

## **FSMA Frequently Asked Questions: Is my non-farm food manufacturing business covered by FSMA?**

**My business manufactures value-added food products for human consumption, and is not part of or located on a farm. How are my food processing activities regulated?**

The FDA defines non-farm food processing or manufacturing as:

“making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.”

If your non-farm business is manufacturing food, your operation likely can be classified as either a **retail food establishment** or a food **facility**.

A **retail food establishment** is 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. Depending on state law and the kind of foods made, a retail food establishments may be regulated by the local health department or may be subject to a ‘cottage food’ law if there is one in your state. ***FSMA does not apply to retail food establishments.***

If less than half of your food sales are directly to consumers, you are likely operating a food **facility**. A food facility is ***required to register*** with FDA. If your business has to register as a facility with FDA, your food processing activities may be subject to at least portions of FSMA’s Preventive Controls Rules for Human Food (PC Rule). For more information about food facility registration, see the FSMA FAQ [\*\*\*‘Is My Food Business Required to Register with FDA?’\*\*\*](#)

To learn more about the requirements of the PC Rule that apply to your business, see the FSMA FAQ Sheet [\*\*\*‘What Are the Basic Requirements of FSMA’s Preventive Controls Rules for Human Food?’\*\*\*](#)

**NOTE: FSMA *does not apply to making or handling meat, poultry or egg* products in establishments that are *exclusively regulated by the US Department of Agriculture.***

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