

FSMA Frequently Asked Questions: What Are FSMA's GMP Requirements?

My food business has to register as a food facility with FDA, and is required to follow Good Manufacturing Practices (GMPs). What are FSMA's GMP requirements?

FSMA applies the federal GMP regulations to almost¹ all food products regulated by the FDA. GMPs are intended to ensure that ingredients, finished products, and packaging materials are handled safely, and that food products are processed in a suitable environment. GMPs are the basis of a food safety program for your facility, and address the microbial, chemical, and physical hazards relevant to the products that you manufacture, pack, or hold that could cause illness or injury to consumers of those products. The GMP regulations are general in nature, and are intended to allow your business the flexibility to develop and implement practices appropriate to your food products.

NOTE: FDA's GMP rules do not apply to facilities that are **regulated exclusively**, throughout the entire facility, **by the U.S. Department of Agriculture** under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

The GMP rules address nine aspects of making and handling food:

1. **Personnel:** Covers food safety and hygiene training for employees, food worker hygiene practices, and preventing ill or infected employees from contaminating food.
2. **Plant and Grounds:** Addresses food facility design, construction, and maintenance elements necessary to avoid contamination, such as: preventing pests from entering the facility; ensuring walls, floors, ceilings are cleanable; separating activities that could cause cross-contamination; providing adequate space for sanitary arrangement of equipment and storage of materials; and controlling areas around the facility that could harbor pests or pathogens.
3. **Sanitary Operations:** Covers general cleaning, sanitizing, and maintenance actions necessary to ensure the plant and all fixtures within it are kept in good repair and maintained in a sanitary condition. Cleaning must be conducted in a manner that minimizes the possibility that foods, or equipment surfaces that contact food, will be contaminated by microbial or chemical hazards, including the ***eight major food allergens: milk, fish, crustacean shellfish, peanuts, tree nuts, wheat, soybeans, and eggs.***

NOTE: Your allergen control program must also ensure any of your products that intentionally contain any of the eight major food allergens are accurately labeled, including monitoring to verify that any labels used on finished products are correct and properly affixed to the product or package. For more information, see the FSMA FAQ ['What Are FSMA's Allergen Labeling Requirements?'](#)

4. **Sanitary Facilities and Controls:** Covers water supply, plumbing, waste water disposal, and toilet and handwashing facilities. In general, any water that comes into contact with food, food contact surfaces, or processing equipment must be safe and of adequate sanitary quality.
5. **Equipment and Utensils:** Requires that equipment and utensils be designed, constructed, and installed so that they are adequately cleanable, minimize potential pathogen contamination, and do not adulterate food with lubricants, fuel, metal fragments, contaminated water, other debris, allergen cross-contamination, as well as. Also requires that food contact surfaces are made from nontoxic materials, and that instruments used to measure critical aspects of food safety (such as pH, water activity, temperature) are calibrated to ensure accuracy.

¹ Off-farm facilities that only package, pack, and hold produce; and farm mixed-type facilities that are drying/dehydrating raw agricultural commodities to produce a distinct product (with no other processing such as pitting, slicing, freezing, etc.) may choose to follow relevant portions of the FSMA Produce Rule in carrying out those activities, instead of applying GMPs. For more information, see the FSMA FAQs ['Is My Produce Packing Operation Covered by the PC Rules?'](#) and ['Is My Business a Farm Mixed-Type Facility?'](#)

6. Processes and Controls: Addresses standard operating procedures in your facility to:

- ensure raw materials are free of contamination, and are stored and conveyed so as to prevent contamination of your food products from microbial, physical or chemical hazards (including allergens);
- monitor for factors that could prevent or cause contamination, such as time, temperature, humidity, and water activity
- minimize the potential that your production processes introduce hazards, such as by improper cooking or contact of food with uncontrolled sources of contamination; and
- provide for traceability through recordkeeping.

7. Warehousing and Distribution: Requires that food be stored and transported under conditions that will protect against allergen cross-contact; prevent deterioration of the food and the container; and protect against microbial, chemical, or physical contamination.

8. Holding and Distribution of Human Food By-products for Use as Animal Food: Covers procedures to avoid contamination of human food by-products that will be used as animal food without additional manufacturing or processing.

9. Defect Action Levels: Addresses steps to prevent foods that don't meet your quality assurance standards from becoming a source of contamination for other foods in your facility.

It is your responsibility to take all reasonable measures and precautions to maintain the basic operational and environmental conditions required to produce safe foods. Communicating the GMP rules with employees through training can minimize food safety risks significantly.

There are many resources and educational programs to help food businesses understand the details of GMPs and apply those practices in producing and handling foods. Options for getting started include:

- Cornell University's online GMP [course](#)
- North Carolina State University's [course](#)
- Carolina Farm Stewardship Association's GMP [manual](#)

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