

FSMA FACT SHEET

What Do Farms Need to Do to Comply with FSMA?

Key Requirements

"Farms" are covered by the FSMA Produce Safety Rule (21 CFR Part 112)

- See the fact sheet entitled "Is My Operation a "Farm" Covered by the Produce Safety Rule?" to determine whether you are a "farm."

There are two options to comply with the Produce Safety rule:

- Option 1: Provide a written disclosure and obtain a written assurance of commercial processing; or
- Option 2: Comply with specific requirements relating to good agricultural practices.

Option 1: Written Disclosure and Written Assurance

The regulations provide that if almonds receive commercial processing that adequately reduces the presence of microorganisms of public health significance, you are not required to comply with the produce rule if you:

- 1) Disclose in documents accompanying the almonds, in accordance with the practice of the trade, that the almonds are "not processed to adequately reduce the presence of microorganisms of public health significance," and either
 - 2) A. Annually obtain written assurance from the customer that performs the commercial processing that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or
 - B. Annually obtain written assurance from your customer that an entity in the distribution chain subsequent to the customer will perform the commercial processing and that corresponding disclosures and assurances will be provided down the chain.

Based on discussions with the FDA, ABC advises meeting this requirement by taking the following steps:

- 1) Growers will provide a written disclosure to the handler: "Almonds are not processed to adequately reduce the presence of microorganisms of public health significance."
- 2) Handlers will provide a written assurance to the grower (as part of their annual contract) that explains that the almonds will be subject to processing (following procedures under the Marketing Order) that will adequately reduce the presence of microorganisms of public health significance, or otherwise the almonds will be exported.

Note: The FDA has not formally sanctioned this approach and it is not entirely aligned with the regulations.

Option 2: Good Agricultural Practices Requirements

The Produce Safety rule sets out standards to address the following six hazards: 1. agricultural water; 2. biological soil amendments; 3. worker hygiene; 4. employee training; 5. buildings, tools and equipment; and 6. domesticated and wild animals. Summaries of several of the key requirements in each of these areas are below.

1. Agricultural Water

Water Quality: The rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic E. coli, which can indicate the presence of fecal contamination.

- No detectable generic E. coli are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact.
- There also is a set of numerical criteria for the microbiological quality of agricultural water that is directly applied to growing produce.

If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year.

Testing: The rule bases testing frequency on the type of water source (i.e., surface or ground water). There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements established in the rule, or if the water is treated in compliance with the rule's treatment requirements.

2. Biological Soil Amendments

Raw Manure: The FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination.

- At this time, the FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.
- The final rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact produce during application and minimizes the potential for contact with produce after application.

Stabilized Compost: Microbial standards that set limits on detectable amounts of bacteria have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

3. Worker Hygiene

Requirements for health and hygiene include:

- Taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons.
- Using hygienic practices when contacting produce or food-contact surfaces, for example, washing and drying hands thoroughly at certain times such as after using the toilet.
- Taking measures to prevent visitors from contaminating produce and/or food contact surfaces, for example, by making toilet and hand-washing facilities accessible to visitors.

4. Employee Training

Farm workers who handle produce and/or food-contact surfaces, and their supervisors, must:

- Be trained on certain topics, including the importance of health and hygiene; and
- Have a combination of training, education and experience necessary to perform their assigned responsibilities.

5. Buildings, Tools and Equipment

- The rule establishes standards related to equipment, tools and buildings to prevent these sources from contaminating produce. This section of the rule covers, for example, toilet and hand-washing facilities.
- Required measures to prevent contamination of produce and food-contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

6. Domesticated and Wild Animals

- The rule establishes the same standards for grazing animals (such as livestock) and working animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers must assess the growing area for evidence of potential contamination during the growing season. If significant evidence of potential contamination is found, farmers must evaluate whether the produce can be harvested and take measures reasonably necessary to assist later during harvest. Such measures might include, for example, placing flags outlining the affected area.
- Farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas.

Exemptions and Modified Requirements

The rule does not apply to:

- Produce that is used for personal or on-farm consumption.
- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less.
- The rule also provides a qualified exemption and modified requirements for certain farms with food sales averaging less than \$500,000 per year and for which the majority of sales were to either consumers or local restaurants or retail food establishments.

Compliance Dates

FSMA Rule	Compliance Date	Notes/Explanations
>\$500,000 in annual produce sales	January 26, 2018	Farms have an additional two years to comply with certain water-related requirements ¹
	January 27, 2020	For compliance with the written customer assurance requirement only; if relying upon written disclosures/assurances for exemption from the rule
\$250,000–\$500,000 in annual produce sales	January 28, 2019	Farms have an additional two years to comply with certain water-related requirements ¹
	January 26, 2021	For compliance with the written customer assurance requirement only; if relying upon written disclosures/assurances for exemption from the rule
\$25,000–\$250,000 in annual produce sales	January 27, 2020	Farms have an additional two years to comply with certain water-related requirements ¹ Exemption for farms with <\$25,000 in produce sales January 26, 2016, compliance date for records supporting eligibility for qualified exemption and compliance with modified requirements
	January 26, 2022	For compliance with the written customer assurance requirement only; if relying upon written disclosures/assurances for exemption from the rule

¹Provisions with extended compliance dates include: (1) The specific microbiological criteria that apply to agricultural water; (2) Corrective measures that must be taken if agricultural water does not meet requirements; (3) The frequency of testing agricultural water; and (4) Records associated with data to support a microbial die-off rate, corrective measures, test results from a public water system, or data used to support alternative die-off rates, criteria or sampling strategies.

Additional Resources

- Almond Board of California: Almonds.com/growers/fsma
- FDA Resources on Produce Safety Rule: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- Produce Safety Alliance: <https://producesafetyalliance.cornell.edu/>
- UC Davis – FSMA Produce Safety Rule website (includes agricultural water calculator tool): http://ucfoodsafety.ucdavis.edu/Pre-_-Post-harvest_Produce/FSMA/
- University of Arizona – Fresh Produce Safety Website: <https://cals.arizona.edu/fps/node/57/>