The Reportable Food Registry – Back to Basics

American Spice Trade Association
2014 ASTA Regulatory Workshop
October 15, 2014
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The Reportable Food Registry (RFR)

- The RFR was established by section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-085) to provide a reliable mechanism to track patterns of adulteration in food in order to support efforts by FDA to target limited inspection resources to protect public health.
- The RFR covers all foods regulated by the FDA except infant formula and dietary supplements.
- 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.

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The Reportable Food Registry (RFR)

- On September 8, 2009, FDA rolled out the electronic portal to its Reportable Food Registry and the obligation to report "reportable foods" to the agency became mandatory on that date.
- Requires a "responsible party" to submit a report to the Registry within 24 hours of determining that a food article is a reportable food.
- "Responsible party" is defined as the person who submits the registration information to FDA for a food facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States. Federal, state, and local public health officials may also use the portal to voluntarily report information that may come to them about reportable foods.

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Responsibilities of "Responsible" Party

- Must submit certain data elements in the initial reports
- Must investigate the root cause of the adulteration if the reportable food originated with the responsible party.
- May be required to share information with suppliers and customers and share information with FDA.
- Must provide amended reports as necessary based on investigation activities and results of the root cause.
- Must maintain records related to each report received, notification made, and report submitted to FDA for 2 years. FDA may inspect these records.

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Recall Classifications

- Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

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Examples of Class I Food Recalls

- Peanut butter contaminated with Salmonella.
- Under-processed canned chili that contained Clostridium botulinum toxin.
- Smoked salmon contaminated with Listeria monocytogenes (Lm).
- Ice cream that did not declare peanut-derived ingredients but contained peanut butter as an ingredient.
- Baby food that posed a choking hazard.

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When to Report to the Registry

- If a 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.
- 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.

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Initial Testing of Ingredients

- If a manufacturer tests samples from a lot of ingredients it receives prior to use, and if the results are positive for pathogens, the company may refuse the shipment and should inform the supplier who then must inform the FDA if it has been shipped to others for use.
- If a manufacturer receives an ingredient that tests positive but it will process the ingredient using a kill step, the manufacturer receiving such ingredient should submit a report to the Registry, although FDA would not likely ask the manufacturer to identify its downstream recipients in this case.

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Data Elements Required for the RFR

1) The registration numbers of the responsible party under section 415(a)(3) of the FD&C Act;

(2) The date on which the article of food was determined to be a reportable food;

(3) A description of the article of food including the quantity or amount;

(4) The extent and nature of the adulteration;

(5) The results of any investigation of the cause of the adulteration if it may have originated with the responsible party, when known;

(6) The disposition of the article of food, when known; and

(7) The product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food.

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Definition of the Transfer of Food

- A transfer to another person occurs when the responsible person releases the food to another person. "Person" is defined in section 201(e) of the FD&C Act as including individuals, partnerships, corporations and associations.
- FDA does not consider an intra-company transfer in a vertically integrated company to be a "transfer to another person," where the company maintains continuous possession of the article of food. For example, if Company A owns a processing plant, warehouse facility, and distribution facility, the intra-company transfer from the processing plant to the warehouse facility and/or the warehouse facility to the distribution facility would not be considered a transfer to another person.

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Exemption from Reporting

- A responsible party is not required to submit a reportable food report when all of the following criteria are met:
  - The adulteration originated with the responsible party; AND
  - The responsible party detected the adulteration prior to any transfer to another person of such article of food; AND
  - The responsible party
    - corrected such adulteration; or
    - destroyed or caused the destruction of such article of food.

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Notification of Suppliers/Customers

- Notification to the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food may be accomplished by electronic communication methods such as e-mail, fax or text messaging or by telegrams, mailgrams, or first class letters. Notification may also be accomplished by telephone calls or other personal contacts but FDA recommends that such notifications also be confirmed in writing and/or documented in an appropriate manner

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Information that is Shared with Suppliers/ Customers

- Product name, brand name, product description, UPC codes, lot number
- Use-by or expiration date or other date-related information;
- Product label for ease in identifying the product at retail/user level;
- Nature of the problem and the potential health hazard;
- The business's contact details;
- Quantity by lot, dates and amounts shipped or received;
- Instructions on what to do with the product;
- A description of the disposition of the product;
- The unique report number (ICSR number) provided by FDA

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Questions?

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