

## FSMA FAQs: What are the Basic Requirements of FSMA's Preventive Controls Rules for Human Food?

### 1. My business manufactures/processes, packs, or holds human food and has to register as a 'facility' with FDA<sup>1</sup>. How are my activities regulated under FSMA?

The processing, packing, and storing of human food in your facility may be subject to at least portions of FSMA's Preventive Controls Rule for Human Food (PC Rule).

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

**NOTE:** If packing and holding produce RACs (Raw Agricultural Commodities) is the only activity your facility performs, you still have to register, but you may follow the Produce Rule's standards for packing and holding produce RACs. To learn more, see the FSMA FAQ '[Is My Produce-Packing Operation Covered by the Preventive Controls Rule for Human Food?](#)'

### 2. What are the PC Rule requirements for food facilities?

The PC Rules have 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 into dried), then you must comply with either the GMP requirements or the Produce Rule standards for packing and holding produce when conducting that processing. To learn more about the Produce Rule's packing and holding requirements, see the Carolina Farm Stewardship Association'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 in your 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 \$1,101,103<sup>2</sup>. This is the 'Qualified Facility' exemption; or

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<sup>1</sup> See the FSMA FAQ '[Is My Food Business Required to Register with FDA?](#)' for more about FDA's registration requirements for certain food businesses.

<sup>2</sup> 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?](#)'

- 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?'](#)

**PARTIAL EXEMPTION:** 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.

For more information about the HARPC and SCP requirements, see the FSMA FAQ ['What are the Requirements of HARPC and SCP Under FSMA?'](#)

**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.

### 3. My facility does not meet any of these exclusions. What do I do now?

Your facility is fully covered by the PC Rule's HARPC requirements, and the SCP requirements if your suppliers are responsible for preventing hazards in the food or ingredients they provide you. See the FSMA FAQ ['What are the Requirements of HARPC and SCP Under FSMA?'](#)

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