

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Registration of Food Facilities

FDA Industry Systems

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OMB Approval Number: **0910-0502**

OMB Expiration Date: **08/31/2016**

See **[OMB Burden Statement](#)**

[\(/Food/GuidanceRegulation/FoodFacilityRegistration/ucm151633.htm\)](/Food/GuidanceRegulation/FoodFacilityRegistration/ucm151633.htm)

The **Public Health Security and Bioterrorism Preparedness and Response Act of 2002** (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:

- Food facilities register with FDA, and
- FDA be given advance notice on shipments of imported food.

These regulations became effective on **December 12, 2003**.

The **FDA Food Safety Modernization Act (FSMA)**, enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Section 415 of the FD&C Act, as amended by FSMA, also requires food facilities required to register with FDA to renew such registrations every other year, and provides FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

FDA Actions on the FSMA

- **FSMA Proposed Rule: Amendments to Registration of Food Facilities**
(/Food/GuidanceRegulation/FSMA/ucm440988.htm)
April 2014
- **Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition)** **(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm)**
November 2014
- **Compliance Policy Guide - Sec. 100.250 Food Facility Registration – Human and Animal Food (PDF - 98KB)**
(/downloads/ICEI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM399369.pdf)
June 2014
- **Guidance for Industry: What You Need to Know About Registration of Food Facilities; Small Entity Compliance Guide**
(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331957.htm)
December 2012
- **Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories**
(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm324778.htm)
October 2012

FDA Actions on the Bioterrorism Act of 2002 Legislation

- **Compliance Policy Guide Guidance for FDA Staff: Registration of Food Facilities**
(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm121288.htm)
August 2006
- **Final Rule: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (70 FR 57505)**
(/Food/GuidanceRegulation/FoodFacilityRegistration/ucm081616.htm)
October 2005

Guides and Tutorials

- **Food Facility Account Management**
(/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073725.htm)
- **User Guides for Online Registration of Food Facilities**
(/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006832.htm)
- **Guide to Biennial Registration Renewal**
(/Food/GuidanceRegulation/FoodFacilityRegistration/ucm324780.htm)
- **Cancellation by Paper (Mail or FAX) or CD-ROM**
(/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073728.htm)
- **Online Registration System Status**
(/Food/GuidanceRegulation/FoodFacilityRegistration/ucm161883.htm)

Additional Resources

- [Registration Statistics \(/Food/GuidanceRegulation/FoodFacilityRegistration/ucm236512.htm\)](/Food/GuidanceRegulation/FoodFacilityRegistration/ucm236512.htm)

Contact FDA

1-800-216-7331

301-575-0156

[furls@fda.gov \(mailto:furls@fda.gov\)](mailto:furls@fda.gov)

FDA Industry Systems

Help Desk

(Technical, Computer & General Questions)

Help desk hours are Monday to Friday from 7:30 am to 11:00 pm Eastern Standard Time

More in Food Facility Registration

[\(/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm\)](/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm)

Acidified & Low-Acid Canned Foods (LACF) Registration

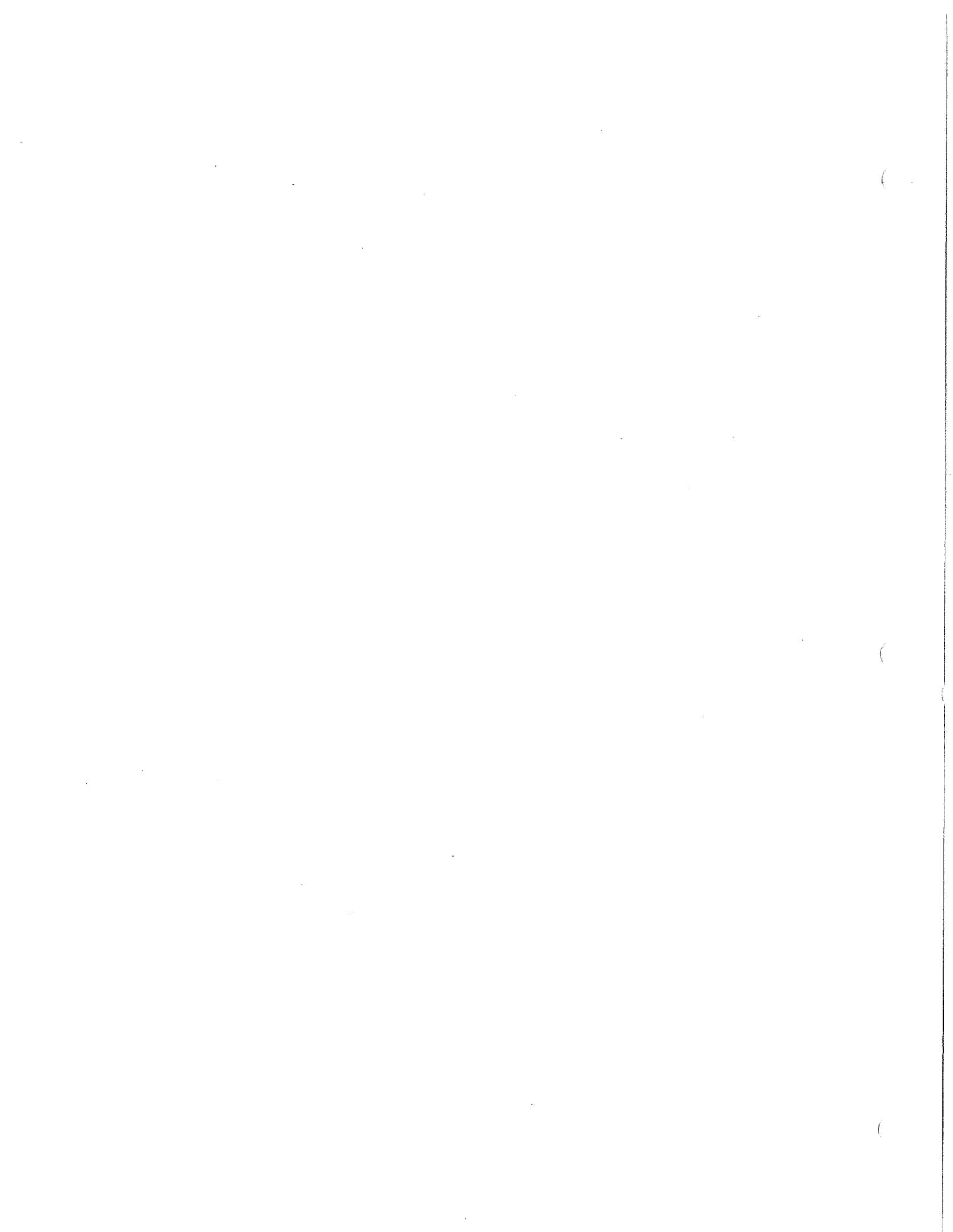
[\(/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm\)](/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm)

New Dietary Ingredients Notifications (NDI)

[\(/Food/GuidanceRegulation/FoodFacilityRegistration/NewDietaryIngredientsNotificationsNDI/default.htm\)](/Food/GuidanceRegulation/FoodFacilityRegistration/NewDietaryIngredientsNotificationsNDI/default.htm)

Shell Egg Producer Registration

[\(/Food/GuidanceRegulation/FoodFacilityRegistration/ShellEggProducerRegistration/default.htm\)](/Food/GuidanceRegulation/FoodFacilityRegistration/ShellEggProducerRegistration/default.htm)



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. Email questions to:

RFRSupport@fda.hhs.gov

The SRP Service Desk for technical and computer-related questions about about the Reportable Food Registry electronic portal Email questions to:

Support.srp@jbsinternational.com



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