Food & Drug

E-ALERT

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FDA Launches Reportable Food Registry

On September 8, 2009, the United States Food and Drug Administration ("FDA") rolled out the electronic portal to its Reportable Food Registry (the "Registry"), and the obligation to report "reportable foods" to the agency became mandatory on that date. The agency also released its Final Guidance on questions raised thus far with respect to the Registry.[1] This client alert summarizes the way that FDA has addressed some of these key questions as raised by industry and other stakeholders. FDA representatives have indicated that the agency continues to consider and revisit a number of issues and welcomes stakeholder feedback, and that it may issue additional guidance in the future.

I. Key Definitions and Obligations

As described in our prior client alerts,[2] the Reportable Food Registry was established by Section 417 of the Federal Food, Drug, And Cosmetic Act ("FDCA"), as added by the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). That section requires a "responsible party" to submit a report to the Registry within 24 hours of determining that a food article is a "reportable food."[3] The FDAAA codifies congressional intent that the Registry enable FDA to track patterns of adulteration in the food supply more quickly and reliably, so that the agency may optimally target its resources to protect the public health.

The "responsible party," with respect to an article of food, means a person who has submitted to FDA the food facility registration currently required under FDCA § 415(a) for the facility where the article of food at issue has been manufactured, processed, packed, or held.[4] A "reportable food" is an article of food (other than infant formula or dietary supplements) "for which there is reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals,"[5] *i.e.*, food the recall of which would be deemed to be a Class I recall. Although the statutory language refers only to "adulteration," FDA has confirmed that a food that is misbranded due to undeclared allergens (currently a large proportion of Class I recalls) would also meet the definition of a reportable food.

The responsible party is not required to submit a report if the reportable condition originated with the responsible party, and that party detected the

[1] FDA's Final Guidance is available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm180761.htm.
[2] Our September 21, 2007, client alert on the statutory amendments that mandated the creation of the Registry is available by clicking here, and our June 19, 2009, alert on FDA's draft guidance on the Registry is available by clicking here.
[3] FDCA § 417(d)(1)(A).
[4] FDCA § 417(a)(1).
[5] FDCA § 417(a)(2).

condition prior to any transfer to another person and either corrected the condition or destroyed the food.[6]

II. KEY QUESTIONS AND CONSIDERATIONS

A. A CHANGE IN PROCEDURE OR SUBSTANCE?

The reportable food requirements were originally viewed by many as simply a procedural change. Before the implementation of Section 417 of the FDCA, a company choosing to provide information to FDA in a Class I recall situation would have submitted the relevant facts directly to the Recall Coordinator in the proximate FDA District. Under new Section 417, the requirement to report such information is now mandatory and the report must be submitted within 24 hours of determining the food is reportable. The required information must be provided in a standardized format through the electronic portal and must also be provided to the District Recall Coordinator.

FDA has made clear, however, that it views the changes ushered in by Section 417 as more substantive than simply providing a expedited and mandatory means of communicating Class I recall information to the agency. FDA representatives have indicated that they consider the Registry and reporting requirements to be a means for the agency to gain information about potential food safety issues beyond simply what they would have received from a company undertaking a Class I recall. For example, FDA considers a food to be reportable even if the company is able to recover all affected food before it hits retail shelves – a situation that would not be treated as a Class I recall. Additionally, FDA currently wants to receive reports from manufacturers that receive potentially contaminated ingredients even if that manufacturer will be processing those ingredients using a kill step that will alleviate a food safety risk. Both of these scenarios are discussed in greater detail below.

B. ARE POSITIVE TEST RESULTS ALWAYS REPORTABLE?

FDA has considered a number of scenarios involving positive test results for the presence of pathogens. As an initial matter, the agency urges the use of validated test methods so that results are reliable and provide clarity in determining whether an adulterated or potentially adulterated food is reportable. FDA has advised that if the test method is reliable, a positive pathogen test will generally mean that a food is a reportable food even if a subsequent test is negative for the pathogen.

1. Testing a Company's Own Products

If a company's testing of its own products, either finished goods or work in progress, yields a positive result for a pathogen, then whether FDA deems the food to be reportable depends upon whether the adulteration originated with that company and whether the food has been transferred to a third party. If a company determines that the problem originated when the food was in its possession, it retains physical custody of the food, and can correct the problem or destroy the food, then it need not make a report to the Registry. If custody of the food has been "transferred" to another person, as discussed below, or the problem originated with a supplier or other entity, then the food is reportable.

If it takes longer than 24 hours after receiving positive test results to determine whether or not the problem originated with the company, then FDA advises that the company should report to the Registry before the 24 hours have passed.

[6] FDCA § 417(d)(2).

2. Testing Incoming Ingredients

FDA has considered three scenarios involving testing of incoming ingredients. In the first scenario, a manufacturer tests samples from a lot of ingredients it receives prior to use, and if the results are positive for pathogens, the company refuses the shipment. FDA currently contends that the receiving company should file a report to the Registry because it holds or has held reportable food. An FDA representative has advised, however, that this position is under review as the agency considers further the definition of "hold" under Section 417 of the FDCA.

A second scenario may arise when a manufacturer receives and tests samples of an ingredient prior to receipt of a full shipment of the ingredient, and upon receiving a positive result for pathogens, refuses delivery of the shipment. FDA acknowledges that this situation may be different from the former case, and that if the samples received by the manufacturer are destroyed during testing, that company may not be obliged to report.

A third situation may arise when a manufacturer receives ingredients it will process using a kill step. For example, it is not unusual for raw agricultural commodities to test positive for pathogens that are found in the environment, but that may be destroyed routinely during processing, such as thermal processing of low acid canned vegetables or fruits. FDA currently takes the position that a manufacturer receiving such ingredients is obliged to submit a report to the Registry, although the agency would not likely ask the manufacturer to identify its downstream recipients in this case. FDA has explained its view that a report is appropriate because other entities in the supply chain may also receive contaminated product and may not utilize a kill step, so FDA wants to be apprised of such contaminated articles.

The statutory basis for FDA's position in this instance seems questionable and reporting about incoming ingredients when the finished consumer good will pose no health risk seems likely to generate a lot of "noise" in the Registry that could make it more difficult for the agency to track and respond to genuine food safety incidents. FDA continues to consider this issue and welcomes the comments of stakeholders, but maintains at this time that a report to the Registry is required in such a case.

In all of the foregoing scenarios, a manufacturer receiving an ingredient that tests positive for a pathogen should report the problem to its supplier. That supplier would then be obliged to submit a report to the Registry, and may be asked by FDA to identify its downstream recipients, which would include the receiving manufacturer.

C. When Does a Company "Transfer" Food?

The question of when a company has "transferred" food is significant in this context because if the food safety problem originated with a company and is detected before the company "transfers" the food to another person, then the food is not reportable if it is either corrected or destroyed. FDA has taken the position that a "transfer" occurs when physical custody is transferred, regardless of who may own or control the food. Accordingly, under FDA's current approach, if a food safety problem is detected after a company ships product or ingredients to a co-packer or third-party warehouse, the food is reportable even if that company retains ownership and control over the food and can retrieve or destroy it so that no affected product ever reaches retail shelves. Under this approach, a food may be reportable even where it is not the subject of a Class I recall. An FDA representative noted, however, that if a company can recover all affected food within 24 hours of determining that the food is reportable, then it might not need to file a report.

III. Additional Details About Reporting Through the Registry Portal

The current version of the Registry portal will not permit reporters to save entries during the process and will "time out" after a short while. Accordingly, it is advisable to become familiar with the Appendix to FDA's Final Guidance,[7] which provides instructions for submitting the report and details about the information that will need to be entered. This can be used to gather information before beginning to enter the data into the portal. FDA is also offering technical support to responsible parties preparing submissions through the Registry portal. FDA recommends that such parties seeking assistance e-mail RFRTechSupport@fda.hhs.gov for a prompt response.

The initial version of the Registry portal will not provide for entry of information about multiple facilities, such as multiple facilities owned by the responsible party at which the reportable food was held. Such information can be transmitted by attachment, however. A responsible party does not need to make multiple reports but, rather, can file one report and attach a list of all of its facilities that handled or received the reportable food.

Reports submitted through the portal will be available to the public in response to a Freedom of Information Act ("FOIA") request, but the Registry itself will not be accessible to the public. To help protect against unauthorized disclosures, confidential business information submitted to the Registry should be marked as such. Additionally, while Section 417(i) of the FDCA provides that a submission to the Registry is not an admission that the food caused or contributed to a death, serious injury, or serious illness, responsible parties making reports to the Registry also may wish to include a safety report disclaimer per Section 756 of the FDCA, stating that the report is not an admission that the food was adulterated or misbranded or posed a risk of harm.

If a report is made for a food that FDA ultimately determines is not a "reportable food," the agency will not purge the Registry of the report, but will "close out" the report, and this record of the agency's conclusion that the food does not pose a reasonable probability of serious adverse health consequences or death will become part of the record that would be released in response to a FOIA request.

IV. Enforcement

Although the reporting requirement became effective on September 8, 2009, FDA announced its intention to exercise its enforcement discretion for 90 days, until December 8, 2009, in cases where the agency determines that a responsible party has made a reasonable effort to comply with the Registry requirements and has "otherwise acted to protect the public health."[8] FDA has expressed its willingness to continue to work with stakeholders to resolve questions of interpretation and implementation. The agency will also accept questions about Registry policies, procedures and interpretations by e-mail at RFRSupport@fda.hhs.gov, but cautions that it may take a while to receive a response and therefore advises companies running up against the 24 hour deadline to make a report in a case of uncertainty.

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[7] The Appendix is available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm180872.htm.

[8] Final Guidance at 5.

Covington & Burling LLP has been closely engaged with FDA and industry stakeholders regarding the Registry, and we will continue to monitor and advise on the agency's implementation of the Registry.

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