

# The Food Safety Modernization Act and the FDA Facility Registration Program

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## WHAT IS FSMA?

The Food Safety Modernization Act (FSMA) represents the most sweeping update to food safety regulation since the Federal Food, Drug, and Cosmetic Act of 1938. This legislation enhances the U.S. Food and Drug Administration's (FDA) ability to require certain specific safety standards for growers and facilities that manufacture, process, pack or hold food products. In Florida, this includes citrus growers, packers, processors, repacking and distribution operations, and anyone else who falls under FDA jurisdiction.

The act also gives the FDA authority to issue recalls if a food product is found to be substandard or contaminated with a pathogen. This legislation arose from concern that an inadvertent or purposeful (bioterrorism) contaminant in the food supply chain could result in significant harm to many people or animals. The FSMA requirement for facility registration is not a new program, but a continuation of one started as part of the Bioterrorism Act of 2002, which required registration of both domestic and foreign producers of foodstuffs consumed in America.

## REGISTRATION

As part of FSMA, registration is required of domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States, effective December 12, 2003 (FDA 2012). Registrants must submit their registration to the FDA containing certain information, such as the general food category (as identified in 21 CFR 170.3, or any other food categories as

determined appropriate by the FDA) of any food manufactured, processed, packed or held at such facility. Among other categories, the FDA added the following citrus-related categories to their food facilities registration form:

### Additional Food Product Categories for Foods for Human Consumption

- Fruit and fruit products: fresh-cut produce; raw agricultural commodities; other fruit and fruit products
- Fruit or vegetable juice, pulp or concentrate products

### Additional Food Product Categories for Foods for Animal Consumption

- Citrus products

## HOW DO I REGISTER?

The owner or operator of one of these facilities (or someone authorized by either of the previous individuals) must register with the FDA biannually. Registration can be achieved in one of three ways:

1. Online at <http://www.access.fda.gov/oa/>
2. Paper submission of Form 3537, which can be requested by phone or mail or downloaded from <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073728.htm>
3. CD-ROM submission using the PDF version of Form 3537 (<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073728.htm>)

Additional information is available through the FDA website (<https://www.access.fda.gov/oa/>). For those logging into the FDA system for the first time, the website prompts new users to create an account before they can register. No fees are associated with registration.

A multitude of exceptions to this registration rule and information about those exceptions can be found at <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf>. This guidance document contains many of the questions and answers asked by people in the food industry about the registration process. Further guidelines for people in the industry, such as who needs to register and how, can be found on the FDA's website (<http://www.fda.gov/>

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm>).

## WHAT IS THE PURPOSE OF REGISTERING?

Every facility that produces, processes, holds, distributes or packs food must register with the FDA. If registration is not completed, the facility will not be allowed to process or deliver any food for human consumption. This registration has a two-fold purpose in that it gives the FDA the ability to identify a facility as the potential source for a foodborne outbreak and also allows the FDA to quickly notify other facilities that may receive foodstuffs from the implicated facility.

Along with registration, these facilities are required to keep written records of their food safety plan and any applicable product testing, along with emergency protocols to reduce potential impacts of a foodborne outbreak originating from that facility. Additional paperwork is required from facilities processing high-risk foods. Currently, the FDA is working on determining how to define and identify high-risk foods, though this group will most likely include those food items that have had a history of associated foodborne illness.


Overall, the facility registration rule of FSMA is intended to streamline the outbreak notification process by using one database that contains all U.S. and importing food processing facility contact information. In addition, the law attempts to be more proactive, instead of reactive, in preventing foodborne outbreaks.

## REFERENCES

FDA. 2012. "Guidance for Industry: What You Need to Know About Registration of Food Facilities Small Entity Compliance Guide." College Park, MD. <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332657.pdf>

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