

## FSMA FAQs: 'Is My Food Business Required to Register with FDA?'

### 1. Is my food or animal feed business required to register with the FDA?

Understanding if your business is required to register with the FDA is essential to determining whether FSMA's Preventive Controls Rules for processing, packing, or holding human food or animal feed govern your operation. Under the Bioterrorism Act of 2002, all domestic and foreign food and feed 'facilities' are required to register with FDA. **The agency defines 'facility' as an:**

- establishment; structure; or group of structures under one ownership at one general physical location; or mobile food business, that
- manufactures/processes, packs, or holds food for consumption in the United States.

FDA further defines **manufacturing/processing, packing, and holding**.

- **Manufacturing/processing** means: "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients."
- **Holding** means: "storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)."
- **Packing** means: "placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing))."

As a general rule, all businesses that manufacture, hold, or pack food are required to register as food facilities with the FDA, based on the Bioterrorism Act of 2002. However, the Bioterrorism Act provides several exceptions to the facility registration requirement. The following are **domestic establishments that do not have to register with FDA:**

- a. A private residence of an individual(s).
- b. A farm. FSMA regulations provide a complex definition of what counts as a 'farm', as FDA considers many of the activities that are normal parts of farming to be processing, packing, or holding if they take place somewhere other than a farm; to learn the details of the 'farm' definition, see the FSMA FAQ ['Is My Food Business a Farm?'](#)
- c. A retail food establishment. FDA defines 'retail food establishment' as a business that manufactures, packs, or holds food and sells more than half those products directly to consumers, including through on-premises sales, farmers markets, community-supported agriculture, roadside stands, online, mail-order and other direct marketing platforms.
- d. A restaurant.
- e. A nonprofit food establishments in which food is prepared for, or served directly to, the consumer.
- f. A fishing vessel—including vessels where harvested fish are headed, eviscerated, or frozen to prepare them for holding on board the harvest vessel. Fishing vessels that do any further processing to prepare fish or shellfish for market, however, must register.
- g. A transportation vehicle if it only holds food only in the usual course of business as a carrier.
- h. A facilities **regulated exclusively**, throughout the entire facility, **by the U.S. Department of Agriculture** under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

**NOTE:** If you operate a farm and **also do food processing, packing, or holding** that is not included within the definition of ‘farm’, your business may be a ‘**farm mixed-type facility**’, and you may have to register with FDA for those non-farming activities. To learn more, see the FSMA FAQ [‘Is My Business a Farm Mixed-Type Facility?’](#)

**NOTE:** Depending on the kinds of foods and activities, a retail food establishment may be regulated by the state or local health department, or may be subject to ‘cottage food’ regulations if your state has them.

**2. My business doesn’t fall into any of these exceptions, or is a farm mixed-type facility. How do I register?**

If you are operating a facility that is required to register with FDA, you are technically supposed to register before commencing any food or feed processing, packing, or holding activities. If you have already started those activities, you should register right away. [FDA offers a step-by-step guide to registering your facility.](#) Beginning in January, 2020, registration must be submitted electronically.

You must provide the following information as part of the registration process:

- The name, address, and phone number of your business, and of the parent company of your business if it is a subsidiary of another entity;
- The names, addresses, and phone numbers of the people who own and operate your facility;
- An emergency contact phone number;
- Any additional trade names that your business uses;
- All the categories of food products your business makes, packs, or holds. You will select from a list of food categories provided by FDA.

**REGISTRATION RENEWAL:** After your initial registration, you must renew your registration and update any changed information between October 1 and December 31 of every even-numbered year.

**3. I have previously registered my business, but my business actually meets one of the exclusions. Can I cancel my registration?**

If your business meets any of the exceptions or exemptions, then you do not have to comply with FSMA’s Preventive Controls Rules (PC Rules). If you have registered when you’re not required to do so, you should cancel that registration to avoid the risk of an FDA-authorized agent arriving at your business to conduct a PC Rule inspection. [FDA provides a tutorial for how to cancel your registration online.](#) You may also cancel your registration by filling out FDA’s form [3537a](#) and faxing the completed form to (301) 436-2804, or by mailing it to:

U.S. Food and Drug Administration/Food Facility Registration  
5001 Campus Drive  
HFS-681  
College Park, MD 20993

**4. My business is a facility that must register with FDA. How do I know if I’m covered by the PC Rules?**

If your business is a farm mixed-type facility, see the FSMA FAQ [‘Is My Business a Farm Mixed-Type Facility?’](#) to learn more about what portions of the PC Rules might apply to your operation.

If your business is any other type of registered facility, see the FSMA FAQ [‘What are the Basic Requirements of FSMA’s Preventive Controls Rules for Human Food?’](#) to learn more about which parts of the PC Rules might apply to your operation.

*This document is not legal advice and is for educational purposes only. It has not been approved by the FDA.*