

FSMA Produce Rule: Domestic and Foreign Farms Impacted

The U.S. Food and Drug Administration's (FDA's or the Agency's) proposed rule, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Produce Rule), will establish science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms.¹

In the Produce Rule, which applies to most fruits and vegetables while they are in their raw or natural (unprocessed) state, FDA proposes to set standards associated with identified routes of microbial contamination of produce, including, but not limited to, the following: (1) agricultural water; (2) biological soil amendments of animal origin; (3) health and hygiene; (4) animals in the growing area; and (5) equipment, tools, and buildings.

The Agency stated that its proposed regulatory approach focuses on the likelihood of contamination of produce posed by the agricultural practices applied to crops, while exempting only the lowest-risk produce. Based on its qualitative assessment of risk (QAR) of hazards related to produce production and harvesting, the Agency determined that produce commodities are potentially subject to similar microbiological hazard pathways (e.g., direct exposure to contaminated water or soil amendment). In response to these similar hazard pathways, FDA is proposing to adopt a regulatory approach to minimize the risks associated with those hazards, while providing industry flexibility to adopt alternative approaches when appropriate.

Scope of Coverage

The proposed Produce Rule would apply to certain farm activities performed on certain produce for use as human food (importantly, the Agency states that produce intended for use as animal food would not be subject to the proposed rule). The Produce Rule will cover food that is a raw agricultural commodity (RAC), as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (FDCA), which falls under the proposed definition of "produce." In the proposed rule, "produce" is defined as any fruit or vegetable (including specific mixes or categories of fruits and vegetables) grown for human consumption and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs (which are included in the definition to leave no doubt as to the status of these foods).

Exempted from the Produce Rule are food grains—meaning the small, hard fruits or seeds of arable crops or the crops bearing these fruits or seeds—that are grown and processed for use as meal, flour, baked goods, cereals, and oils rather than for fresh consumption. Further, the proposed rule provides an exclusion for produce that is rarely consumed raw and includes an "exhaustive" list of specific fruits and vegetables that would be exempt, including the following: arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chickpeas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams.

Additionally, produce receiving commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., a "kill step") would be eligible for exemption from the requirements of the Produce Rule as long as certain documentation is kept. One cited example of a product that receives commercial processing is green beans destined for a canning operation.

Under the proposed Produce Rule, a "farm" is defined as a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

In addition, a "mixed-type facility" is defined as an establishment that engages in both activities that are exempt

1. View the proposed rule at http://www.ofr.gov/OFRUpload/OFRData/2013-00123_PI.pdf.

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from registration under section 415 of the FDCA and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition but which also conducts activities that require the establishment to be registered.

The Produce Rule would apply to both domestic and imported covered produce. However, some farms would not be covered by the rule or would be eligible for a partial exemption based on factors including, but not limited to, the monetary value of their food sales and the types of persons or entities to whom they sell.

Additionally, the Produce Rule would not cover farms that have an average annual value of food sold during the previous three-year period of \$25,000 or less.

Finally, the Produce Rule would provide a qualified exemption and modified compliance requirements for farms that meet the following two requirements: (1) the farm must have food sales averaging less than \$500,000 per year during the last three years, **and** (2) the farm’s sales to “qualified end users” must exceed sales to others. A qualified end user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state as the farm or not more than 275 miles away. Instead, these farms would be required to include their names and complete business addresses either on the label of the produce that would otherwise be covered (if a label is required under the FDCA and related regulations) or at the point of purchase. However, FDA may withdraw this exemption in the event of an active investigation of an outbreak that is directly linked to the farm or if it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions on the farm that are material to the safety of the produce.

Rule Framework as Compared with Other FDA Regulations

In some instances, FDA’s proposed requirements in the Produce Rule are very similar to those contained in the food-related current good manufacturing practices (cGMPs) regulations, 21 C.F.R. pt. 110. This is particularly true where the routes of contamination are well understood and appropriate measures are well established and generally applicable across covered produce commodities (e.g., personnel qualifications; training, health, and hygiene; harvesting, packing, and holding activities; and equipment, tools, buildings, and sanitation).

In other cases, FDA has proposed specific numerical standards against which the effectiveness of a farm’s measures would be compared as well as actions to be taken to bring the operation into conformance with the standards, as necessary (e.g., proposed standards for agricultural water, biological soil amendments of animal origin, and sprout environmental testing and spent sprout irrigation water testing). FDA proposes to rely on such an approach where the effectiveness of individual measures (e.g., protection of agricultural water sources from contamination, establishment of application intervals for certain soil amendments, and chemical disinfection treatment of seeds before sprouting) is not complete or fully known and/or because much of what affects the on-farm route of contamination is outside the control of the farm (e.g., the quality of a particular surface water source). The Agency’s proposed use of numerical standards is similar to the requirement for egg testing in the Shell Egg Regulation, 21 C.F.R. pt. 118.

With regard to some other provisions in the Produce Rule, FDA has proposed a standard that requires farms to inspect or monitor an on-farm route of contamination and take appropriate measures if conditions warrant. The Agency explained that it relies on such a monitoring approach where the diversity of conditions that can be expected relative to an on-farm route of contamination is very high, making it impractical to set out a standard that specifies the appropriate measures for each possible circumstance (e.g., a requirement for monitoring for animal intrusion and a requirement for inspection of an agricultural water system). The Agency’s use of inspection and monitoring, followed by appropriate corrective action, is similar to the requirement to monitor for rodent activity and to take corrective action on egg farms in the Shell Egg Regulation.

Finally, for other instances not addressed above, FDA has proposed a standard that requires farms to develop written plans committing to specific measures (e.g., sprout environmental testing and spent sprout irrigation water testing). According to the Agency, the use of written plans is appropriate where the details of the measures to be taken are more than can be reasonably expected to be retained in memory, especially where the details may change over time and a historical record of the evolution of the measures is important for the operator to assess whether further changes to the measures are needed (e.g., changes or rotations in the sampling sites for sprout environmental testing). FDA’s proposed use of written plans in these specific instances is similar to the

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requirement for a written *Salmonella Enteritidis* prevention plan on egg farms in the Shell Egg Regulation.

Science-Based Minimum Standards

The Produce Rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms in the following major areas: (1) worker training and health and hygiene; (2) agricultural water; (3) biological soil amendments; (4) domesticated and wild animals; (5) equipment, tools, and buildings; and (6) sprouts.

Worker Training and Health and Hygiene

The Produce Rule would do the following:

- Establish qualification and training requirements for **all** personnel who handle (contact) covered produce or food-contact surfaces, as well as their supervisors.
- Require documentation of required training.
- Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance (e.g., bacteria and viruses that can cause disease).

Regardless of the nature of a farm's workers, FDA proposes that each worker receive training upon hiring and at the beginning of each growing season, with periodic training updates as necessary in order to prevent contamination of covered produce.

Agricultural Water

The Produce Rule would do the following:

- Require that all "agricultural water" be of safe and sanitary quality for its intended use. "Agricultural water" is defined in the proposed rule as water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (such as irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and water used in harvesting, packing, and holding activities (such as water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).
- Establish requirements for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce.
- Require treatment of agricultural water if the farm knows or has reason to believe that the water is not safe and of adequate sanitary quality for its intended use, including requirements for treating such water and monitoring its treatment.
- Establish specific requirements for the quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water and requiring certain actions to be taken when such water does not meet the quality standards.
- Require certain records to be kept, including documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, water testing results, and scientific data or information relied on to support any permitted alternatives to requirements.

FDA's proposed definition of "agricultural water" in the Produce Rule is different from its definition of "agricultural water" in the Agency's Good Agricultural Practices Guide—both because such water is not limited in the proposed Produce Rule to water in the growing environment and because FDA proposes to exclude water that does not contact covered produce from this definition based on the information in the Agency's QAR.

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Biological Soil Amendments

The Produce Rule would do the following:

- Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated and for its handling, conveying, and storing.
- Prohibit the use of human waste for growing covered produce except in compliance with U.S. Environmental Protection Agency regulations for such uses.
- Establish requirements for the treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical, and/or chemical processes or composting processes that satisfy certain specific microbial standards.
- Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin.
- Require certain records to be kept, including documentation of application and harvest dates relevant to application intervals, documentation from suppliers of treated biological soil amendments of animal origin, and periodic test results.

FDA proposes to prohibit the use on covered produce of biological soil amendments that present the greatest likelihood of pathogen contamination (i.e., untreated human waste). Untreated manure or other untreated biological soil amendments of animal origin, which are less likely to be contaminated with human pathogens than human waste but are relatively likely to be contaminated, would be permitted under the Produce Rule, subject to stringent requirements. Manure or other biological soil amendments of animal origin that have been properly composted to reduce the level of pathogens contained therein would be subject to less stringent requirements, and certain chemically or physically treated biological soil amendments of animal origin that receive more robust treatments to eliminate pathogens would be subject to the least stringent requirements.

Domesticated and Wild Animals

The Produce Rule would do the following:

- If animals are allowed to graze or are used as working animals in fields where covered produce is grown and where, under the circumstances, there is a reasonable probability that grazing or working animals will contaminate covered produce, the Produce Rule would require, at a minimum, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed, as well as measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.
- If, under the circumstances, there is a reasonable probability that animal intrusion will contaminate covered produce, the Produce Rule would require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and, as needed, during the growing season.

The Produce Rule would not prohibit the use of on-farm domesticated working animals, but it would require covered farms to take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce if working animals are used in a growing area where a crop has been planted and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

Equipment, Tools, and Buildings

The Produce Rule would do the following:

- Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta.
- Require certain records to be kept related to the date and method of cleaning and sanitizing equipment used in growing operations for sprouts and in covered harvesting, packing, or holding activities.

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Additional examples of equipment and tools provided in the Produce Rule are knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport).

Additional examples of buildings provided in the Produce Rule are any fully or partially enclosed buildings used for covered activities, including minimal structures that have roofs but do not have any walls. FDA explained that fully enclosed buildings are typically used to grow covered produce, such as sprouts and mushrooms, and may be used to grow a variety of covered produce indoors to create or extend the growing season in a particular geographic area. FDA also explained that partially enclosed buildings can be used to grow covered produce, such as tomatoes, and are often used to pack covered produce. Buildings that are subject to the requirements of the Produce Rule would also include storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials).

Sprouts

The Produce Rule would do the following:

- Establish measures that must be taken related to seeds or beans for sprouting.
- Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts.
- Require that covered farms test the growing environment for *Listeria* spp. or *L.monocytogenes* and that covered farms test each production batch of spent irrigation water or sprouts for *E. coli* O157:H7 and *Salmonella* species and take appropriate follow-up actions.
- Require certain records to be kept, including documentation of the treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, and certain methods used.

Because sprouts have been frequently associated with foodborne illness outbreaks, FDA proposed minimal standards specifically for them. FDA explained that sprouts present a special concern with respect to human pathogens, as compared with other covered produce, because of the warm, moist, and nutrient-rich conditions required to produce sprouts—the same conditions that are also ideal for the proliferation of pathogens if present. FDA is seeking comment on whether, or to what extent, the proposed requirements in the Produce Rule should be applied to soil-grown sprouts.

Alternatives and Variances

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

The Produce Rule also would allow a state or foreign country to request from FDA a variance from some or all provisions of the rule if the state or country determines that it is necessary in light of local growing conditions and if practices under the proposed variance provide the same level of public health protection as the requirements of the Produce Rule without increasing the risk of adulteration.

Implementation and Compliance Time Frames

While the proposed Produce Rule has an effective date of 60 days after the final rule is published in the *Federal Register*, FDA proposes a longer timeline for farms to come into compliance. Farms that are considered “small businesses” would have three years after the effective date to comply with most of the Produce Rule’s requirements (except for some of the rule’s water requirements, for which they would have five years to comply). For purposes of the Produce Rule, FDA considers small businesses to be those covered farms and, on a rolling basis, those farms for which the average annual monetary value of food sold during the previous three-year period is no more than \$500,000.

In addition, farms that are classified as “very small businesses” would have four years after the effective date to

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comply with most of the Produce Rule's requirements (except for some of the rule's water requirements, for which they would have six years to comply). For purposes of the Produce Rule, FDA considers very small businesses to be those covered farms and, on a rolling basis, those farms for which the average annual monetary value of food sold during the previous three-year period is no more than \$250,000.

All other farms (i.e., those not classified as "small businesses" or "very small businesses") would have two years after the effective date to comply with most of the Produce Rule's requirements (except for some of the rule's water requirements, for which they would have four years to comply).

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