

Registering Your Food Business with the FDA

As a result of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and supported by the Food Safety Modernization Act, **any owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs, or holds food for human or animal consumption in the U.S., or an individual authorized by one of them, must register that facility with FDA.** The purpose of this mandate is to more readily identify foods in the event of an intentional attack on the United States food source. Even if the foods do not enter interstate commerce, all facilities must be registered. There is no cost associated, and registration can be done online, by fax, or through the mail.

There are a number of facilities that ***do not have to register***. These facilities are:

- Foreign facilities, if food from such a facility undergoes further manufacturing/processing (including packaging) by another facility outside the US
- Farms, which are establishments devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.
- Retail food establishments, which are establishments that *sell food directly to consumers as their primary function*.
 - If an establishment's annual sales to consumers exceed its sales to non-consumers, the establishment is an exempt retail establishment.
 - The Food Safety Modernization Act amended the definition of a retail establishment to include the sale of food at a roadside stand or farmers market, sale and distribution through a community supported agriculture commodity, or any other direct sales endeavor of this nature.
- Restaurants, which are establishments that prepare and serve food directly to consumers for immediate consumption.

- Nonprofit food establishments, which are charitable entities that prepare or serve food directly to consumers, or otherwise provide food for consumption by humans or animals in the U.S.
- Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. Fishing vessels that otherwise engage in processing fish are required to register.
- Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*)

Information on how to register can be found on the FDA webpage found at this link:

<http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm>

If you wish to register your facility online, you may do so at this link:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/default.htm>

Registration for Acidified and Low-Acid Foods

If you are producing an acidified or low acid canned food, you must register your facility and your scheduled process with the FDA as well. This is in addition to registering your facility as part of the Bioterrorism Act.

Your facility must be registered using FDA form 2541. Instructions for filling out form 2541 are listed on the FDA website, found here:

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/EstablishmentRegistrationThermalProcessFiling/Instructions/ucm125755.htm>

A PDF of form 2541 can be found here:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076778.pdf>.

In addition to registration of your facility, you must also fill out a scheduled process and submit your information to the FDA using form 2541A. This form can be found here:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076784.pdf>.