

Food Allergy Safety Treatment Education and Research Act ("FASTER") - Sesame Update

Legal Alert
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As a result of the passage of the Food Allergy Safety Treatment Education and Research Act (FASTER Act) in 2021, sesame was declared as the ninth federally recognized major food allergen. The change became effective as of January 1, 2023, and will impact how many organizations around the country operate as it relates to labelling sesame as an allergy in packaged food.

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WHAT IS THE NEW LAW?

As of January 1, 2023, sesame is now required to be declared as an allergen on packaged foods, including dietary supplements. Sesame joins eight other foods previously declared as major food allergens by federal law. This designation and labeling requirements were implemented under the FASTER Act. The law was passed by Congress and signed by the President in April 2021, with the effective date of January 1, 2023. The law is self-implementing, meaning that FDA is not required to publish regulations to implement the Act, although FDA may issue regulations (not currently in process) incidental to the law.

WHY IS THIS IMPORTANT?

It is estimated that more than 1.5 million people living in the US are allergic to sesame. As with other allergens, reactions to sesame vary in severity from mild symptoms involving hives and lip-swelling to severe, life-threatening symptoms that may involve fatal respiratory problems. Preventive and therapeutic strategies are being developed, but food allergies currently cannot be cured. Therefore, labeling is considered necessary to inform customers of the presence of allergens so that they can avoid exposure.

The original eight food allergens requiring declaration were established under the Food Allergen Labeling and Protection Act of 2004 (FALCPA). The original eight are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

WHAT NEEDS TO BE DONE?

There are two ways of identifying the presence of sesame on a food label. It may be listed in the ingredients declaration and/or it may be disclosed in a separate "Contains sesame" statement. In a "Contains" statement, sesame may be included with any other allergens present as (or in) ingredients. If a product has a "Contains" statement for other allergens, sesame must be included in that statement even if it also is declared in the ingredient list.

As with the other allergens, if sesame is present as a constituent of another ingredient, such as tahini, sesame may be declared in a parenthetical following the name of the ingredient in the ingredient list. Sesame must be declared if it is included in an ingredient that is permitted to be named collectively, such as "natural flavor" or "spice," so care must be taken by brands to know the complete content of multi-constituent ingredients.

The labeling is required only for products that are introduced into interstate commerce or delivered for introduction into interstate commerce after January 1, 2023. Therefore, packaged food on retail shelves or in warehouses waiting for delivery to store shelves before January 1, 2023 is not required to be relabeled.

HOW DOES THIS IMPACT SESAME OIL?

Under the statutes, a "major food allergen" requiring labeling does not include any "highly refined oil" derived from a "major food allergen" or any ingredient derived from such highly refined oil. 21 USC § 321 (qq)(2). Neither the statutes nor FDA has defined "highly refined oil." The commonly cited definition of "highly refined oil" is derived from the Senate Report on FALCPA: Oils resulting from a process that involves degumming, neutralizing, bleaching, and deodorizing the oil extracted from plant-based starting materials such as soybean and peanuts.

Companies need to recognize, however, that sesame oil, even if exempt from allergen labeling, is subject to the general regulation regarding ingredient labeling of oils. That regulation, 21 CFR § 101.4 (b)(14), requires as follows: "Each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., ... 'cottonseed oil')." Therefore, even if exempt from allergy labeling as "highly refined," sesame oil must be listed in the ingredient declaration. In addition, even if sesame oil is "highly refined," and therefore exempt from allergen labeling, brands need to be careful with their labeling to minimize the possibility of civil liability due to an alleged adverse allergic reaction blamed on

sesame oil.

WHAT ELSE NEEDS TO BE UNDER CONSIDERATION?

The requirement of declaring sesame as an allergen applies to its presence as an ingredient or a constituent of an ingredient, not to its accidental presence due to cross-contact or cross-contamination. However, companies need to observe Current Good Manufacturing Practice (cGMP) to avoid cross-contamination. This may include, but is not limited to, segregating allergens and non-allergens in a facility, scheduling products with allergens at the end of daily production cycles, and sanitation and cleaning of equipment after processing products containing allergens.

HOW CAN I AVOID CROSS-CONTAMINATION?

One way that brands address the potential for cross-contamination is to use "advisory" labeling such as "may contain [name of allergen]" or "produced in a facility which also handles [name of allergen]." "Advisory" labeling does not excuse departures from cGMP; however, it can help minimize exposure to civil litigation based on alleged harm from exposure to sesame.

Avoiding cross-contamination is a particular issue for brands that use co-manufacturers. This may be of special concern to emerging companies that may not have the resources to have their own production facilities. The question also deserves special attention when the co-manufacturer is not in the same country as the brand owner. Co-manufacturing agreements should require the manufacturer to observe US FDA cGMP. Based on experience, it is advisable for brand owners to send representatives expert in food manufacturing to review a co-manufacturer's facility, including cGMP and food safety plans and procedures. Avoiding allergen cross-contamination should be part of this review. A problem in this regard is the lack of established safe levels of exposure to allergens, which complicates testing for residual levels and emphasizes the importance of processes to avoid any residual allergens.

WHAT WILL FDA OVERSIGHT LOOK LIKE?

The FDA inspects food production facilities, regardless of location, although the inspection is not continuous, unlike facilities subject to inspection by the US Department of Agriculture. The agency also reviews the labeling of products at retail outlets. In the case of an undeclared presence of sesame, the FDA has a number of enforcement options, including product recall. The FDA has indicated that it has developed the xMAP food allergen detection assay that can simultaneously detect sixteen allergens, including sesame, in a single analysis. In the FDA's words, xMAP "will enhance FDA's ability to monitor the food supply for undeclared allergens

and take action when they are found".