

# FDA Food Facility Registration Renewal Questions & Answers

The U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) was signed into law in 2011 for the purpose of enabling the FDA to better protect public health by strengthening the food system. In order to improve the agency's ability to respond to a food-related emergency quickly and efficiently, the FSMA requires that all domestic and foreign facilities that manufacture, process, pack or

hold food for human or animal consumption in the U.S. register with the FDA. The Act also requires biennial renewal of food facility registrations.

If you manufacture, process, pack or hold food for human or animal consumption in the U.S., you need to be familiar with some of the more pertinent details of the Food Safety Modernization Act. To help with this, we've compiled a list of commonly asked questions.

## Who must register, or renew registration?

Owners, operators, or agents in charge of either a domestic or foreign facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the U.S. must register with the FDA, unless the facility is exempt under 21 CFR 1.226 from the requirements to register. If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf.

## How do I update my Food Facility Registration to comply with the FSMA?

Biennial food facility registration updates are done online at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration>.

Once you have logged in to FDA industry systems, choose "Food Facility Registration" from the list of systems available. From the Main Menu in the Food Facility Registration Module (FFRM) Home page, choose "Biennial Registration Renewal". Once you have reviewed the information and made updates where necessary, choose to Submit Biennial Registration Renewal.

## I operate a farm; do I need to register with the FDA?

No. Currently farms, restaurants, and retail food establishments are not required to register or renew food facility registrations with the FDA.

## When do I need to renew my food facility registration information by?

The FSMA stipulates that food facilities must renew their registration every even-numbered year, between October 01 and December 31.

## How do I submit my registration?

Your registration can be submitted online or in paper format. If submitting online, you can do so by logging in here: <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration>. If submitting a hardcopy, you need to complete Form FDA 3537.

## What kind of information do I need to provide when registering or renewing my registration?

Registrants need to provide the following:

1. The e-mail address for the contact person of the facility or if a foreign facility, the e-mail address of the U.S. agent for the facility.
2. Appropriate additional food categories (as determined by the FDA) of any food manufactured, processed, packed, or held at the facility.
3. An assurance that the FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act.

### Do I need a U.S. agent?

Every non-U.S. food facility must have a U.S. agent that acts as the domestic communications representative for that facility. Livingston offers this U.S. agency service to foreign importers. This is a fee-based service that requires a special payment terms agreement. If you are interested in Livingston's U.S. agency service, please contact [fda@livingstonintl.com](mailto:fda@livingstonintl.com) for more information.

### Can the FDA suspend a facility's registration?

Yes, the FDA has the authority to suspend the registration of a registered food facility.

### Under what conditions can the FDA suspend a facility's registration?

If it reasonably determines that the food being manufactured, processed, packed, received, or held by a registered facility can have serious adverse health effects or cause death to humans or animals, the FDA can suspend that facility's registration.

A facility's registration can also be suspended if:

- There is a reasonable probability that the facility created, caused, or was otherwise responsible for serious adverse health consequences or death to humans or animals.
- The facility packed, received or held food, knowing, or having reason to know, of the reasonable probability of causing serious adverse health consequences or death to humans or animals.

### What is the impact to a facility if its registration is suspended?

If a facility's registration is suspended, the business cannot import or export food into the U.S.

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