

## FDA OPENS FEDERAL FOOD REGISTRY REQUIRING REPORTING OF POTENTIALLY DANGEROUS PRODUCTS

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In response to recent outbreaks of food-borne illness from a variety of products, including peanuts, spinach, cookie dough and hot peppers, the United States Food and Drug Administration ("FDA") has opened an electronic portal, called the "Reportable Food Registry" ("RFR"), designed for early intervention in potential food contamination cases.

Enacted pursuant to 2007 legislation, the system requires any facility that manufactures, processes or holds food for consumption in the United States to advise the FDA within twenty-four hours if it finds a reasonable probability that a food article will cause severe health problems or death to a person or animal. The reporting requirement applies to all foods and animal feeds regulated by the FDA, with the exception of infant formula and dietary supplements, which are covered under separate regulatory requirements. Responsible parties are required to submit initial information through the RFR and follow up with supplemental reports.

An exception to the reporting requirement is allowed when the responsible party isolates any adulterated food and destroys it before it leaves the party's facility. Furthermore, the FDA is required to issue an alert or a notification about a food on the registry if the Secretary deems it necessary to protect the public health.

The FDA has supplied a list of certain data that must be included in an initial report to the FDA, including:

- The food facility registration number of the responsible party making the report
- The date on which the article of food was determined by the responsible party to be a food required to be reported
- A description of the article of food that the responsible party has determined to be a food required to be reported, including the quantity or amount
- The extent and nature of the adulteration of the article of affected food
- The results of any investigation of the cause of adulteration, if it may have originated with the reporting party
- The disposition of the adulterated food

- The product information typically found on packaging to identify the article of food (such as product codes, expiration dates, names of manufacturers, packagers and distributors)

The FDA draft guidance specifies that, for each instance of reportable food, FDA intends to assign a unique number allowing for the submission of amended reports and related notifications. The electronic portal also is designed to link multiple reports concerning the same article of food, for example, reports submitted by several responsible parties within the same food chain or additional reports submitted by public health officials.

Under certain circumstances, the FDA can require a responsible party to investigate the cause of the adulteration, provide a notification to the immediate previous source of the article of food, or to the immediate subsequent recipient of the article of food. In addition, FDA is required to notify the Director of Homeland Security if it believes a food item may have been deliberately adulterated. Violators face injunctions, fines or other punishment.

The RFR is being hailed as a significant step in President Obama's pledge toward making food safety a higher priority, and is intended to allow for the fast removal of contaminated food products from the stream of commerce. The FDA has been criticized for its response to a number of problems with food safety. FDA representatives have expressed the hope that the RFR system will help the FDA get involved in food contamination cases before consumers get sick.

This very significant development in the food industry may result in an increase in claims and will affect insurance issues, including the timing of claims and the obligation to provide notice. We will continue to closely monitor this development and its impact on the insurance issues surrounding food contamination.

*For a further analysis of coverage issues involving food contamination, please contact Kevin Haas, Chair of Cozen O'Connor's Food Contamination & Product Recall Practice area, in our New York office. Cozen O'Connor is a nationally recognized leader in representing the insurance industry in all coverage areas.*

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