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Complying with food registry no easy task

FDA's new food registry requires that food facilities report any instances of potentially adulterated food, but there are steps companies can take to ensure compliance.

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FOOD producers beware: The Food & Drug Administration's new Reportable Food Registry is now live, and it presents a variety of potential pitfalls for food facilities that must comply with the registry's requirements.

The Reportable Food Registry, originally passed as part of the Food & Drug Administration Amendments Act of 2007, became effective Sept. 8 following more than a year of delays. FDA issued a guidance document for the industry on the same date.

Generally, the registry requires all food facilities registered with FDA to investigate and report, within 24 hours, all instances of potentially adulterated food.

FDA has established an electronic portal (which also went live on Sept. 8) to allow food facilities and public health officials to submit these reports. Food items falling under the regulatory jurisdiction of the U.S. Department of Agriculture (such as meat and poultry) are exempt from the registry's requirements.

A reportable food article?

The statute defines "reportable food" as "any article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such an article of food will cause serious adverse health consequences or death to humans or animals."

FDA has not provided any further guidance as to what constitutes a "reasonable probability" other than acknowledging that this standard is substantially the same as for a Class I food recall. Examples of previous Class I food recalls may be found in FDA's weekly enforcement reports.

However, determining whether a food article meets this definition will likely be a case-by-case, fact-specific determination.

Reporting period

When a food facility determines that it has a reportable food article, it must perform an investigation as to the source of the adulteration and report the food article on the electronic portal within 24 hours.

There is some ambiguity as to what types of test results will trigger the 24-hour investigation and reporting period. Although it is clear that a confirmatory test result will trigger the reporting period, FDA has indicated that a presumptive test result may also trigger the reporting period under some circumstances.

The electronic portal allows a registrant to submit amended reports if it learns of new information — such as if a registrant submits a report based upon a positive presumptive test result that is subsequently confirmed as a negative result.

Exception

Facilities are not required to report a food article if the adulteration originated with the facility *and* the facility detected the adulteration before the food article was transferred to anyone else *and* the facility either corrected or destroyed the adulterated food article.

FDA has taken the position that intra-company transfers, such as transfers among a processing plant, distribution center and warehouse owned by the same company, are *not* "transfers" to another person, so long as the company maintains continuous possession.

On the other hand, transferring food articles to a third-party warehouse, even where the food facility retains ownership and direct control over the food article, eliminates this exception.

REPORTABLE: FDA's Reportable Food Registry requires food facilities to report any food or feed article that could result in "serious adverse health consequences or death to humans or animals."

Who can submit reports?

Only FDA-registered food facilities and public health officials may submit a report on the electronic portal. The electronic portal refers consumers to other avenues of reporting potentially adulterated food, such as FDA's consumer complaint coordinator and local health officials.

As a practical matter, public health officials may submit reports based on consumer complaints. Likewise, registered facilities must report food articles based on direct consumer complaints where the food article otherwise meets the definition of a reportable food.

Responsibilities

A facility's responsibility does not end when it submits a report. FDA may require the food facility to provide notifications of the reportable food article to others, both above and below it in the supply chain, and may require the food facility to amend its report to add additional information. The facility must also submit an amended report when it either learns of new facts or determines that previously submitted facts were false.

FDA use and disclosure

After receiving information through the electronic portal, FDA may share the information with other local, state and federal public health agencies. It may also issue a notification to the public based on the information reported.

Reports submitted to the registry will not be available to the public except under a Freedom of Information Act request. More importantly, Congress exempted civil liability based upon the submission of a report by providing that submission of a report or notification shall not be considered an admission that the article of food is adulterated or caused or contributed to death, serious injury or serious illness.

Tips for compliance

There are several steps regulated companies can take to ensure compliance with the registry's requirements.

First, companies should put policies and procedures in place that ensure that information regarding potentially adulterated food articles is appropriately routed within the company.

Companies should designate one person within the company, such as a regulatory compliance officer, as the "responsible person" for complying with the registry's requirements. The responsible person should lead an effort within the company to examine its hazard analysis and critical control point plans and develop policies that inform employees of which kinds of test results or food adulteration issues trigger reporting requirements.

Companies should educate managers within each facility and end user support personnel, such as customer service representatives, on the registry's requirements and the company's internal policies for relaying potential food adulteration issues to the responsible person.

Second, companies should avoid transferring food articles outside of company-owned facilities until product testing is completed. By doing so, a company can increase its chances of detecting and destroying or reconditioning adulterated food articles and thereby avoid the need to submit a report.

Finally, companies should seek the advice of legal counsel, whether internal or external, when they are unclear as to how to proceed. This is especially important because failure to appropriately investigate and report an otherwise reportable food article could result in criminal charges.

Conclusion

Fortunately, FDA has indicated that it will exercise discretionary enforcement of the Reportable Food Registry's prohibited acts until Dec. 8, so long as a company has made reasonable efforts to comply with the registry's requirements and has otherwise acted to protect public health.

FDA has also expressed its eagerness to work with the industry in further developing appropriate guidance documents and regulations. We encourage industry representatives to submit comments at www.regulations.gov. ■

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