

FSMA Frequently Asked Questions: ***Are You 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 manufactures 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 processed 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).

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 Sheet ‘***Is Your Farm Covered by the Produce Rule?***’)

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

So 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 on farm. To learn more about what harvesting and handling activities are covered under the Produce Rule, see the FSMA FAQ Sheet ‘***Are You a Farm?***’

NOTE: In 2017, farm mixed-type facilities that (a) have 2014-16 average annual produce sales greater than \$26,632; (b) have 2014-16 average annual sales of all food, livestock products and crops of less than \$532,645 (c) and that make the majority of those food sales in ‘local’ markets, are exempt from most of the Produce Rule. ***Farm mixed-type facilities must include all processed food sales in calculating annual revenue*** to determine if they meet the Produce Rule ‘qualified exemption.’ See the FSMA FAQ Sheet ‘***Is Your Farm Covered by the Produce Rule?***’ for more information about how the Produce Rule qualified exemption is determined.

3. What PC Rule requirements apply to farm mixed-type facilities?

The PC Rule applies to food processing or manufacturing, which FDA defines as:

“making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.”

NOTE: The PC Rule ***does not apply to meat*** products and foods ***regulated by the US Department of Agriculture.***

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)** and **Supply-Chain Programs (SCP)**.

A. **GMPs:** GMPs are not new, and a business making human food that currently meets the definition of a farm mixed-type facility has likely already been complying with them. PC Rule for Human Food makes some changes to GMP regulations, and those changes take effect in either:

- September 2017 if your farm mixed-type facility is a small business. The PC Rule for Human Food defines ‘small business’ as an operation with a 2014-16 average of annual combined sales of crops, livestock products and processed human foods of \$1,065,291 or more, in but fewer than 500 employees; or
- September 2018 if your facility is a very small business. The rule defines ‘very small business’ as an operation that has an annual average over the previous three years of less than \$1,065,291¹ in combined sales of crops, livestock products and processed human foods.

NOTE: Facilities with more than 500 employees are already required to be in the compliance. For information about the GMP rules, see the FSMA FAQ Sheet ‘**What Are FSMA’s GMP Rules?**’

B. **HARPC and SCP:** HARPC and SCP are a new a set of prevention-oriented food safety requirements. The HARPC and SCP requirements do not apply to a farm mixed-type facility if it:

- is already covered by existing rules for seafood HACCP, juice HACCP, dietary supplements, or alcoholic beverages;
- only holds and stores RACs that are not fruits or vegetables;
- has 2014-16 average annual sales of crops, livestock products and processed human foods of less than \$1,065,291 (or \$2,663,227 of average annual animal feed sales under the PC Rule for Animal Feed)². This is the ‘Qualified Facility’ exemption; or
- it has fewer than 500 employees and the only food processing activities it conducts are ‘low-risk’ as defined by FDA. For more information on the low-risk exemption, see the FSMA FAQ Sheet ‘**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 Sheet ‘**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.

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 PC Rule. Your deadline for compliance with the PC Rule depends on your facility’s size: See the FSMA FAQ Sheet ‘**Preventive Controls Rule Compliance Deadlines.**’ For information about the specific requirements of the PC Rules for human food, see the FSMA FAQ Sheets ‘**What are the Requirements of FSMA’s Preventive Controls Rule for Human Food?**’

¹ By the Sept. 2018 deadline for very small businesses to comply with relevant parts of the PC Rule for Human Food, the threshold for qualifying as a very small business will be adjusted for inflation, and so likely will be higher than \$1,065,291.

² This threshold amount is good for 2017. 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 Sheet ‘**What Are the Special Rules for Qualified Exempt Facilities?**’