

# The Food Safety Modernization Act and the FDA Facility Registration Program<sup>1</sup>

Susanna Richardson, Renée Goodrich Schneider, Keith R. Schneider, Mark A. Ritenour, and Michelle D. Danyluk<sup>2</sup>

## What is FSMA?

FSMA is the Food Safety Modernization Act (<http://www.fda.gov/Food/GuidanceRegulation/>), which President Obama signed into law on January 4, 2011. It represents the most sweeping update to food safety regulation since the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938. This legislation enhances the U.S. Food and Drug Administration's (FDA) ability to require certain specific safety standards for facilities that manufacture, process, pack, or hold food products, which include fruits, vegetables, and nuts. In Florida, this includes produce packers, processors, repacking and distribution operations, nut shellers, 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 the United States.

## Registration

As part of FSMA, registration is required of domestic and foreign facilities that manufacture, process, pack or hold food, as defined in 21 CFR 1.227 (<http://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol1/CFR-2012-title21-vol1-sec1-227/content-detail.html>), and requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA (FDA 2018). Section 415(a) (2) of the FD&C Act, as amended by section 102 of FSMA, states that 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. The FDA believes the following additional food product categories are necessary and appropriate for food facility registration and has included such categories as mandatory fields in the food facility registration form:

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

- Acidified food (see 21 CFR 114.3(b))
- Baby (infant and junior) food products, including infant formula

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2. Susanna Richardson, technician; Renée Goodrich Schneider, associate professor; and Keith R. Schneider, professor, Department of Food Science and Human Nutrition Department; Mark A. Ritenour, associate professor, UF/IFAS Indian River Research and Education Center; and Michelle D. Danyluk, assistant professor, UF/IFAS Citrus REC; UF/IFAS Extension, Gainesville, FL 32611.

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- Cheese and cheese product categories: soft, ripened cheese; semi-soft cheese; hard cheese; other cheeses and cheese products
- Dietary supplement categories: proteins, amino acids, fats and lipid substances; animal by-products and extracts; herbals and botanicals
- Fishery/seafood product categories: fin fish, whole or filet; shellfish; ready-to-eat (RTE) fishery products; processed and other fishery products
- Fruit and fruit products: fresh-cut produce; raw agricultural commodities; other fruit and fruit products
- Fruit or vegetable juice, pulp or concentrate products
- Low-acid canned food (LACF) products (see 21 CFR 113.3(n))
- Nuts and edible seed product categories: nut and nut products; edible seed and edible seed products
- Shell egg and egg product categories: chicken egg and egg products; other egg and egg products
- Vegetable and vegetable product categories: fresh-cut products; raw agricultural commodities; other vegetable and vegetable products
- If none of the human food categories listed in the registration form apply, print the applicable food category or categories.

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

- Grain or grain products (e.g., barley, grain sorghums, maize, oat, rice, rye, wheat, other grains or grain products)
- Oilseed or oilseed products (e.g., cottonseed, soybeans, other oilseeds or oilseed products)
- Alfalfa products or lespedeza products; amino acids or related products
- Animal-derived products
- Brewer products
- Chemical preservatives
- Citrus products
- Distillery products
- Enzymes
- Fats or oils
- Fermentation products
- Marine products
- Milk products
- Minerals or mineral products
- Miscellaneous or special-purpose products
- Molasses or molasses products
- Nonprotein nitrogen products
- Peanut products
- Recycled animal waste products
- Screenings
- Vitamins or vitamin products; yeast products
- Mixed feed (e.g., poultry, livestock, equine)
- Pet food
- Pet treats or pet chews
- Pet nutritional supplements (e.g., vitamins, minerals)
- If none of the above food categories apply, print the applicable food category or categories (that does not or do not appear above).

## 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 <https://www.access.fda.gov/oaa/>
2. Paper submission of Form 3537, which can be requested by phone or mail or downloaded from <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073728.htm>
3. Fax submission using the PDF version of Form 3537 <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073728.htm>

Additional information is available through the FDA website (<https://www.access.fda.gov/oaa/>). When 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/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 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 (FDA 2024). 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 United States 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. 2024. Food Safety Modernization Act (FSMA). Accessed November 27, 2024. <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>

FDA. 2018. *Guidance for Industry: What You Need to Know About Registration of Food Facilities Small Entity Compliance Guide*. College Park, MD.

## Resources

FDA. 2024. FSMA Rules & Guidance for Industry. Accessed November 27, 2024. <http://www.fda.gov/Food/Guidance-Regulation/FSMA/ucm253380.htm>

FDA. 2024. Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition). Accessed November 27, 2024. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition>

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