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SPECIAL SUPPLEMENT | July 23, 2021

FOOD & BEVERAGE LITIGATION UPDATE

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FIRM NEWS

Webinar: That FDA Inspection Question You've Always Wanted to Ask

Shook Of Counsel John Johnson III will join AIB International's Judi Lazaro for the second webinar in a series on answering frequently asked questions about the U.S. Food and Drug Administration. During the webinar, Johnson and Lazaro will ask each other questions, then they will end the session with an open Q&A. Join the session on Monday, July 26, 2021, from 2:00 to 2:30 p.m. CDT.

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SPOTLIGHT

Look Beyond the Label: How the FASTER Act Impacts Food Manufacturing

By Anna El-Zein and John Johnson III

Sesame is the ninth Major Food Allergen with the passage of the Food Allergy Safety, Treatment, Education, and Research Act (FASTER) Act on April 23, 2021. Starting on January 1, 2023, any food "introduced or delivered for introduction into interstate commerce" must appropriately declare the presence of "sesame" as a major food allergen. However, the FASTER Act is more than just updating food labels; it also implicates supplier controls, Food Safety or HACCP Plans, sanitation practices and other

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For additional information about Shook's capabilities, please contact

Mark Anstoetter
816.559.2497
manstoetter@shb.com

procedures. With the compliance deadline looming, companies must start thinking about how FASTER affects their procedures sooner rather than later.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), a packaged food is misbranded if the label fails to declare the presence of a major allergen, either in the ingredient list or in a "contains" statement. With the addition of sesame to the "Big 8," Section 403(w) of the Act now lists nine major food allergens: milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans and sesame.

The FASTER Act's Impact on Food Manufacturing Requirements

As part of the Food Safety Modernization Act (FSMA), a facility must have written processes to ensure that all major food allergens are appropriately identified on a food's label and have procedures to protect against cross-contamination. The regulations define a "food allergen" as "a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act." The definition for "allergen cross-contact" also points back to the "food allergen definition." Thus, FDA does not need to amend the regulations to require a facility to update its preventive control and sanitation programs to account for sesame. Simply adding "sesame" to the list of major food allergens is Section 201(qq) updated the regulations.

Under the preventive control regulations, a facility must perform a hazard analysis, which is the process of identifying and evaluating "known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards that require a preventive control." "Food allergens" (which, as mentioned above, includes all major food allergens) are a type of chemical hazards that must be controlled. Prior to the FASTER Act, sesame was not a "food allergen" and thus was not considered in the hazard analysis. But with FASTER Act's passing, sesame is a major food allergen and therefore a potential chemical hazard. Consequently, facilities must reanalyze their hazard analysis to determine if they have a hazard requiring a control. Some facilities—which in the past may have had no need to implement allergen controls—will now need to create and implement such a control.

Beyond the preventive control regulations, the current Good Manufacturing Practice (cGMP) regulations require sanitary operations to manage "allergen cross-contact." By way of an example, a facility may have certain practices for handling ingredients and finished products that contain a major food allergen, or have specific cleaning procedures for equipment that

M. Katie Gates Calderon
816.559.2419
kgcalderon@shb.com

Lindsey Heinz
816.559.2681
lheinz@shb.com

James P. Muehlberger
816.559.2372
jmuehlberger@shb.com

ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility

has been exposed to a major food allergen. Previously, that facility may not have subjected sesame or sesame-containing foods to those practices. However, now that sesame is a major food allergen, the facility must update its practices accordingly.

Moreover, sesame's change in status impacts seafood facilities, which must comply with the Hazard Analysis Preventive Critical Control Point (HACCP) regulations. Although the HACCP regulations fail to mention the word "allergen," seafood facilities still have allergen-related requirements. First, the HACCP regulations point back to the cGMP regulations, so seafood facilities must take appropriate steps to manage allergen cross-contact. As it relates to the HACCP program directly, FDA interprets an undeclared major food allergen as a potential hazard. Thus, seafood processors, too, must reevaluate their processes.

Food importers must verify that all major food allergens are appropriately declared as part of the Foreign Supplier Verification Program (FSVP) regulations. FSVP requires importers to conduct hazard analyses to "identify and evaluate . . . known or reasonably foreseeable hazards for each type of [imported] food." This includes an analysis of potential chemical hazards, which incorporates "food allergens." Like other regulations, the FSVP defines "food allergens" as "major food allergens as defined in section 201(qq)" of the FDCA. Thus, food importers must now reanalyze their hazard analyses to ensure proper control and declaration of sesame. In turn, this could implicate an importer's appropriate verification activity to ensure that a foreign supplier has processes and procedures providing at least the same level of public health protection as FDA's requirements.

Companies must broadly consider their processes, procedures and relevant documentation to ensure sesame is recognized as a major food allergen. As an example, companies often prepare internal labeling guides (such as FDA's Food Labeling Guide) that provide direction on labeling major food allergens. If the guide's list of allergens is not updated, a reviewer may mistakenly fail to ensure that a food containing sesame appropriately declares its presence on the label. After the effective date, this could result in a recall and additional FDA scrutiny. All guidances, procedures and manuals must be reviewed and updated as soon as possible.

The Uncertainty of the FASTER Act's Effective Date

The FASTER Act states that labeling sesame as a major food allergen will "apply to any food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023." However, this provision is more complex and unclear than it appears.

inspections, subject to FDA, USDA and FTC regulation.

As written, a food labeled on December 31, 2022, and shipped on January 1, 2023, must include the sesame declaration. This becomes far more complicated, if not impossible, for a food manufactured and labeled well before being shipped on January 1, 2023. The law offers no guidance for entities that merely ship products but have no knowledge of their contents beyond their current label. This begs the question: will FDA expect shippers to relabel the product? The previous allergen law (Food Allergen Labeling and Consumer Protection Act (FALCPA)) is unhelpful in predicting FDA's actions because FALCPA's effective date was tied to the date a food was labeled, not shipped. Recognizing this, we anticipate that FDA will issue interpretive guidance.

Furthermore, it is unclear when FDA will begin requiring facilities and importers to consider sesame as a major food allergen in their sanitation, preventive control, HACCP and FSVP processes. FDA did not have to consider these issues when implementing FALCPA because its compliance date predated the finalizing of the preventative control, updated sanitation and FSVP regulations by nine years. The seafood HACCP regulations also provide no historical guidance, despite being in existence when FALCPA was passed. FDA's leading interpretive guidance for these regulations, the Fish and Fishery Products Hazard and Control Guidance, did not list major food allergens as a critical hazard until April 2011—almost five years after FALCPA's effective date. We expect FDA's (eventual) guidance to address these concerns.

Moving Forward, Recognizing FDA's Focus

FDA's focus on allergens is not new. As we previously discussed in A Taste of FDA's 2021 Food Priorities: Undeclared Major Food Allergens, FDA prioritized compliance with the major food allergen requirements even prior to the FASTER Act, and we expect FDA will continue to prioritize major food allergen compliance well into 2023. Like the other major food allergens, FDA will expect companies to recall a food product if the label fails to declare the presence of sesame. Such a recall will likely trigger an FDA facility inspection and, in some cases, a publicly issued Warning Letter.

Companies should begin handling sesame like the other major food allergens, despite January 1, 2023, seeming far away. To do this, companies should take a holistic approach:

- analyze their formulations, which includes talking with their suppliers, especially those providing spices and flavors where the presence of sesame may not be obvious;
- adjust their labeling and advertising accordingly, being careful to consider the label's claims (for example, is there an "allergen free" claim in a food containing sesame?);

- analyze their processes and procedures, and not just those required by regulations but also those that impact food production, supplier selection, and labeling and advertising;
- pay attention to FDA statements about implementing the FASTER Act and major food allergens generally.

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