

FSMA Frequently Asked Questions: Is My Business a Farm Mixed-Type Facility?

1. I run a farm, but I also make foods on-farm. How are my food processing activities regulated?

If you are making processed foods on farm, your operation likely can be classified as either a **retail food establishment** or a **farm-mixed type facility**.

A **retail food establishment** is a business that processes, packs, or holds food and ***sells more than half of that food directly to consumers***, including through on-premises sales, farmers markets, community-supported agriculture, roadside stands, online, mail-order and other direct marketing platforms. A grocery store, a vending machine, and an on-farm ice cream shop are all examples of retail food establishments. 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 **farm mixed-type facility**. A farm mixed-type facility is **required to register** with the US Food and Drug Administration (FDA), and the food processing done on farm may be subject to at least portions of FSMA's Preventive Controls Rules (PC Rules) for Human Food (or for Animal Feed if the only processed foods you make are for animals). For more information about food facility registration, see the FSMA FAQ ['Is My Food Business Required to Register with FDA?'](#)

NOTE: FSMA **does not apply to making or handling meat, poultry or egg** products in establishments **regulated exclusively by the US Dept. of Agriculture**. Such establishments do not have to register with FDA.

2. If my operation is a farm mixed-type facility and the farm grows produce, what FSMA rules apply?

If your farm mixed-type facility also grows produce, the produce farming activities on the farm may be regulated under the FSMA Produce Rule. (To learn more about whether and how you might be affected by the Produce Rule, see the FSMA FAQ ['Is My Food Business a Farm?'](#))

NOTE: The PC Rules only apply to **food processing activities on your farm that are not covered** by the Produce Rule.

If your operation **ONLY** conducts harvesting, packing, and holding activities that are covered in the FDA's farm definition, your business is **not a farm mixed-type facility**: You are **not required to register** with FDA.

It is possible that a farm mixed-type facility growing produce is subject to the Produce Rule for its production, harvesting and handling of produce crops, **and** to the PC Rules for the food that is manufactured, packed, or held on farm and that is not covered by the Produce Rule. To learn more about what harvesting and handling activities are covered under the Produce Rule, see the FSMA FAQ ['Is My Food Business a Farm?'](#)

NOTE: With respect to produce operations, farm mixed-type facilities that

- (a) had average annual produce sales over 2016-18 greater than \$27,528;
- (b) had 2016-18 average annual sales of all food, livestock products, and crops of less than \$550,551; and
- (c) that made the majority of those food sales in 'local' markets,

are exempt from most of the Produce Rule. **Farm mixed-type facilities must include all food sales in calculating annual revenue** to determine if they meet the Produce Rule 'qualified exemption.' See the Carolina Farm Stewardship Association's FSMA FAQ ['Is Your Farm Covered by the Produce Rule?'](#) for more information about how the Produce Rule qualified exemption is determined.

3. If I am operating a farm mixed-type facility, what PC Rule requirements apply?

The PC Rule has two main components: regulations on sanitary operations, known as **Good Manufacturing Practices (GMPs)**; and regulations on **Hazard Analysis and Risk-Based Preventive Controls (HARPC)**, including **Supply-Chain Programs (SCP)**.

- a. **GMPs:** GMPs are not new, and a business that meets the definition of a facility making human food likely already has been complying with them. FSMA made some changes to GMP regulations, and those changes took effect in 2018 for all facilities that are covered by the PC Rules. Facilities that are solely engaged in (1) holding and/or transporting RACs; and/or (2) hulling, shelling, drying, packing and/or holding nuts without additional processing (such as roasting), are not required to comply with GMPs.

For information about the GMP rules, see the FSMA FAQ '[What Are FSMA's GMP Requirements?](#)'

SPECIAL RULES FOR DEHYDRATED PRODUCE: If your farm mixed-type facility is drying/dehydrating covered produce to create a distinct commodity (such as grapes into raisins, or fresh herbs to dried), you must either comply with GMPs or the Produce Rule standards for packing and holding produce when conducting that processing. To learn more about the Produce Rule's harvesting, packing, and holding requirements, see CFSA's FSMA FAQ '[What Are the Basic Requirements of the Produce Rule?](#)'

NOTE: In the case of farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of on-farm harvesting, packing, or holding. To learn more about the Produce Rule's harvesting, packing, and holding requirements, see CFSA's FSMA FAQ '[What Are the Basic Requirements of the Produce Rule?](#)'

- b. **HARPC and SCP:** HARPC and SCP are new prevention-oriented food safety requirements added by FSMA. The HARPC and SCP requirements do not apply to processing, handling or storing food on your farm mixed-type facility *if*:
- the food you make is already covered by existing rules for seafood HACCP, juice HACCP, dietary supplements, or alcoholic beverages; or
 - you only hold and store RACs that are not fruits or vegetables (e.g. grains); or
 - for 2019, you had 2016-18 average annual sales of crops, livestock products and processed human foods of less than \$1,101,103ⁱⁱ. This is the 'Qualified Facility' exemption; or
 - you have fewer than 500 employees and the only food processing activities your facility conducts are 'low-risk' as defined by FDA. For more information on the low-risk exemption, see the FSMA FAQ '[What are the Special FSMA Rules for Low-Risk Food Processing Activities?](#)'

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?](#)'

NOTE: Farm mixed-type facilities that are **covered by existing FDA rules for thermally processed low-acid canned foods are exempt** from HARPC and SCP with respect to **microbial hazards**. These facilities still must have HARPC programs to prevent contamination with chemicals, toxins, unapproved additives, allergens or physical hazards such as glass, metal fragments, etc.

Training: The PC Rule also requires all food-handling employees have the food safety training or experience appropriate to their jobs, and that a Preventive Controls Qualified Individual (PCQI) creates and manages your food safety plan.

4. **My farm mixed-type facility does not meet any of these exemptions. What do I do now?**

Your farm mixed-type facility is fully covered by PC Rule's HARPC and SCP requirements, in addition to GMPs. See the FSMA FAQs '[What Are the Requirements of HARPC and SCP Under FSMA?](#)' and '[What Are FSMA's GMP Requirements?](#)'

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

ⁱ The sales thresholds to in this paragraph are adjusted annually for inflation. For more information, see CFSA's FSMA FAQ '[What Are the Special Rules for Qualified Exempt Farms?](#)'

ⁱⁱ This threshold amount is good for 2019. The dollar thresholds for the qualified exemption is to be adjusted for inflation. For more information, see the FSMA FAQ '[What Are the Special Rules for Qualified Exempt Facilities?](#)'