

Food Facility Registration: Who, How, and When?



The Bioterrorism Act of 2002 and the Food Safety Modernization Act of 2010 are federal laws that require certain types of food facilities to register with the U.S. Food and Drug Administration. Food facilities registering with the FDA are now required to provide food product category information as part of the registration process. In October 2012, the FDA provided a guidance document titled *Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories* that contains complete listings of food categories. This document is available through the FDA website, <http://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 feed or food that are not otherwise exempt are required to register. Registration must be done before manufacturing/processing, packing, or holding operations begin.

Am I exempt from registration?

Retail establishments, including restaurants, are not required to register. Farms are not required to register if one or more of the following apply:

- The farm does not engage in manufacturing or processing of food or feed, OR
- All food or feed that is packed or held on the farm was grown or raised on the farm, 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 or roadside stand) and not to businesses

In August 2004, 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.

You may use the flow chart on the reverse side of this document to help determine whether you need to register.

How do I register?

Facilities may register through the FDA website at <https://www.access.fda.gov/oaa/>. Additional information is available through that website. Registration is free.

When can I register?

Biennial registration renewal is required during the period beginning on October 1 and ending on December 31 of each even-number year.

NOTE: Renewal submissions MUST be electronic as of January 4, 2020, unless the facility has received a waiver.

Glossary of Helpful Terms

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

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). 21 CFR 1.227(b)(6).

Packaging – Placing food in a container that directly contacts with the food and that the consumer receives. 21 CFR 1.227(b)(8).

Packing – Placing food into a container other than packaging the food. 21 CFR 1.227(b)(9).

Harvesting – The process of collecting and storing crops. Harvesting of produce includes washing with water that has not been specially treated, trimming of outer leaves, cooling, and storing the produce in the manner typically associated with that product. 21 CFR 1.227(b)(3), *Guidance for Industry: Questions and Answers Regarding Registration of Food Facilities*.

Holding – The storage of food, including warehouses, cold storage, silos, grain elevators, and liquid storage tanks. 21 CFR 1.227(b)(5).

Food Facility Registration Flow Chart



