actual ingredients.

B. Statement of Grounds

i. Background on Sesame Allergen Labeling

An estimated 1.1 to 1.5 million American children and adults have sesame allergy.⁷ The FASTER Act offered protection for these Americans by amending FALCPA to add sesame as the ninth “major food allergen.” Under FALCPA, a food that bears or contains a major food allergen is considered misbranded if that allergen is not declared in the ingredients list or in a separate “contains” statement.⁸

The FDA has also incorporated the major food allergens defined in FALCPA into its rules for current good manufacturing practices (cGMPs) and into food safety regulations promulgated under the Food Safety Modernization Act (FSMA). These food safety rules identify major food allergens as a form of “chemical hazard,”⁹ and require companies to control the hazard by providing assurance that it will be “significantly minimized or prevented.”¹⁰ This includes, in the case of allergens, “ensuring protection of food from allergen cross-contact,”¹¹ which is defined as the unintentional incorporation of a food allergen into a food.¹² Food safety rules also require accurate labeling of the finished food, including ensuring that the food is not misbranded by the existence of undeclared allergens.¹³

While not regulated by federal law, some food manufacturers may also provide voluntary precautionary allergen labeling (PAL) declarations, such as “may contain [allergen],” to indicate whether cross-contact risks are, or are not, present in the manufacturing environment. Such statements are not regulated by the FDA, but the agency has stated in guidance that advisory

⁶ Food and Drug Administration. Questions and answers regarding food allergens, including food allergen labeling requirements of the federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry. Draft Guidance. November 2022.

⁷ Warren, CM, Chadha, BS, Scherer SH, Prevalence and severity of sesame allergy in the United States. *JAMA Netw Open*. 2019;2(8):e199144.

⁸ Food Allergen Labeling and Consumer Protection Act of 2004. P. L. 108-282, Title II, § 203. *Codified as 21 U.S.C. § 343(w)*.

⁹ 21 C.F.R. § 117.130(b)(ii); 21 C.F.R. § 117.3 (defining “food allergen” to mean “major food allergens”).

¹⁰ 21 CFR § 117.135(a)(1).

¹¹ 21 CFR § 117.135(c)(2)(i).

¹² 21 CFR § 117.3.

¹³ 21 CFR § 117.135(c)(2)(ii).

labeling “is not a substitute for adherence to current good manufacturing practices,”¹⁴ indicating that companies that utilize PAL statements still must implement food allergen controls.

Manufacturers’ food safety obligations resulting from the FASTER Act are abundantly clear: companies that manufacture foods with sesame ingredients now must take reasonably appropriate steps to identify cross-contact opportunities and mitigate those risks. This can be done by, for example, ensuring that sesame products are not processed on shared equipment with non-sesame products or by cleaning the equipment when changing over between products. Failure to take such reasonable steps to mitigate these risks with respect to sesame is a violation of FDA’s food safety regulations.

ii. Industry Practices in Response to the FASTER Act and the Impact on Consumers

Since the passage of the FASTER Act, companies have had two years to incorporate sesame into their existing food safety and labeling programs. Many had already taken appropriate steps in advance of the effective date. For example, Calise and Sons Bakery, Inc, has assessed its facility for sesame cross-contact hazards and labeled its Bulkie Rolls product with the advisory statement “Made in a facility that does not use nuts or sesame seeds.” (Fig 1)

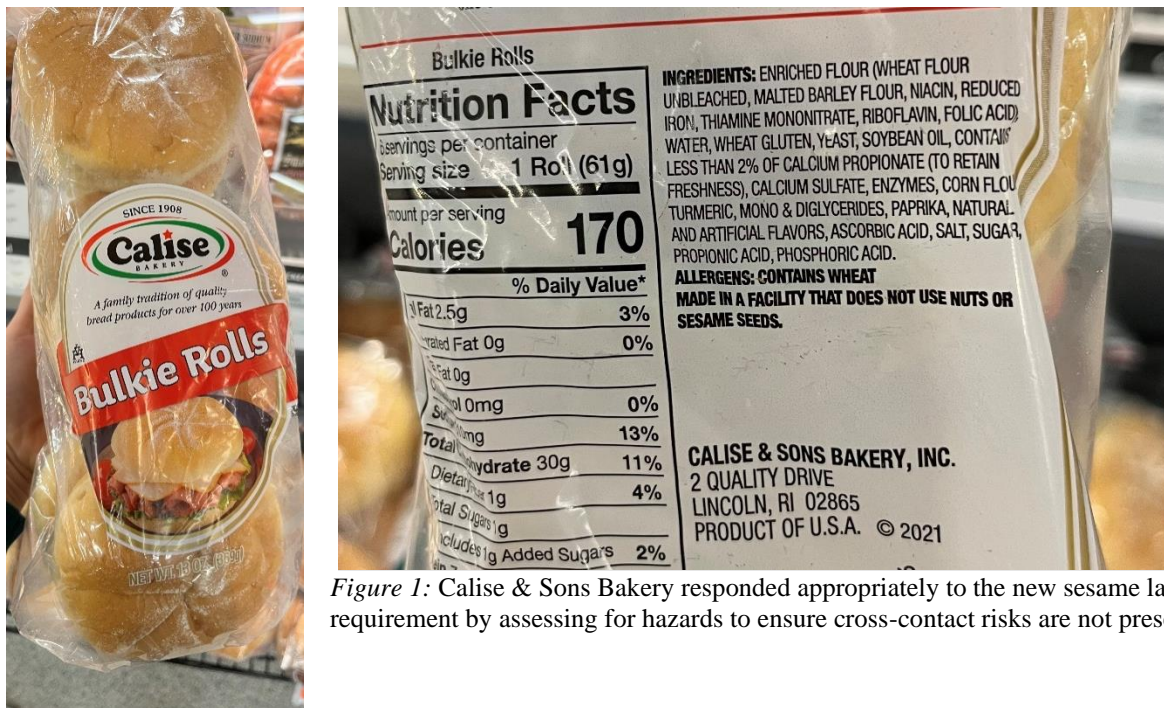


Figure 1: Calise & Sons Bakery responded appropriately to the new sesame labeling requirement by assessing for hazards to ensure cross-contact risks are not present.

Yet other manufacturers have not taken this approach, and instead are seeking to skirt food safety requirements by declaring (and presumably intentionally adding) sesame as an ingredient in products that did not previously contain sesame.

¹⁴ U.S. Food & Drug Administration. Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry. November 2022.

At least five companies, detailed below, have admitted to adding sesame to products in response to the FASTER Act either in published statements or in written response to inquiries by CSPI staff.

1) *Pan-O-Gold*

In April 2022 the blog Snack Safely published the following excerpt from a written exchange between a reader and a representative from the Pan-O-Gold Baking Company:

The FDA has now included sesame as a major allergen and the requirement will be enforced the beginning of 2023. In order to meet the requirements of the FDA, we would need to conduct allergen cleaning (removal of all protein) and post cleaning allergen protein verification for all of our processing equipment before baking breads and buns that do not include sesame seeds. This requirement is to assure food safety for those customers who would be affected.

The unfortunate reality is that our equipment and bakeries are not setup for allergen cleanings that would be required to prevent sesame cross-contamination and was [sic] not an option for us. What we needed to do in order to assure the safety of our products from cross-contamination was to make sesame common to all of our products and include sesame allergen as a warning on all of our packaging labels.

In order to include sesame as an ingredient on a package label, the FDA requires that the ingredient be present which is why we will be adding trace amounts of sesame flour in all of our bread and bun dough recipes to comply. The end result will be that we will have both wheat and sesame as common allergens in all of our products eliminating the requirement for allergen cleaning. We will not begin the addition of the sesame flour until all of our packaging is updated to include the warning. We set a goal for completion the beginning of January of 2023 and plan to begin including trace amounts of sesame flour at that point.

I am sorry that this change to the FDA requirements has brought us to this action, but it is better to assure food safety than to create potential risks to the health of those affected by sesame allergies.¹⁵

2) *Chick-fil-A*

In a public statement on its website, the restaurant chain Chick-fil-A stated:

In 2021, the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act was signed into law, declaring sesame as the ninth major food allergen recognized in the United States by the U.S. Food and Drug Administration. All labeling of sesame as an allergen is required by law across the United States, effective Jan. 1, 2023. This industrywide matter led to a recipe change for our white bun and multigrain brioche bun

¹⁵ Bloom D. Company will add trace amount of allergen to all products to skirt safety regulation. SnackSafely.com. April 29, 2022. <https://snacksafely.com/2022/04/company-will-add-trace-amount-of-allergen-to-all-products-to-skirt-safety-regulation/>. Accessed January 22, 2023.

*to now include sesame as an ingredient. Our flaxseed flour flat bread and Chick-fil-A Cool Wrap have always contained sesame.*¹⁶

3) *Flowers Bakeries, LLC (Dave's Killer Bread)*

Flowers Bakeries, LLC, published an alert in partnership with Food Allergy Research and Education (FARE) on December 9, 2022, indicating that all of the company's buns, rolls, hoagies, and dinner rolls, as well as Dave's Killer Bread breads, buns, and bagels, will include sesame as an ingredient.¹⁷ In response to an inquiry from CSPI submitted through the Dave's Killer Bread consumer contact form, a customer representative stated:

*To ensure compliance while minimizing any impact on product availability, this product does contain a minute amount of sesame flour in the flour mix – approximately 0.031% (three hundredths of one percent). As a result, sesame will be listed as an ingredient under the “less than 2%” section on the packaging. This product did not previously contain sesame. We have started producing products with the addition of sesame flour now in order to meet the 2023 requirements. Right now you will be able to tell if your product package contains products using the new recipe by looking at the ingredients list on the back of the package. Sesame will be listed in the 'less than 2%' section.*¹⁸

4) *Culver's*

In an email to CSPI staff, also in response to an inquiry through its consumer contact form, a representative of Culver's restaurant chain stated:

*Thank you for reaching out to Culver's with your concern about the sesame allergen. Earlier this year, our four Kaiser(hamburger)[sic] bun suppliers collectively made the strategic decision to add a small amount of sesame flour to all their products to eliminate any uncertainty around the possibility of allergen cross-contact.... The amount of sesame flour ranges from .00009 to 0.031 percent, depending on the bakery. December 16th is when the first bakery made the change.*¹⁹

5) *Olive Garden*

Olive garden made a statement to the Associated Press published in a December 21, 2022 article covering food industry response to the FASTER Act. According to the article:

¹⁶ Chick-fil-A. Nutrition and allergens. <https://www.chick-fil-a.com/nutrition-allergens>. Accessed January 6, 2023.

¹⁷ FARE. Ingredient Notice (Sesame): Flowers Bakeries, LLC. December 9, 2022. <https://www.foodallergy.org/living-food-allergies/food-allergy-essentials/allergy-alerts/ingredient-notice-sesame-flowers>. Accessed January 24, 2022.

¹⁸ Email from Janet, Customer Relations, customer.relations@flowersfoods.com, Ref: 541171. December 27, 2022. On file with author.

¹⁹ Email from Doug Nelson, Customer Relations, culvers@casesupport.smg.com, Case Id: 814-115502. December 22, 2022. On file with author.

Olive Garden said that starting this week, the chain is adding "a minimal amount of sesame flour" to the company's famous breadsticks "due to the potential for cross-contamination at the bakery."²⁰

In addition to these five cases in which a company admitted to changing its recipe or accepting changes from a supplier post-FASTER Act, numerous additional manufacturers have quietly slipped sesame into the ingredient list without public explanation or comment. Because the companies have failed to publicly acknowledge the nature of and reasoning for the change, it remains unclear in these cases whether sesame has been added to the recipe, was previously present and undeclared, or is merely a cross-contact risk being declared inappropriately as an ingredient or in the “contains” statement.

For example, Wendy’s French Toast Sticks menu item currently lists sesame as the last ingredient in the bread component of the item (Fig 2),²¹ yet the company only listed sesame in a “may contain” statement in August 2022, when Wendy’s sent out a notice stating the sticks “contain wheat, milk, egg and soy, and *may contain* sesame” (emphasis added).²² When contacted by CSPI through the company’s customer service portal, Wendy’s stated “Wendy’s updated its nutrition and allergen information in December 2022 to include a sesame allergen, where applicable” and provided no further explanation for the change.²³ It therefore remains unclear whether sesame was always present as an ingredient and is only now being correctly declared, has been added as an ingredient, or is now being declared as an ingredient in an effort to warn consumers of a cross-contact risk, when it is not truly an ingredient.

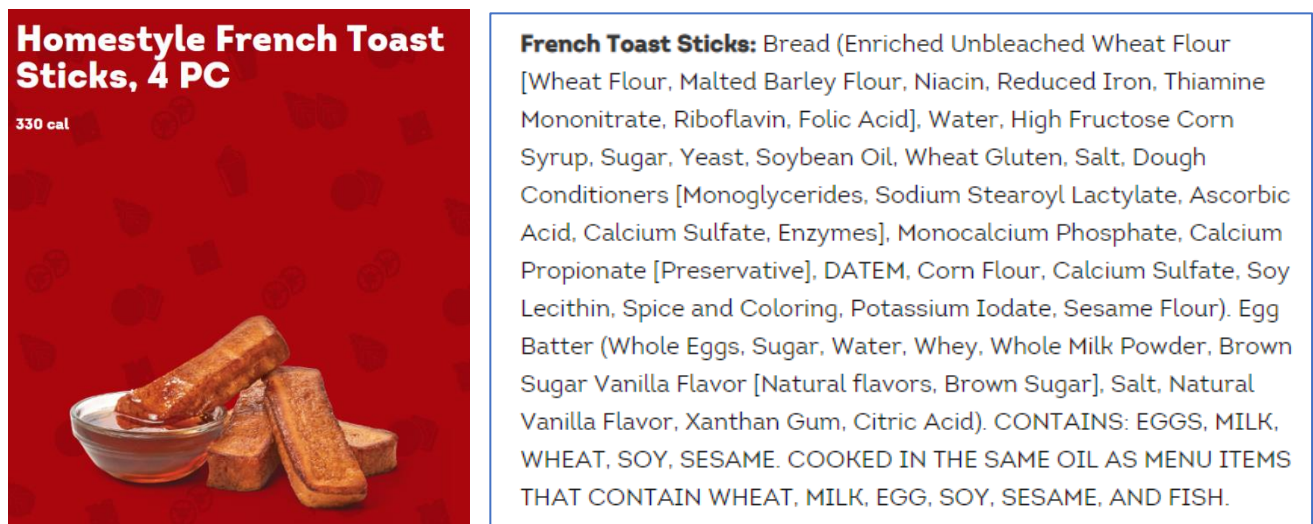


Figure 2: Wendy's French Toast sticks were introduced with a statement that they "may contain" sesame, but sesame flour is now declared as an ingredient in the bread.

²⁰ Aleccia J, New label law has unintended effect: sesame in more foods. AP News. December 21, 2022. <https://apnews.com/article/sesame-allergies-label-b28f8eb3dc846f2a19d87b03440848f1>, Accessed January 21, 2022.

²¹ Wendy’s Homestyle French Toast Sticks. <https://order.wendys.com/product/31443/homestyle-french-toast-sticks-4-pc>. Accessed January 21, 2023.

²² FARE. Ingredient Notice (Egg, Milk, Sesame, Soy, and Wheat): Wendy’s. July 25, 2022. <https://www.foodallergy.org/living-food-allergies/food-allergy-essentials/allergy-alerts/ingredient-notice-egg-milk-sesame-soy>. Accessed January 21, 2023.

²³ Email from Wendy’s International, LLC, customercare@wendys.com, ref: _00D37PbrE._5001G17jPh0:ref. December 14, 2022. On file with author.

In another example, Sara Lee White Made with Whole Grain Bread, manufactured by Bimbo Bakeries USA, the largest commercial baking company in the United States,²⁴ did not previously declare sesame in its ingredients or PAL statement, or include a complex ingredient like “spice” or “natural flavors” that could have contained sesame as a component, yet versions of the product are now appearing at retail with “sesame seeds” listed as the last ingredient. (Fig 3)

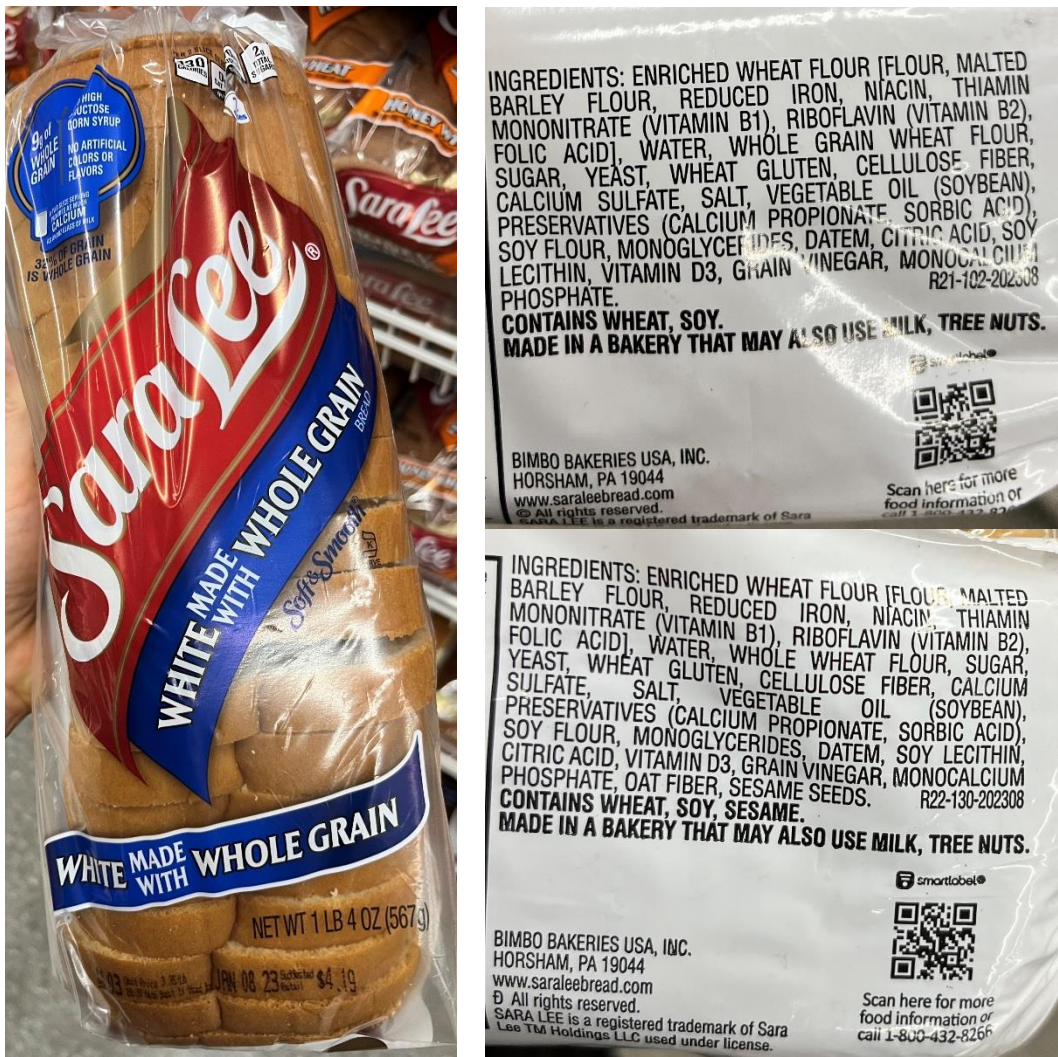


Figure 3: Sara Lee White Made with Whole Grain Bread, prior to and after the declaration of sesame seeds as the last ingredient.

When CSPI staff contacted Bimbo Bakeries USA through its customer service portal regarding the new sesame declarations on Sara Lee products, a representative replied with a message indicating, confusingly, that the labeling was precautionary, and that the company’s recipes had not changed:

Due to a new FDA requirement identifying sesame as an allergen, food manufacturers are labeling sesame as a precaution for sensitive consumers in the unlikely event sesame is carried over from other products produced on the same production line. BBU conducts all proper sanitation to minimize cross-contact but cannot assure every seed has been

²⁴ Bimbo Bakeries USA. About Us. <https://www.bimbobakeriesusa.com/about-us>. Accessed January 22, 2023.

*removed. BBU remains committed to assuring the safety of our consumers, particularly those with allergen sensitivities. No changes have been made to our recipes to add sesame.*²⁵

This statement is ambiguous, leaving it unclear whether sesame is now being declared as an ingredient in order to warn consumers of potential cross-contact risks (even though it is not an ingredient), or if sesame was always present as an ingredient and is only now being declared.²⁶

The examples provided in this petition are, by their nature, anecdotal, and CSPI is not aware of any systematic survey documenting the extent of these new practices, leaving the full scope of this problem unknown. Yet the behavior has become sufficiently widespread that some consumers are taking to social media to express frustration that there are no longer bakery products available that meet their families' needs.

One consumer, Nicole Rinehart, stated on the Facebook group Sesame Allergy Information and Awareness, "I know this has been discussed, but it finally happened to me... I stood in the bread aisle at the grocery store today teary eyed and half in shock as there are no longer any safe breads or buns for my son."²⁷ Another, Jennifer Grant, similarly posted "I just got the call I was dreading from my daughter who is allergic to multiple foods including sesame. She returned to college after the break and the majority of items she ate previously (for the last 18 months) and safely just weeks ago are all labeled 'contain sesame' ... this sesame warning has limited her options to barely nothing. Today she wandered around her dining hall and called me in tears, showing me pictures of her safe foods now labeled with huge 'contains sesame' signs."²⁸

The practice of intentionally adding sesame ingredients to a product has the potential to trigger a reaction in consumers. The discrete dose of sesame protein predicted to provoke a reaction for 5 percent of the sesame-allergic population (the "ED₀₅") is approximately 2.4 mg.²⁹ Added sesame flour can swiftly reach an eliciting dose, even when added in minute amounts relative to other ingredients.

Two companies have provided CSPI with information on how much sesame was added: a representative of Flowers Bakeries LLC reported in the statement we quote above that the company is adding sesame flour to its Dave's Killer Bread to comprise approximately 0.031 percent of the flour mix, a seemingly small amount, placing it near the end of the ingredients list in the "less than 2%" section. A representative of Culver's similarly informed CSPI in a statement, also quoted above, that the amount of sesame flour in its buns ranges from 0.00009 to 0.031 percent.

²⁵ Email from The Customer Relations Department, "Sara Lee (Bimbo Bakeries USA) - Response from Consumer Relations 02623662." December 22, 2022. On file with author.

²⁶ While it is possible that sesame was present in the product previously and undeclared as a component of an ingredient (for example, "spice" or "natural" flavor), this seems unlikely given the bread in this example did not include spices or flavors, and the communication from the company do not describe sesame being a previously undeclared component of an ingredient, instead focusing on cross-contact risks.

²⁷ Post on file with author.

²⁸ Post on file with author.

²⁹ Turner PJ, et al. Updated threshold dose-distribution data for sesame. *Allergy*. 2022 Oct;77(10):3124-3162.

If “sesame flour” constitutes 0.031 percent by weight of the “flour mix” in Dave’s Killer Bread, it is possible that a sandwich containing two slices of a given bread, such as the 100% Whole Wheat, could provide the ED₀₅ (2.4 mg) of sesame protein. The company’s response did not state what percent of the bread is made up of the “flour mix,” nor what percent of the “sesame flour” ingredient is made up of sesame protein, so we conservatively estimated both.³⁰ Based on the assumptions that the bread contains at least 25 grams of “flour mix” and that sesame flour contains at least 30 percent protein by weight, a single slice of Dave’s 100% Whole Wheat bread likely contains at least 2.3 mg sesame protein (about the ED₀₅), or 4.6 mg per two slices (about twice the ED₀₅).

In addition, if the added sesame flour were to clump together unevenly in the flour mixture, it would further elevate the potential for a single person to consume a dose sufficient to elicit an allergic reaction.

Never before has the practice of adding major allergens to skirt food safety requirements been documented so clearly and on such a wide scale. We have not identified any public reports of the practice in Canada when that country adopted sesame labeling in 2009, and, to our knowledge, no company publicly acknowledged adding any other major food allergen as a response to allergen food safety requirements prior to the passage of the FASTER Act. However, the blog Snack Safely did previously report examples of peanuts and tree nuts, also major food allergens in the United States, being incorporated without public explanation as the last ingredients in foods that did not previously contain these ingredients, suggesting the practice may have been utilized at least quietly in the past by U.S. food manufacturers.³¹ The first of these examples was reported by Snack Safely in 2016,³² shortly after FDA finalized food safety rules requiring companies to identify and control food safety hazards under the Food Safety Modernization Act (FSMA).³³

FDA’s FSMA rules, to which sesame is now incorporated thanks to the FASTER Act, may have created an unintended economic incentive for companies to add allergens as an ingredient. Not only do companies pay the direct production cost of controlling cross-contact risks, but they must also pay for a recall in the event that an undeclared major food allergen renders a product

³⁰ The 100% Whole Wheat bread declares that it contains 25 grams of whole grains per 42-gram slice. Dave’s Killer Bread. 100% Whole Wheat. <https://www.daveskillerbread.com/100-whole-wheat>. Accessed January 25, 2023. We therefore conservatively estimated the total weight of the “flour mix” per slice to be 25 grams, even though it is likely slightly more than 25 grams because sesame is not a grain. According to the USDA Food Data Central database, the protein content of sesame flour ranges from 31 percent to 50 percent by weight. We therefore conservatively estimated the protein content of the “sesame flour” ingredient to be 30 percent. U.S. Department of Agriculture. FoodData Central. Seeds, sesame flour, high-fat. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/170192/nutrients>. Accessed January 21, 2023. U.S. Department of Agriculture. FoodData Central. Seeds, sesame flour, low-fat. <https://fdc.nal.usda.gov/fdc-app.html#/food-details/170560/nutrients>. Accessed January 21, 2023. This results in an estimate of 2.3 mg sesame protein per slice (0.00031 * 25 g flour mix * 0.30 * 1000 mg/g) = 2.3mg.

³¹ Bloom, D. Company will add trace amount of allergen to all products to skirt safety regulation. SnackSafely.com. April 29, 2022. <https://snacksafely.com/2022/04/company-will-add-trace-amount-of-allergen-to-all-products-to-skirt-safety-regulation/>. Accessed January 21, 2023.

³² Bloom, D. Advisory: various Keebler and Austin cracker varieties to be reformulated with peanut flour. SnackSafely.com. March 31, 2016. <https://snacksafely.com/2016/03/advisory-various-keebler-and-austin-brand-cracker-varieties-to-be-reformulated-with-peanut-flour/>. Accessed January 21, 2023.

³³ Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. Final Rule, 80 Fed. Reg. 55908 (September 17, 2015).

adulterated or misbranded.³⁴ Undeclared allergens are the leading cause of food recalls in the United States. In 2014 they accounted nearly half of all entries in the FDA’s reportable foods registry, a registry where companies must report problems with a food that is likely to result in harm.³⁵ Manufacturers fear massive costs from such recalls: in a survey of member companies conducted by the Grocery Manufacturers of America, published in 2011, 81 percent of respondents deemed the financial risk of a recall to be “significant to catastrophic.”³⁶ This fear may motivate food manufacturers to add major food allergens as a quick-and-dirty means to address cross-contact risks and protect against the financial risk of a recall.

iii. Companies Cannot Address Cross-Contact Risks by Adding Major Allergens to Products

It is critical that the FDA take the decisive step now to clarify, in a notice to manufacturers and in its Allergen Questions and Answers, that a major food allergen cannot be added to a product as an approach to mitigating cross-contact risks. This practice violates both the letter and intent of FDA’s food safety rules because it takes an existing hazard identified by the company (the cross-contact risk) and further elevates the risk to consumers by increasing potential exposure to the allergen.

FDA rules governing cGMP and preventive controls make clear that manufacturers must “identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented.”³⁷ Adding sesame intentionally to a recipe, even if declared, does not “significantly minimize or prevent” the hazard created by potential cross-contact, and may even increase the risk relative to cross-contact.

First, small amounts of intentionally added sesame ingredient may be sufficient to trigger an allergic reaction, as already described above. Second, declaring the allergen does not fully eliminate the potential that a consumer will be exposed to the new sesame ingredient, as reactions have been known to occur even when a product is labeled. For example, researchers at CSPI and Children's Hospital of Philadelphia previously reported results of an online questionnaire for adverse events and labeling errors related to sesame, which showed that sesame was declared on the label in 44 percent of reports.³⁸ The risk that consumers miss key labeling information is likely to be exacerbated when sesame is added to a product that previously did not include a declaration, as consumers accustomed to eating the product will presumably be less likely to review the label before every purchase.

³⁴ U.S. Food and Drug Administration. CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens. Updated 2005-11-29.

³⁵ U.S. Food and Drug Administration. The reportable food registry: a five year overview of targeting inspection resources and identifying patterns of adulteration. May 22, 2016. <https://www.fda.gov/media/97862/download>. Accessed January 21, 2023. The reportable foods registry includes entries for articles of food for which there is “a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.” FDA does not independently report when a reportable food is associated with a product recall.

³⁶ Capturing Recall Costs, Measuring and Recovering the Losses. Grocery Manufacturers Association. 2011.

³⁷ 21 C.F.R. 117.135(a)(1).

³⁸ Nguyen K, Greenthal E, Sorscher S, Lurie P, Spergel JM, Kennedy K, Adverse events and labeling issues related to suspected sesame allergy reported in an online survey. *Ann Allergy Asthma Immunol.* 2022;128(3):279-282.

Adding sesame flour intentionally to a recipe may also substantially increase risks compared to the potential for cross-contact with intact sesame seeds applied to the surface of a baked good, as reports suggest that ground sesame flour or paste may be less tolerated than intact seeds, possibly because seeds are frequently not broken during mastication, resulting in lower exposure to sesame protein contained within the seed.³⁹

The policy we urge FDA to adopt would not serve as a blanket prohibition on the addition of new major allergens to foods. We recognize that manufacturers are entitled to change their recipes for culinary reasons. Instead, we expect it to curb the practice of adding major allergens *as a measure to address cross-contact risks and prevent recalls*. FDA and its state partners could enforce the policy by investigating consumer complaints and through regular inspections required under FSMA. Under that law, manufacturers are required to document hazards and mitigation steps in a written food safety plan,⁴⁰ and frequently generate other written records that can be used to discern if this practice has occurred.

We expect such a policy would be an effective deterrent as, in addition to direct enforcement, manufacturers will seek to comply with food safety rules in order to satisfy the requirements of large retail customers, who typically verify that suppliers have followed federal requirements, and to avoid the risk of potential civil litigation.

iv. Clarifying that “Contains” and Ingredient Declarations Cannot be Used for PAL Statements

In addition to clarifying to manufacturers that major allergens cannot be added as a measure to address cross-contact risks, we ask FDA to clarify that the “Contains” and ingredient declarations cannot be used as a form of PAL statement to declare cross-contact risks if an ingredient is not a component of the recipe.

This practice is clearly prohibited under FDCA section 403(a)(1), which states that a food is misbranded if it is “false or misleading in any particular.”⁴¹ Declaring an ingredient or allergen on the ingredients list when it has not been intentionally added to the food is false or misleading and renders the food misbranded. While we have no clearly documented examples of companies acknowledging this practice, we recommend that the FDA clarify that this practice is prohibited in its Allergen Questions and Answers in order to resolve any potential for confusion.

C. Environmental Impact

As required by 10 CFR § 10.30(3), we are claiming an exclusion from the environmental impact assessment requirement. This petition is excluded under 21 CFR § 25.32(m) because this petition is to “restrict or reduce the use of a substance in food.” Accordingly, an environmental impact assessment is not included with this petition.

D. Certification

³⁹ Turner PJ, et al. Updated threshold dose-distribution data for sesame. *Allergy*. 2022;77(10):3124-3162.

⁴⁰ 21 C.F.R. § 117.126.

⁴¹ 21 U.S.C. § 343(a)(1).

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



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