



July 17, 2023

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact. Docket number: FDA-2023-D-1103

To Whom it May Concern:

The Center for Science in the Public Interest (CSPI) submits this comment on CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact (the Draft CPG), asking the agency to extend the scope of the document to prevent companies from adding allergens intentionally to foods as a paradoxical approach to addressing 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 corporate donations and is supported by foundation grants, donations, and subscribers to its magazine, Nutrition Action.

In a petition submitted January 30 of this year,¹ CSPI highlighted the urgent need for FDA to address a disturbing industry practice that has emerged following implementation of the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act, which added sesame to the list of “major food allergens” subject to federal allergen labeling requirements. The FASTER Act also triggers an obligation for companies to mitigate the risk that sesame will make its way unintentionally into foods through cross-contact between sesame and non-sesame products on shared equipment. Companies can do this by segregating sesame and non-sesame products to be processed on different equipment, or by thoroughly cleaning between production runs.

As we document in the petition, companies in the baking industry have responded to the new requirements by adding sesame to the ingredient list across a broad array of products that did not previously contain sesame. Applying a perverse logic, these companies believe they will no longer have to mitigate the risk of undeclared sesame if sesame is always declared on their products. As our petition documents, this quick-and-dirty approach to the problem of cross-contact has become so widespread in the baking industry that sesame-allergic consumers have experienced difficulties accessing safe bakery products. More disturbingly, companies report

¹ Center for Science in the Public Interest. Petition to FDA to notify manufacturers that they cannot mitigate allergen cross-contact risks by adding sesame and other major allergens to foods. January 30, 2023. <https://www.cspinet.org/sites/default/files/2023-01/Petition%20to%20Prohibit%20Allergen%20Addition.pdf> Accessed July 17, 2023.

adding amounts of sesame that we calculate are sufficient to trigger allergic reactions in consumers. Such reactions have indeed begun to be documented in the media.²

Unfortunately, the Draft CPG does not effectively address this practice. Instead, it states only that “[m]ajor food allergens unintentionally incorporated into a food are not to be declared in the ingredient list or the “Contains” statement.” Although this statement is a correct and important clarification of FDA’s position, it does not address the practice of *intentionally* incorporating sesame as an ingredient. Because FDA has not addressed this practice, companies may infer that intentionally adding allergens to foods is an appropriate means of addressing cross-contact risks.

To more effectively curtail this practice, we petitioned FDA to declare that the practice violates both the letter and intent of the agency’s food safety rules. Specifically, companies are responding inappropriately to an existing cross-contact hazard by increasing potential consumer exposure to the allergen, when the company’s obligation is to mitigate such risk.

The agency has acknowledged that the Draft CPG does not effectively respond to the practice we identified in our petition, stating in a press release announcing the Draft CPG:³

The FDA is aware that some manufacturers are intentionally adding sesame to products that previously did not contain sesame and are labeling the products to indicate its presence. While the draft CPG does not specifically address the issue of industry adding sesame to products that did not previously contain it, the draft CPG does address the FDA’s enforcement policy for labeling and cross-contact controls for major food allergens, including sesame. The FDA is engaged with various stakeholders on this issue. The FDA recognizes that this practice may make it more difficult for sesame-allergic consumers to find foods that are safe for them to consume—an outcome that the FDA does not support.

This statement is inadequate because, while acknowledging the problem, it does nothing to prohibit the harmful practice. Moreover, while the agency acknowledges that the practice limits access to safe foods for sesame-allergic consumers, it fails to make clear that the practice has the potential to increase the risk that consumers will experience an allergic reaction.

Accordingly, we ask the FDA to amend its Draft CPG by prohibiting manufacturers from adding allergens intentionally to foods as a means of addressing cross-contact risks.

Sincerely,



Sarah Sorscher, JD/MPH
Director of Regulatory Affairs
Center for Science in the Public Interest

² Weese K, To comply with a new sesame allergy law, some businesses add – sesame. *Washington Post*. April 11, 2023. <https://www.washingtonpost.com/wellness/2023/04/11/sesame-allergy-law-consequences/> Accessed July 17, 2023.

³ Food and Drug Administration. FDA releases draft compliance policy guide on major food allergen labeling and cross-contact. May 16, 2023. <https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-draft-compliance-policy-guide-major-food-allergen-labeling-and-cross-contact> Accessed July 17, 2023.