

## FSMA FAQs: What are the Special FSMA Rules for Low-Risk Processing?

### 1. I understand that FSMA's Preventive Controls Rules for Human Food regulates 'low-risk' foods differently than other foods. What are 'low-risk' foods under FSMA?

Congress included in FSMA a requirement that FDA study different types of food processing, packing, or holding activities applied to various foods to establish if there are combinations of activities and foods that are 'low-risk'. Congress also said that if FDA identified any such low risk combinations, the agency should exempt small processors located on farms from any Hazard Analysis and Risk-based Preventive Controls (HARPC) requirements under FSMA's PC Rule.

[FDA's analysis](#) found many food processing and handling activities that, when applied to certain raw materials or processed foods, present a low risk of causing serious adverse health consequences for consumers if the manufacturer fully follows Good Manufacturing Practices (GMPs). In other words, **if a business abides by the GMP portions of the PC Rule** in its processing or handling activities for those foods, **it will automatically control any food safety risks** that might be relevant for those foods.

For instance, if you are making and canning jams from high acid fruits, the combination of the acidity of the fruit and the high temperatures necessary to successfully can the jam (i.e. achieve an air-tight seal) will kill any pathogens that might be present in the food before processing.

FDA's PC Rule provides that an **on-farm establishment that only makes or handles foods on FDA's 'low-risk' list**, and that meets FDA's definition of a 'small' facility, is exempt from both the HARPC and the Supply Chain Program (SCP) portions of the PC Rule. **A 'small' facility is one with fewer than 500 employees.**

The 'low-risk' list is extensive, and covers many of the value-added activities that are commonly performed by start-up local foods businesses and on-farm producers. Find [the full 'low-risk' list here](#).

### 2. My business only produces/handles foods on the 'low-risk' list, and has fewer than 500 employees, but is not located on a farm. Does the exemption from HARPC and SCP apply to me?

No, the exemptions only apply to on-farm processing, **however, they still are important if your small business isn't on a farm.** That's because **the first step for compliance with both the HARPC and SCP** portions of the PC Rules is to **conduct an analysis of the food safety risks applicable to the foods** you handle or make and the processing activities you conduct. In the case of the 'low-riks' foods, FDA has already done that analysis for you, and **you can rely on FDA's determination that following GMPs addresses all the relevant risks** for those foods.

So you can fulfill your HARPC and SCP requirements by simply (1) documenting that the only foods you make are on the 'low-risk' list, citing the [FDA's analysis](#) that there are no hazards or supply chain risks that require additional controls; and (2) abiding by the GMP rules and documentation requirements.

### 3. What are the GMP requirements for these foods?

To learn more about the essentials of GMPs, see the FSMA FAQ ['What Are FSMA's GMP Rules?'](#)

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