

FSMA Frequently Asked Questions: Is my non-farm food distribution business covered by FSMA?

My business packs, stores, and distributes produce or other human food products, and is not part of or located on a farm, or majority-owned by farmers. How are my food activities regulated?

Under FDA rules, the term ‘holding’

“means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets).”

Examples of holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

FDA rules state that ‘packing’

“means 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).”

If you are packing and holding foods, 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 foods 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, unless the only food it handles is packaged meat and egg products supplied from an establishment that is exclusively regulated by the US Department of Agriculture. Such establishments do not have to register with FDA.

If your business has to register as a facility with FDA and packs or holds foods for human consumption, those packing and holding activities may be subject to at least portions of FSMA’s Preventive Controls Rule 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 Rules that apply to your business, see the FSMA FAQ [*‘What Are the Basic Requirements of FSMA’s Preventive Controls Rules for Human Food?’*](#)

NOTE: If your non-farm facility only conducts the harvesting, packing, and holding, activities that are covered in the FDA’s definition of a farm, there are special rules applicable to your business. To learn more, see the FSMA FAQ [*‘Is My Produce-Packing Operation Covered by the Preventive Controls Rule for Human Food?’*](#)

Your business may be covered by portions of FSMA’s Sanitary Transportation Rule. To learn more, see the FSMA FAQ [*‘Is My Business Covered by the FSMA Rules for Transportation of Food?’*](#)

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