

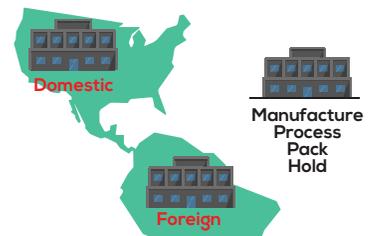
FOOD SAFETY MODERNIZATION ACT



Penn State Extension is helping produce growers, food processors, and feed manufacturers prepare for new regulatory standards required under the Food Safety Modernization Act (FSMA) of 2011.

Who is Covered Under the Preventive Controls for Human Food Rule?

In general, this rule applies to domestic or foreign food facilities that manufacture, process, pack or hold human food for consumption in the United States.



"Requires Domestic and Foreign Facilities that Manufacture, Process, Pack, or Hold Food for Human or Animal Consumption in the United States to Register with FDA"

The requirements apply to your company if your facility is required to register with FDA under section 415 of the Federal Food, Drug and Cosmetic Act.

Entities defined in FSMA as "farms," retail food establishments, and restaurants are some of the entities that are not subject to the preventive controls requirements because they are not required to register.

Not Required to Register

In addition, there are several exemptions or modified requirements that may apply. Facilities must comply with the requirements for risk-based preventive controls mandated by the FDA Food Safety Modernization Act (FSMA), as well as the modernized Current Good Manufacturing Practices (GMPs) of this rule (unless an exemption applies).

It is important to note that applicability of the GMPs is not dependent upon whether a facility is required to register. In general, the requirements for current good manufacturing practices (GMPs) apply to you if you manufacture, process, pack or hold human food.

As with the preventive controls requirements, there are exemptions and modified requirements, but they are not identical.

Compliance dates are staggered, based on the size of the business, with separate dates for the requirements of the supply chain program.

Supply Chain Program

To learn key facts about the preventive controls for human food rule visit: <https://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm584807.pdf>

For more information, please follow us at extension.psu.edu/fsma.

This program was developed by Food Safety CTS, LLC, for the USDA Food Safety and Agricultural Sustainability Training program and Penn State Extension.



Penn State College of Agricultural Sciences research and extension programs are funded in part by Pennsylvania counties, the Commonwealth of Pennsylvania, and the U.S. Department of Agriculture.

This publication is available in alternative media on request.

Penn State is an equal opportunity, affirmative action employer, and is committed to providing employment opportunities to all qualified applicants without regard to race, color, religion, age, sex, sexual orientation, gender identity, national origin, disability, or protected veteran status.