

FSMA Frequently Asked Questions: ***What are the basic requirements of the Produce Rule?***

1. My farm is covered by the Produce Rule. What farming practices are governed by the rule?

Regulations under the FSMA Produce Rule require covered farms to address six potential routes of contamination for fresh produce: Workers, water, animal-derived soil amendments, animals, tools and equipment, and post-harvest handling.¹ This document provides a top-level overview of those requirements; for a more in-depth discussion of the specifics of each area, see the report from the National Sustainable Agriculture Coalition, "[Understanding FDA's FSMA Rule for Produce Farms.](#)"

a. Worker Training, Health and Hygiene

The Produce Rule standards on worker health and hygiene are similar to requirements for Good Agricultural Practices (GAPs). These include:

- reassignment of ill workers so they don't touch produce;
- employee personal cleanliness;
- handwashing;
- avoiding cross contamination when handling produce;
- having eating/break areas for workers that are separate from produce harvesting and handling areas;
- clean restroom facilities; and
- policies and practices to keep visitors from contaminating produce.

In addition, the rule sets food safety training requirements for all employees, and mandates that a 'responsible person' (i.e. a supervisor or manager) take an FDA-approved FSMA training.

b. Agricultural Water

The Produce Rule has a very complex rules governing 'agricultural water.' FSMA defines agricultural water as "water that is intended to, or likely to, contact the harvestable portion of covered produce or food-contact surfaces", and sets acceptable levels of fecal contamination for agricultural water. Water that does not come into contact with produce or food-contact surfaces is not covered by the rule.

The rules address the maintenance of your water system, and testing and treatment of your water supplies. Testing frequencies vary based on the source of the water and whether the water is treated to control pathogens, and the testing standards for potential fecal contamination vary based on the use of the water: Water used in harvest and post-harvest handling cannot have any detectable level of fecal contamination. The rule establishes procedures you must follow if a water source exceeds the allowable levels of fecal contamination.

Because of their complexity, covered farms have an additional two years to comply with key portions of the water rules. For information on these staggered and extended compliance deadlines, see the FSMA FAQ Sheet '[Produce Rule Compliance Deadlines by Farm Size.](#)'

c. Biological Soil Amendments of Animal Origin

The Produce Rule sets standards for handling, transporting, storing, treating, and applying biological soil amendments of animal origin (BSAAOs), which are soil amendments that consist partially or entirely of materials of animal origin. This includes, for example, raw and composted manure, agricultural teas that

¹ FSMA provides separate rules for the production and harvest of sprouts, which are not addressed in this document.

include animal materials in the mix, bloodmeal, feathermeal, and fishmeal.² The standards applicable to a BSAO depend on whether it is ‘treated’ or ‘untreated.’

To be counted as a treated soil amendment, the material must have been subject to a scientifically valid controlled physical, chemical, or biological process or combination of processes. For example, compost including animal material that is subject to either

- static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; or
- turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing,

is considered a ‘treated’ BSAO. Treated BSAAOs can be applied in a crop production area without any waiting period between application and harvest of produce from that area.

FDA is studying how long an interval should be required between applying untreated BSAAOs to a crop production area and harvesting that crop, but for now doesn’t have enough scientific information to justify a standard. At this time, FDA recommends produce farms follow the National Organic Program standards of maintaining a 120-day interval between the incorporation of untreated BSAAOs into the soil and the harvest of crops that come into contact with the soil during production, or a 90-day interval for crops that do not come into contact with the soil during production.

d. *Domesticated and Wild Animals*

You may not harvest produce that has been contaminated by animal waste. If there is a reasonable probability that grazing animals, working animals, or intrusion by wild or domesticated animals will contaminate produce in outdoor or partially-enclosed crop production areas, then you must assess those areas for evidence of potential contamination as needed during the growing season. If you find significant evidence of potential contamination (such as by observing animals, animal feces, or crop destruction), you must evaluate whether the nearby produce can be harvested, and take measures during growing to prevent the harvest of product that is reasonably likely to have been contaminated.

You are not required to totally exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. You are allowed to grow produce crops in fields where animals have grazed, so long as there is not a reasonable probability that the produce will be contaminated by excreta from the animals.

e. *Equipment, Tools, and Buildings*

The Produce Rule sets standards for the cleaning and sanitization of equipment and tools that are likely to contact covered produce, as well as requirements on buildings where produce is handled or stored to prevent contamination and harborage of pests.

f. *Post-Harvest Handling*

The Produce Rule requires you to take measures to avoid cross contamination and to handle harvested produce in a way that prevents contamination by known or reasonably foreseeable hazards; and to use packaging that is unlikely to support the growth or transfer of bacteria.

2. What else does the Produce Rule cover?

For each of the six areas identified above, you must keep records to prove you are following the rule’s requirements. In general, records must include:

- The name and location of the farm;

² FSMA prohibits the use of human waste as a soil amendment, including sewage sludge biosolids.

- Actual values and observations obtained during monitoring;
- A description of the produce relevant to the record (i.e. commodity type and lot number);
- The location of the growing or post-harvest area (e.g. specific field or packing shed); and
- The date and time of the activity documented.

Records should be created at the time an activity is performed or observed; be accurate and legible; and be dated and signed or initialed by the person who performed the documented activity. The farm supervisor must either make or review any records pertaining to: training; water tests results; water treatment monitoring; allowable applications of water that exceeds fecal contamination thresholds; composting process controls for compost you make on your farm; and cleaning and sanitizing tools and equipment.

Records can: be based on existing records; be in written or electronic form; be either the original or photocopied or scanned copies; and be stored offsite as long as they can be retrieved within 24 hours. You must retain all required records for at least two years past the date the record was created.

Congress made sure that FSMA **does not** require you to register your farm with the federal Food and Drug Administration (FDA) or with state food safety authorities, nor require you to obtain a third-party food safety audit. But be warned that FDA is trying to find ways around those Congressional prohibitions. CFSA and other farmer organizations are working to prevent FDA from circumventing the law.