FDA's Reportable Food Registry Guidance for Industry May Be Accessed at

http://www.fda.gov/ReportableFoodRegistry

Reportable Food Registry (RFR):

At A Glance

- 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 the public health.
- The RFR covers all foods regulated by FDA except infant formula and dietary supplements.
- The RFR requires a responsible party to file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Such foods are "Reportable Foods."
- "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.
- As of May 24, 2010, The RFR electronic portal became part of the Department of Human Services' Safety Reporting Portal. The entire set of data elements can be accessed at www.safetyreporting.hhs.gov.

Responsible parties:

- Must report as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food
- Must submit certain data elements in the initial report
- Must investigate the root cause of the adulteration if the reportable food originated with the responsible party
- Will be issued a unique number after report submission, called the Individual Case Safety Report (ICSR) number, that identifies the report and allows FDA to properly link associated reportable food reports in the Registry
- May be required to provide notification to immediate previous sources (suppliers) and immediate subsequent recipients (customers) of the reportable food and share information including the ICSR number, after consultation with FDA
- Must provide amended reports as necessary- for example, FDA understands that it may take more than 24 hours to perform investigation activities and obtain information such as the results of any investigation of the root cause of the adulteration (when applicable) and the disposition of the reportable food
- Must consult with FDA to follow up as necessary
- Must maintain records related to each report received, notification made, and report submitted to FDA for 2 years

- Failure to report a reportable food is a prohibited act under the Federal Food, Drug, and Cosmetic Act.

- A responsible party is not required to submit a reportable food report if ALL of the following three conditions are met:

    1. The adulteration originated with the responsible party; AND
    2. The responsible party detected the adulteration prior to any transfer to another person of the article of food; AND
    3. The responsible party corrected the adulteration or destroyed or caused the destruction of the article of food.

- Data elements that a responsible party may include in initial and follow-up RFR reports to FDA:
    - Food Facility Registration Number
    - Date the article of food was determined to be reportable
    - Description of the food, including quantity and amount
    - Extent and nature of the adulteration
    - Results of investigation of the root cause of the adulteration if it may have originated with the responsible party, when known
    - Disposition of the article of food, when known
    - Product information typically found on packaging sufficient to identify the article of food
    - Contact information for the immediate previous sources (suppliers) and/or immediate subsequent recipients (customers) of the article of food, when required by FDA

- A record in the RFR is subject to Freedom of Information Act (FOIA) rules, with appropriate redactions to protect proprietary information and the reporting facility's Food Facility Registration Number.

- RFR submissions will not be viewable by any other submitters.

Contact FDA about the RFR

The **RFR Center** answers questions about Reportable Food Registry policies, procedures and interpretations. Submit questions to:
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/ContactCFSAN/

The **SRP Service Desk** for technical and computer-related questions about the Reportable Food Registry electronic portal. Email questions to:
SRPSupport@fda.hhs.gov

For additional information, please visit FDA's RFR homepage:
www.fda.gov/ReportableFoodRegistry

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