

Food Safety Modernization Act (FSMA)

Proposed – Sec. 105 Produce Rule

Following is a summary from the Food and Drug Administration's presentations on FSMA. This is not a complete summary.

The first two proposed rules were published in the Federal Register on January 16. You can obtain copies at the FSMA website: www.fda.gov/fsma. The first, the produce safety rule, proposes enforceable standards for the growing, harvesting, packing and holding of produce on farms.

The second, preventive controls for human food would require food companies to develop a formal plan for preventing food at their facilities from causing illness. The plan would identify potential hazards, put in place steps to address them, verify that the steps are working, and outline how to correct any problem that arise.

These two proposed rules are the first among five rules that will lay the cornerstone of a prevention-based food safety system. These proposed rules work together to address hazards in the commodities the Food and Drug Administration (FDA) regulates and to address food safety both in domestically produced and imported foods. FDA expects to soon propose the other three rules: Foreign Supplier Verification Program, Preventive Controls for Animal Food and Accredited Third Party Certification.

The following discussion covers the food safety rule only which directly impacts growers. The proposed produce safety rule will cover farms that grow, harvest, pack or hold most produce in their raw or natural state. It also covers farm portions of mixed-type facilities. These are farms that are also engaged in activities that do not fit in the definition of farm and require food facility registration. An example is a farm that grows and harvests produce, but also processes fresh-cut produce that requires the packinghouse to be registered. In this case, what the farm grows and packs would be subject to the produce rule, but the fresh-cut operation may fall under the preventive controls proposed rule.

The proposed rule would cover farms with an average annual value of food sold during the previous three-year period of more than \$25,000. Farms less than \$25,000 are not covered since they represent less than one percent of all produce in commerce. This proposed rule would cover domestic and imported produce.

Crops covered under this rule are raw fruits and vegetables plus mushrooms, sprouts, herbs and tree nuts. The following are **not** covered:

1. Product that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership.
2. Produce that is not a raw agricultural commodity e.g. fresh-cut salads

3. Produce identified in the rule that is rarely consumed raw e.g. beets, Brussels sprouts, cranberries, eggplant, okra, peanuts, white and sweet potatoes. See the proposed rule for additional crops.
4. Produce that will receive commercial processing that adequately reduces the presence of microorganisms of public health significance provided documentation is kept.
5. The rule contains exemption for farms with retail food sales less than \$500,000 per year, using a 3-year average and sell to qualified end users (direct to consumer, restaurant, retail food establishment in same state or within 275 miles of where the produce was grown).

The proposed rule focuses on identifying routes of microbial contamination. They are:

1. Agricultural water
2. Biological soil amendments of animal origin
3. Domesticated and wild animals
4. Equipment, tools, buildings and sanitation
5. Growing, harvesting, packing and holding activities
6. Worker health and hygiene
7. Specific requirements for sprouts

Agricultural Water

The proposed rule defines agricultural water as water that is used in covered activities and on produce where it will or is likely to come in contact with produce or food-contact surfaces, including:

- Water used in growing (irrigation directly applied, spray water and sprout growing).
- Water used in harvesting, packing and holding including washing, cooling or to prevent dehydration.

All agricultural water must be safe and of adequate sanitary quality for its intended use. At the beginning of the growing season, the agricultural water system under the farm's control would have to be inspected to identify conditions that are reasonably likely to introduce pathogens to produce or food-contact surfaces and maintained to prevent it from becoming a source of contamination. When changes are made, the system would need to be re-inspected and tested or treated. There are specific requirements for certain usage with periodic analytical testing.

Biological Soil Amendments of Animal Origin

The proposed rule focuses on biological soil amendments of animal origin because of the potential for these types of soil amendments to contaminate produce with pathogens of public health concern. It defines treated and untreated amendments and how to handle, convey and store the amendment. It establishes requirements for treatment of the soil amendments with scientifically valid, controlled, physical and/or chemical processes or composting processes that meet or exceed specific microbial standards. The proposal establishes application requirements and minimum application intervals

for untreated and treated amendments of animal origin. Records would be needed for application and harvest dates, suppliers of treated amendments and scientific data or information to support any permitted alternatives.

Domesticated/Wild Animals

Domesticated and wild animals are a possible route of contamination because pathogens can be introduced into fruit and vegetables through animal feces. These requirements would only apply when there is a reasonable probability that animals will contaminate covered produce. For example, when covered produce grows completely underground, FDA expect that there would not be a reasonable probability of contamination by animals that may graze or encroach into fields. If grazing or working animals will likely contaminate covered produce, you would be required to:

- Wait an adequate amount of time between grazing and harvesting any growing area to ensure the safety of the harvested crop, and
- If working animals are used in a growing area where a crop has been planted, implement measures to prevent the introduction of hazards onto covered produce from the animals. For example, if you use draft horses, you could establish and use horse paths that are segregated from the produce.

If there is a reasonable probability that animal intrusion will contaminate covered produce, you would be required to monitor for evidence of animal intrusion immediately before harvest and, as needed, during the growing season.

- If you see evidence of animal intrusion, such as significant quantities of animals, animal excreta, or crop destruction via grazing, you must evaluate whether some or all of the covered produce can be safely harvested. For example, if you see evidence of bird excreta on a head of lettuce, you would not be allowed to harvest it.

Equipment, Tools and Buildings

The proposed rule would set standards for certain equipment and tools, buildings and sanitation used for produce operations.

Equipment and tools

- Must be of adequate design, construction and workmanship to enable them to be adequately cleaned and properly maintained
- Must be stored and maintained to protect the produce from being contaminated and to prevent equipment and tools from attracting and harboring pests
- Food-contact surfaces must be inspected, maintained, cleaned and sanitized as frequently as reasonably necessary to protect against contamination
- Instruments used to measure, regulate or record temperatures, pH, sanitizer efficiency, or other conditions that control or prevent contamination must be accurate and adequately maintained

Buildings

- Must be suitable in size, construction and design to facilitate maintenance and sanitary operations for covered activities to reduce potential for contamination
- Adequate space must be available for placement of equipment and storage of materials
- Constructed in such a manner that floor, walls, ceilings, fixtures, ducts and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials.
- Must take reasonable measures to protect against contamination of covered produce from domesticated animals and pests
- Must have adequate, readily accessible toilet and handwashing facilities
- Proper disposal of sewage, trash, litter and waste
- Plumbing systems must be properly designed, installed and maintained

Growing, Harvesting, Packing and Holding Activities

- For operations handling both crops covered and excluded produce, if excluded produce is not handled in accordance with the rule, separate the two types of produce and clean and sanitize, as necessary, food contact surfaces used on excluded produce before those surfaces come in contact with covered produce.
- Identify and not harvest covered product that is reasonably likely to be contaminated, including not harvesting produce visibly contaminated with animal excreta.
- Handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards. For example, avoid the soil coming in contact with cut surfaces of harvested produce with the soil.
- Not distributing covered produce that drops to the ground before harvest unless it will be commercially processed to kill pathogens
- Food packing materials must be adequate for their intended use (cleanable or designed for single use, and unlikely to support growth or transfer bacteria)
- If food-packing material is to be reused, measures must be taken to ensure the food contact surfaces are clean.

Worker Health and Hygiene

- Personnel who handle covered produce or supervise such personnel must receive training including specified topics
- Measures to prevent contamination of covered produce and food-contact surfaces from any person with an applicable health condition, such as a communicable illness, infection, open lesion, vomiting, or diarrhea
- Personnel who work in operations in which covered produce or food-contact surfaces are at risk of contamination must use hygienic practices to the extent necessary to protect against such contamination. Includes:
 - Maintaining adequate personal cleanliness
 - Avoiding contact with animals other than working animals

- Minimizing contact with covered produce when in direct contact with working animals
- Washing hands thoroughly before and after certain activities and at other times, and
- Maintaining gloves appropriately (if gloves are used)
- Measures to ensure that visitors are aware of policies and procedures to protect covered produce and food-contact surfaces from contamination; toilet and handwashing facilities must be accessible to them.

Requirements for Sprouts

Sprouts present a unique risk because the warm, moist, and nutrient-rich conditions required to produce sprouts are the same conditions that are also ideal for the growth of pathogens. Sprout firms would also be subject to all other relevant subparts of the proposed rule. Following are some of the proposed rules:

Building and sanitation

- Growing, harvesting, packing and holding of sprouts must be done in a fully-enclosed building
- Any food-contact surfaces that come in contact with sprouts, seeds, or beans must be cleaned and sanitized;

Beans and seeds

- If your farm grows seeds or beans for use to grow sprouts, you must take measures reasonably necessary to prevent the introduction of hazards into or onto seeds or beans
- If you know or have reason to believe that a “lot” of seeds or beans have been associated with foodborne illness, you must not use it
- You must visually examine seeds, beans, and packaging used to ship them for signs of potential contamination

Seed treatment

- Treat seeds or beans using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. Prior treatment by a grower, handler, or distributor of seeds or beans does not eliminate your responsibility to treat seeds or beans immediately before sprouting at your covered farm

Spent irrigation water testing

- Test spent irrigation water from each production batch of sprouts, or the sprouts themselves, for *E. coli* O157:H7 and *Salmonella* species

Listeria testing

- Monitoring the growing, harvesting packing, and holding environment for *Listeria* spp. or *L. monocytogenes*. Take appropriate follow-up actions if needed.

Written plan

- Establish and implement a written environmental monitoring plan (that also includes a sampling plan that addresses *Listeria* species or *L. monocytogenes*) and a written sampling plan for sampling sprout irrigation water or sprouts.

Records

- Require certain records, including documentation of your treatment of seeds or beans for sprouting, the written environmental monitoring plan and sampling plan, test results, and certain methods used

Alternatives Permitted

The proposed rule would provide that farms may establish alternatives to certain requirements related to: water and biological soil amendments of animal origin if the alternative is scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration.

Variations Allowed

The proposed rule also is flexible in that it would allow a state or foreign country to request a variance from some or all provisions of the proposed rule. The state or country would need to determine that it is necessary in light of local growing conditions. Practices under the proposed variance provide the same level of public health protection as the requirements of the proposed rule without increasing the risk of adulteration. The proposed rule provides a process by which FDA would consider such requests and approve or deny them.

Recordkeeping Required

The proposed rule would require certain records, for example, to document that certain of the standards are being met. Agricultural water testing results are an example. However, it would not require duplication of records already being kept for other purposes.

Compliance Dates Staggered

Compliance dates for the produce safety rule are staggered based on size. FDA is proposing 60 days as the effective date after the final rule is published, but farms do not have to meet the requirements on this date.

Very Small Farms – Very small farms that have an average annual value of food sold of more than \$25,000 and no more than \$250,000. These farms would have four years after the effective date to comply. For some water requirements, they would have six years to comply. This is a total of six years to comply.

Small Farms - Small farms that have an average annual value of food sold of more than \$250,000 and no more than \$500,000. They would have three years after the effective

date to comply. For some water requirements, they would have five years to comply. This is a total of five years to comply.

Farms over \$500,000 - Other farms that do not meet the definition of “very small” or “small” would have two years after the effective date to comply. For some water requirements, they would have four years to comply. This is a total of four years to comply.