AMERICAN BAKERS ASSOCIATION

May 15, 2023

Via Electronic Mail

The Honorable Ron Wyden
The Honorable Doris Matsui
The Honorable Patrick T. McHenry
The Honorable Christopher S. Murphy
The Honorable Richard Blumenthal
The Honorable Debbie Dingell
The Honorable Dean Phillips
The Honorable Ro Khanna
Congress of the United States
Washington, DC 20515

Re: May 2, 2023 Congressional Letter Regarding Sesame and the FASTER Act of 2021

Dear Senators and Representatives:

The American Bakers Association ("ABA")[1] is writing in response to your letter dated May 2, 2023, concerning sesame and the 2021 Food Allergy Safety, Treatment, Education, and Research ("FASTER") Act ("the Letter"). We appreciate the opportunity to explain the approach of some of our members to complying with the FASTER Act. We emphasize that the baking industry's priority remains the allergic community's safety.

We welcome the opportunity to explain that it is consumer safety, not cost savings, that has driven the decisions of some bakers to add sesame flour to their products in order to comply with the FASTER Act and best protect the allergic community. Since the passage of that Act, our members have been deeply committed to implementing the manufacturing and labeling changes necessary to comply. To ensure bakers understood the impacts to the allergic community and compliance with the FASTER Act, ABA held trainings and information sessions for our bakers with sesame allergen experts. Our member bakers have spent considerable time and resources examining their production facilities, determining where and how sesame cross-contact arises and can be controlled, segregating production lines where feasible, implementing state-of-the-art cleaning processes and current good manufacturing practices (cGMPs) appropriate to a dry production environment, and testing for sesame residues. Despite these efforts, some bakers

[1] ABA is the Washington-D.C.-based voice of the baking industry. Serving members from wholesale baking companies and suppliers to baking industry entrepreneurs, ABA is the only bakery-specific national and state trade association, delivering results on priorities affecting the companies that feed the world. ABA members produce bread, rolls, cookies, crackers, bagels, sweet goods, tortillas, and many other wholesome, nutritious, baked products feeding America's families. Since 1897, ABA has worked to build the talent pool of skilled workers with specialized training programs, and forge industry alignment by establishing a more receptive environment to grow the baking industry. ABA's membership has grown to represent more than 350 companies with a combined 1200+ facilities.

601 Pennsylvania Ave. NW, Ste. 230
Washington, DC 20004
info@AmericanBakers.org
www.AmericanBakers.org
(202) 789-0300
(202) 898-1164

found that the risk of sesame cross-contact cannot be eliminated for certain products. Moreover, establishing dedicated facilities to produce either sesame-containing or sesame-free products is generally not feasible for the bread and buns sector, which is typically regional to ensure the delivery of fresh product to consumers' local stores.

Faced with the facts that (1) traces of sesame often cannot be eliminated, (2) FDA typically expects recalls for products containing traces of allergens – even for products bearing "may contain" labeling, and (3) allergens present due to cross-contact cannot be listed as ingredients in a food, some bakers determined that the only way to comply with the FASTER Act and protect consumers was to intentionally add sesame ingredients so they could be labeled as such to alert allergic consumers to the presence of sesame.

This addition of sesame would likely not be needed if FDA would establish allergen thresholds or otherwise set forth clear guidance as to when advisory or precautionary labeling (*i.e.* "may contain" statements) may be used to alert allergic consumers to the risk of cross-contact after the implementation of good cGMPs, as has been done in Canada. The trace amounts of sesame that may be present after the implementation of cGMPs would likely fall below any thresholds FDA might set, *i.e.*, levels below which sesame-allergic consumers are not likely to react. Notably, cross-contact with sesame likely had long been occurring prior to the enactment of the FASTER Act, yet our members report they had not historically received complaints about sesame reactions to products that didn't contain sesame as a deliberate ingredient. It was only after sesame was designated as a major food allergen by that Act that consumers would expect no traces of sesame in products not labeled as containing it, and that the longstanding risk of traces of sesame due to cross-contact would trigger recalls. FDA personnel with whom ABA has engaged on this issue have suggested that data may exist that could support the establishment of such thresholds, but have indicated that agency work on thresholds is not forthcoming. We urge Congress to direct FDA to use its existing authority to establish thresholds for sesame and other allergens or otherwise provide clear guidance that traces of allergens that may remain after excellent cGMPs would not trigger recalls, especially when the product contains a precautionary label. Such regulatory certainty would ameliorate the need to add sesame and label it as an ingredient in order to protect sesame-allergic consumers.

We address the foregoing issues in greater detail below.

I. Controlling sesame is much more difficult than controlling other allergens in the baking sector.

A. Sesame is different from other allergens.

Sesame is unlike the eight major food allergens established by the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), which the FASTER Act expanded to include sesame, because in the baking sector, it is most typically used as a topping, rather than an inclusion (like wheat, eggs, soy, or milk are in many baked goods). The particulate nature of sesame seeds makes them much more difficult to control in the baking production environment, as detailed further below.

Bakers have nearly twenty years of experience controlling for major food allergens in their production environments under FALCPA. Given this history and expertise, bakers initially expected that they could readily control for sesame as well. That is why one baking company representative expressed in a July 2021 podcast hosted by ABA that she expected companies would be able to comply with the FASTER Act by the compliance deadline. However, as

companies diligently worked toward compliance in the approximately twenty months between the Act's enactment (April 2021) and compliance date (January 2023), they discovered that sesame presented unique challenges, many of which could not be overcome or would not have been known when the Act was being discussed in Congress.

Sesame's physical characteristics make it particularly difficult to control. The individual seeds are small and light in nature. They can easily and unintentionally get into crevasses and hard to access areas. Because sesame seeds are often used as a topping rather than mixed into a product, they are more likely than incorporated allergens to be found in unintended products, equipment, and other parts of facilities. Based on sesame's physical attributes, bakers needed to innovate and experiment with different methods for controlling sesame, including various cleaning and sanitation methods and changes in equipment design. Bakers conducted deep cleaning in between production of sesame and non-sesame containing products. For bread and bun productions, they implemented dry cleaning by using vacuums, low volume compressed air, and hand wiping with controlled use of moisture/chemicals, and/or steam cleaning. Some manufacturers broke down their equipment to clean it, but largely, entire lines cannot be broken down. For context, a bread or bun line can be hundreds of feet long. Bakers also generally cannot use clean-in-place systems, which involves wet cleaning, because doing so raises the risks of microbial contamination through the spread of pathogens. Some bakers found that even after conducting best practices for allergen cleaning, sesame proteins were still detected via swabbing in the cracks and crevices of the equipment, and sesame seeds occasionally were detected upon visual inspection in or near some equipment.

B. The baking sector is different from other industry sectors.

The baking sector is different from other industry sectors in the way it uses sesame (generally as a topping, as discussed above), in the nature of its facilities, and in the distribution system to get fresh bread to consumers.

As noted above, wet cleaning is not an option for baking facilities because it would pose risks of microbial contamination. Tunnel ovens used to bake products pose a particular challenge. These are shared pieces of equipment in most commercial baking operations. The ovens, depending on their design and the production capacity of the bakery, are often hundreds of feet long. When seeded buns move through the ovens, sesame seeds can fall off and become entrapped or otherwise virtually impossible to remove from the ovens.

Because many baked goods such as breads, buns, and bagels are fresh products with limited shelf lives, the national distribution system for these products is that they are produced relatively locally throughout the U.S. and are typically trucked to regional stores to provide consumers with fresh product soon after it is made. For this reason, many baking companies cannot, for example, establish a single facility that produces products with sesame seeds for distribution throughout the country while keeping other facilities sesame-free, or vice versa. Further, bread, buns, and bagels have short shelf lives, so seeded or sesame-free lots cannot be produced en masse and stored for distribution over the long term, as can be the case for nonperishable products. For similar reasons, extensive shut-downs for allergen cleaning between sesame and non-sesame runs is not feasible for most in the baking sector. Buns, for example, are produced at a rate of about 10,000 buns per hour. If an 12-16 hour cleaning were needed to remove all traces of sesame (to the extent such cleaning would even be possible and effective), this would result in a production loss of about 80,000-100,000 buns during each change-over, which could cause product shortages and supply chain disruptions. Multiplied across the baking sector, this could impact food security for Americans with such an important and staple food product.

II. The decision of some bakers to add sesame was not reached lightly, but only after concluding that it was the best way to protect the public health under existing law and FDA's regulatory approach.

The bakers who determined the need to add sesame to their formulas did so only after exhaustive evaluations, application of state-of-the-art cGMPs that still resulted in sesame traces, reconsideration of their product offerings, and changing their production practices. These were product-, facility- and production line-specific considerations.[2] For example, one baker removed sesame entirely from the production lines of its conventional white and wheat loaf breads, so there would be minimal chance of cross-contact in pans, conveyors, belts, and similar equipment. After these changes, the risk of cross-contact was very low. But for the company's bun line production, it found it could not reasonably control sesame cross-contact while also making seeded buns, which are desired by many consumers. Similarly, for its brand largely known for its seeds and other inclusions, the baker likewise couldn't adequately remove sesame traces when running non-seeded specialty breads under that brand. Accordingly, the company determined it needed to add sesame flour to those breads and to its non-seeded buns and label it as an ingredient to protect consumers, because it could not otherwise label the products as containing sesame under FDA's interpretation of and enforcement approach to the Federal Food, Drug and Cosmetic Act, as amended by FALCPA and the FASTER Act.[3]

In this regard, the FDA's approach is significantly different from that taken in Canada. Bakers have been asked why they can control sesame cross-contact in Canada but can't do the same in the U.S. The reason has no bearing on the companies' practices; they are doing the same things in both countries – applying rigorous cGMPs and preventive controls to control for allergen cross contact, and then using advisory labeling when needed. Rather, the difference lies in the approach of regulators in the respective countries.

FDA has long expressed the view that advisory or precautionary labeling such as "may contain" statements cannot be a substitute for good cGMPs, but has suggested they may be appropriate where a risk remains even after rigorous controls.[4] As a practical matter, however, FDA typically requests recalls of products found to contain traces of allergens, even if the products bore "may contain [allergen]" precautionary labeling and were produced under rigorous cGMPs. This is evident in the fact that undeclared allergens have long been the number one leading cause of food recalls,[5] in many food companies' experiences with FDA, and even in

---

[2] We also note that for some bakers, their customers, such as restaurant facilities, asked the bakers to add sesame to all products they supplied, out of concern for potential sesame cross-contact among seeded and non-seeded breads in their restaurant facilities (which are not regulated under the FASTER Act). Those customers could then ameliorate risk to sesame-allergic consumers by menu notifications, signage, or other means to signal that all bread products served have sesame. Those customers thought this was the safest way to protect the sesame allergic consumer from sesame at the restaurant facilities.

[3] *See, e.g.,* FDA, Draft Guidance, Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5) (November 2022), at D.13 ("The food allergen labeling requirements of the FD&C Act do not apply to a major food allergen that is unintentionally incorporated in a food as a result of cross-contact.")

[4] *See, e.g.,* A Conversation with Stefano Luccioli, M.D., current as of May 5, 2021 ("The FDA has made clear that the advisory statement is not to be used instead of current good manufacturing practices (CGMPs). These are FDA regulations that require adequate control of allergen cross-contact. In other words, manufacturers cannot just place an advisory statement on a product without first taking measures to prevent allergen cross-contact to the best degree possible."), *available at* https://www.fda.gov/food/conversations-experts-food-topics/current-food-allergen-landscape.

[5] *See, e.g.,* FDA-TRACK: Reportable Food Registry Data Dashboard, current as of March 8, 2023, *available at* https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard.

the same FDA statement seeming to acknowledge that advisory labeling can be appropriate.[6] FDA maintains that it does not take a "zero tolerance" approach to allergen cross-contact, but rather evaluates each incident on a case-by-case basis. But this approach is simply unworkable for products for which it is *known* that there will likely be traces of sesame even after the implementation of rigorous cGMPs. Such products simply cannot be produced and distributed, because they would need to be recalled.

Canada, however, takes a different approach to allergen cross-contact risk and precautionary labeling, including specifically with respect to sesame. The Canadian Food Inspection Agency (CFIA) and Health Canada understand there is real potential for cross-contact that can be unavoidable, and that the use of a precautionary label adequately warns allergic consumers of this risk. Moreover, Canadian consumers are educated by government, health professionals and Food Allergy Canada to always read ingredient labels and avoid products with precautionary labels. Various stakeholders including CFIA, Health Canada, allergists, industry, and Food Allergy Canada have collaborated to develop Allergen Management Guidelines for Food Manufacturers (September 2022) for the use of precautionary labels based on allergen risk management.[7] Canada's guidance states that a precautionary label is necessary if the manufacturer determines through a qualitative assessment that "[t]here is sufficient supporting evidence that the control measures in place cannot consistently prevent the occurrence of unintentional allergen(s) despite all the measures in place to mitigate the risk."[8] In Canada, manufacturers need to demonstrate that they have procedures in place to ensure their lines are visibly clean. However, Health Canada and CFIA acknowledge that due to the particulate nature of the sesame seeds, there is still a risk for cross-contact for products that do not contain sesame, but share the same facility or production line as a sesame containing product.

Canada's Allergen Management Guidelines contain an example of a qualitative assessment, in which the experts assess a baker's ability to control for sesame where sesame bagels are made in the same facility as other bagels without sesame. The experts noted the following:

- The volume of production requires that all ovens and oven racks are used when sesame bagels are processed. It is not possible to have only one oven dedicated to sesame bagels.

- Although dedicated tools are used when handling sesame, sesame seeds are sometimes found in scales and on the floor of the staging area.

- The facility's ovens are old and certain parts cannot be fully accessed during cleaning. Replacement or modifications are not possible at the moment. Therefore, oven cleaning does not consistently meet a visually clean standard. Sesame seeds are sometimes found in oven areas that cannot be accessed during cleaning.

- The facility is cleaned every day at the end of production. Staging and production areas consistently meet visibly clean standards. However, sesame seeds are sometimes found in these areas at the start of the next day's production shift.

---

[6] A Conversation with Stefano Luccioli, M.D., *supra* ("Every product found to have an undeclared allergen is reviewed on a case-by-case basis. A major food allergen is considered a serious potential hazard for the public. Thus, a product that is found to contain an undeclared major food allergen is likely to be subject to recall.").
[7] Available at https://foodallergycanada.ca/professional-resources/foodservice/allergen-management-guidelines-for-food-manufacturers/.
[8] *Id.* at 54.

The Guidelines conclude that the evidence strongly indicates that the control measures in place cannot consistently prevent the occurrence of sesame traces in products not intended to have sesame. Since sesame bagels are produced every day and a dedicated line cannot be implemented, the Guidelines state that a precautionary label for sesame should be used on all the products made in this facility.

This baker's situation is highly similar to the ABA member's situation noted above. If the ABA member's products were produced in Canada, a precautionary label would likely suffice. However, in the U.S., such a label likely would not be deemed to adequately warn sesame allergic consumers, and sesame cross-contact may lead to a recall. Therefore, for products that run a high risk of containing traces of sesame, a U.S. baker must take a different approach such as adding sesame to the product and labeling it, in order to better protect sesame allergic consumers.

ABA strongly urges FDA to follow the Canadian model described above, and to confer with its Canadian counterparts to align the agency's approach to sesame allergen cross-contact and precautionary labeling with that of Canada. Most importantly, it would be essential for the agency to publicly announce its approach to such sesame cross-contact risks and precautionary labeling, including whether these scenarios could trigger a recall, rather than taking a case-by-case approach after production of baked goods. If FDA were to set forth clear guidelines to U.S. bakers like the Canadian authorities have done, U.S. bakers would not likely need to add sesame to products that didn't previously contain it.

III. Congress should urge FDA to establish allergen thresholds

The issues surrounding sesame have renewed the need for allergen thresholds. To better protect allergic consumers and create uniform approaches to allergen risk and mitigation strategies, Congress should call on FDA to use its existing authority to establish thresholds for priority allergens, specifically sesame. An allergen threshold is the maximum amount of an allergenic food that can be tolerated without producing any adverse reaction in the allergic population. FDA has evaluated various approaches for establishing thresholds that would be scientifically sound and efficacious in relation to protection of public health in a comprehensive report.[9] Institutions such as the University of Nebraska-Lincoln Food Allergy Research and Resource Program (FARRP) and an ad hoc Joint Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) Expert Consultation on Risk Assessment of Food Allergen group have researched and studied allergen thresholds extensively. Manufacturers could use thresholds as a realistic measure of how adequate their cGMPs, preventive controls, and sanitation are at minimizing cross-contact. Manufacturers can conduct production line and final product testing to ensure that trace amounts of allergen due to cross-contact are below a certain established threshold. Moreover, thresholds can be used by FDA to establish standards for when a precautionary label is appropriate and when a product should be recalled. For the former, this will create a uniform standard for all manufacturers and will make allergic consumers more comfortable when choosing products with precautionary labels. It will also afford those who have a tolerance for a trace amount of allergen more food choices. In the interim to the establishment of thresholds, Congress should direct FDA to provide clear guidance that traces of allergens that may remain after excellent cGMPs would not trigger recalls, especially when the product contains a precautionary label.

---

[9] FDA, *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food* (Mar. 2006), available at https://www.fda.gov/media/78205/download.

In sum, ABA members take sesame allergen control very seriously and will continue to work to control for sesame cross-contact in their facilities. Those who have concluded they must add sesame and label it have provided notice of their formula changes through a variety of methods such as their websites, labeling, signage, and through engagement with the allergic community. In particular, ABA has held numerous discussions with Food Allergy Research & Education. Since the FASTER Act was passed, ABA has had discussions with FDA allergen experts on risk and mitigation strategies regarding sesame and will continue to do so. The baking industry's priority remains the health and safety of consumers. We hope to have a continuing dialogue with you and the food allergy community at large on sesame. Please do not hesitate to reach out with any questions you may have.

Respectfully submitted,

W. Eric Dell
ABA President and CEO