

FSMA FAQ: Is My Produce-Packing Operation Covered by the Preventive Controls Rule for Human Food?

1. My business only packs and holds produce, but is not located on a farm and is not majority-owned by a farmer or farmers. Does FSMA apply to my operation?

Your produce packinghouse does not meet the FSMA definitions of a Primary Production Farm or a Secondary Activities Farm (see the FSMA FAQ '[Is My Food Business a Farm?](#)'), so you need to determine whether your activities **holding and packing** produce make you a 'facility'.

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).”

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 produce, your operation 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 the kinds of foods and activities, a retail food establishment may be regulated by the state or local health department, or may be subject to 'cottage food' regulations if your state has them. ***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 **facility**. A facility is required to register with FDA. For more information about food facility registration, see the FSMA FAQ '[Is My Food Business Required to Register with FDA?](#)'

If your business has to register as a facility with FDA, your produce packing and holding activities are regulated under FSMA's Preventive Controls Rules for Human Food (PC Rules).

If your operation only packs and holds produce, the PC Rule's regulations on sanitary operations, known as **Good Manufacturing Practices (GMPs)**, apply to your business. However, FDA has modified these requirements in the case of off-farm produce packinghouse facilities. The PC Rule allows off-farm produce packinghouses to comply with applicable parts of the FSMA Produce Rule instead of the GMPs. Relevant Produce Rule regulations include rules on employee training; worker health and hygiene; sanitation and design of equipment, tools, and buildings; post-harvest handling; and recordkeeping. For an overview of the

Produce Rule standards, see the Carolina Farm Stewardship Association's FSMA FAQ '[What Are the Basic Requirements of the Produce Rule?](#)'

NOTE ON WASHING PRODUCE: Washing produce is not a 'packing' or 'holding' activity: FDA considers washing part of 'processing.' If you wash any of the produce you handle, you also may have to comply with the PCR regulations on **Hazard Analysis and Risk-Based Preventive Controls (HARPC)** and **Supply-Chain Programs (SCP)**.

HARPC and SCP are new prevention-oriented food safety requirements added by FSMA. The HARPC and SCP requirements do not apply to your produce packing facility **if** for 2019, you had 2016-18 average annual sales of crops, livestock products and processed human foods of less than \$1,101,103¹. This is the 'Qualified Facility' exemption. **Moreover**, [FDA has stated](#) that it will not enforce HARPC or SCP against facilities like yours, regardless of your revenues, until further notice.

To learn more about the specifics of HARPC and SCP, see the FSMA FAQ '[What Are the Basic Requirements of HARPC and SCP Under FSMA?](#)'

NOTE: If you meet the Qualified Facility exemption, there are still special preventive control requirements you must meet. For more information see the FSMA FAQ '[What Are the Special Rules for Qualified Exempt Facilities?](#)'

Training: The PC Rules also require all food-handling employees have the food safety training or experience appropriate to their jobs, and that your food safety plan is created and managed by a Preventive Controls Qualified Individual (PCQI). A PCQI is someone who has completed FDA-authorized training on preventive controls, or who has sufficient job experience to develop and apply preventive controls.

Also, 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?](#)'

2. **Do packinghouses like mine that are on-farm, or majority farm-owned, have to comply with HARPC, SCP, the special Qualified Facility exemptions, and preventive controls training?**

No. Produce packing operations that are located on farms, or that are off-farm but majority owned by farmers, are subject to the Produce Rule, not the PC Rule. You may be thinking, and FDA has acknowledged, that is inconsistent to treat produce packing operations differently based on their ownership structure. FDA has pledged to revisit this aspect of the rules [and in the meantime has stated](#) that it will not actively enforce the PC Rules against off-farm packing facilities that would be governed by the Produce Rule if they were on a farm or were majority-owned by farmers.

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

¹ This threshold amount is good for 2019. The dollar thresholds for the qualified exempt and very small business exemptions are to be adjusted for inflation. For more information, see the FSMA FAQ '[What Are the Special Rules for Qualified Exempt Facilities?](#)'