

Food Facility Registration: Who, How, and When?

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 directs the Food and Drug Administration (FDA) to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply. Section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption for consumption in the United States to register with the Food and Drug Administration (FDA). The FDA Food Modernization Act (FSMA) amended section 415 of the FD&C Act requiring facilities to submit additional registration information to FDA. More information can be found on the FDA website (www.fda.gov).

The purpose of this document is to help food facilities, including certain farms, determine whether they need to register with the FDA, and to provide information on the registration process.

Do I need to register?

All facilities that engage in manufacturing or processing of food for human or animal consumption that are not otherwise exempt are required to register.

Am I exempt from registration?

If your facility is involved in one of the following activities, it does NOT have to register with FDA.

- Private residence of individuals
- Non-bottled water drinking water collection and distribution establishments and structures
- Transport vehicles that hold food only in the usual course of their business as carriers.
- Restaurants
- Retail food establishments
- Nonprofit food facilities (such as food banks, soup kitchens, food delivery services)
- Fishing vessels
- Facilities regulated exclusively by the U.S. Department of Agriculture
- Farms (including primary production and secondary activities farms as amended by FSMA) provided that:
 - The farm does not engage in manufacturing or processing of human or animal food , OR
 - All food that is manufactured or processed on the farm is consumed there (or on another farm under the same ownership) or was sold directly to consumers (e.g. farmers' market, roadside stand, CSAs) and not to businesses (see definitions on the next page for further information)

In November 2016, the FDA provided a guidance document titled Guidance for Industry: Questions and Answers Regarding Registration of Food Facilities. This document provides additional information about the farm exemption, and other rules for facilities that may be required to register. This document is available through the FDA website.

How do I register?

Facilities may register through the FDA website at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/>. Additional information is available through that website. Registration is free.

You must register your facility before manufacturing/processing, packing, or holding operations begin. Facilities are required to renew their registrations every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year.

When will registration close?

A new facility can register at any time; so, therefore, registration does not close for new facilities. However, required biennial renewal occurs during even-numbered years between October 1 and December 31.

Glossary of Helpful Terms

These definitions may help you determine whether you need to register or if you are exempt (21 CFR 1.227). Refer to these definitions when using the flow chart on the reverse side of this document.

Farm (includes two types)

- 1) Primary production farm** – an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:
 - a. Pack or hold raw agricultural commodities;
 - b. Pack or hold processed food, as long as the food is either consumed on that farm or another farm under the same management;
 - c. Manufacture/process food, as long as:
 - i. The food is consumed on that farm or another farm under the same management; or
 - ii. Manufactured/processed food intended for sale consists only of:
 1. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (e.g., slicing)
 2. Treatment to manipulate the ripening of raw agricultural commodities (e.g., ethylene gas), and packaging and labeling without additional manufacturing/processing.
 3. Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.
- 2) Secondary activities farm** – an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s):
 - a. Grows, harvests, and/or raises the majority of the raw agricultural commodities handled at the secondary activities farm (e.g., packinghouse)
 - b. Owns, or jointly owns, a majority interest in the secondary activities farm.

A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described above.

Harvesting – applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding – storing of food, including warehouses, cold storage, silos, grain elevators, and liquid storage tanks.

Manufacturing/processing – Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples include cutting (other than the cutting of outer leaves associated with harvesting), peeling, trimming, cooking, freezing, cooling, pasteurizing, homogenizing, milling, grinding, extracting juice, labeling, or packaging. Manufacturing/processing does not include harvesting (see below). (

Mixed-type facility - an establishment that engages in both activities that are exempt from FDA registration (i.e., farm) and activities that require the establishment to be registered (manufacturing/processing). An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packaging – Placing food in a container that directly contacts with the food and that the consumer receives. (

Packing – 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). (