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SPOTLIGHT

A Taste of FDA's 2021 Food Priorities: Undeclared Major Food Allergens

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Recent actions by the U.S. Food and Drug Administration (FDA) suggest that, in 2021, the Agency will sharpen its focus on enforcement efforts to ensure packaged foods appropriately declare the presence of major food allergens. In a series of high-profile warning letters and press releases, FDA confirmed that it is moving beyond expecting non-compliant food to be recalled and is concentrating on how companies are preventing the issue. Manufacturers and private labelers need to audit their practices and expect an FDA inspection, especially if they have had an allergen-related recall.

What the Law Requires

The Federal Food, Drug, and Cosmetic Act (FDCA) deems a packaged food misbranded if the label fails to declare the presence of a major allergen, either in the ingredient list or in a "contains" statement. This requirement and the list of major food allergens is found in Section 403(w) of the Act, and includes what are commonly known as the "Big 8": milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts and soybeans.

Prior to the Food Safety Modernization Act (FSMA), FDA did not require food manufacturers to institute processes to ensure that major food allergens were appropriately declared. FSMA and the implementing regulations changed this; now a manufacturer must have processes in place to ensure that allergens are appropriately

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identified on food packages and written procedures to protect against cross-contamination.

If a food package fails to declare the presence of a major food allergen, FDA generally will expect the food to be recalled. These recalls are typically a Class I recall—which pose the highest risk to the public—and are accompanied by a press release notifying the public about the risk. Undeclared food allergens have been the most common reason for Class I recalls for several years running, and, in recent months, FDA sent warning letters to over a dozen food manufacturers and distributors that had previously initiated Class I recalls.

Lessons from Two Recent Warning Letters

FDA's Warning Letter to Frito-Lay, Inc. reflects the Agency's first critical analysis of a manufacturer's allergen controls. In the past, FDA typically only faulted manufacturers for not having an allergen control. This warning was more critical.

FDA observed that Frito-Lay established a quality control that required that the product be tasted to ensure the proper chip found its way to the proper bag. According to Frito-Lay's paperwork, this procedure was completed (as in, an employee actually tasted the chips), but Frito-Lay failed to notice that cheddar and sour cream chips were placed in an original chip bag. Beyond this type of detailed analysis, FDA dedicated an entire paragraph (which is notable for a warning letter) to the company's five allergen recalls over the last five years, as well as the firm's systemic corrective action.

FDA's Warning Letter to Whole Foods similarly reflected on the number of allergen-related recalls the firm had initiated: 32 between October 2019 and November 2020. FDA "noticed similar patterns of numerous recalls for undeclared allergens in previous years as well." Notably, this was the first-ever warning to a food *retailer* for receiving foods that were not appropriately labeled, indicating that FDA is prepared to hold retailers and their private brands responsible for undeclared allergens.

Now What?

FDA is committed to decreasing the number of recalls caused by undeclared allergens. As reflected in the Warning Letters, FDA is focusing on more than just processes and procedures; FDA is examining the entire supply chain through targeted inspections and product testing (such as FDA's survey of milk in dark chocolate products). We expect FDA to continue focusing its efforts in this area until consistently fewer allergen-related recalls arise and companies demonstrate they have established a food

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safety culture—one of the four core elements in FDA's blueprint New Era of Smarter Food Safety.

We regularly work with firms to establish a culture of food safety, starting with the basic tenets of FSMA:

- Understand the requirements for product labeling and safe manufacturing practices;
- Audit regularly and fix (if necessary);
- Improve processes and controls; and
- Repeat.

inspections, subject to FDA, USDA and FTC regulation.

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