Understanding FSMA: The Produce Safety Rule

Discussion of farming activities and produce covered in the Produce Safety Rule under the Food Safety Modernization Act (FSMA), key requirements, possible exemptions, and deadlines for compliance.

Food Safety Modernization Act

The Food Safety Modernization Act (FSMA) is considered to be the most sweeping reform of food safety laws in more than 70 years. Signed into law by President Obama on January 4, 2011, it directs the U.S. Food and Drug Administration (FDA) to shift the focus away from merely responding to contamination events toward establishing systems to prevent them from occurring. Seven regulations were written under the law, each of which will affect the vast and complex food production, processing, and distribution network that provides consumers with an uninterrupted supply of safe, nutritious, and affordable food. One of these regulations, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," is of critical importance to growers of fresh produce. Known more simply as the "Produce Safety Rule," this regulation establishes, for the first time, science-based minimum food safety standards for growing, harvesting, packing, and holding fruits, vegetables, mushrooms, and sprouts intended for human consumption.

The following is a discussion of:

1. farming activities and types of produce that are covered under the rule,
2. key requirements within the regulation,
3. certain exemptions and modified requirements for which farms may be eligible, and
4. deadlines for complying with the rule.

Coverage under the Produce Safety Rule

When we say that a type of produce, a produce-growing activity, or a farm or orchard is "covered" under the regulation, we mean that growers who meet the criteria for coverage will need to comply with the farm food safety standards written in the regulation. Not all produce or growing activities are covered. Retail establishments where produce is sold or served to consumers (e.g., farm stands, farmers markets, grocery stores, and restaurants) are not covered under the regulation, although they may be covered under other state or local regulations. Only commercial produce farms are affected. Home gardens are not regulated.

Criteria for determining which farms or types of produce are covered are based on the size of the farm in terms of annual sales and the inherent risk for some commodities to cause illness if they were to become contaminated.

Fruits, vegetables, sprouts, and mushrooms covered under the regulation are:

1. Grown on commercial farms with average annual produce sales of at least $25,000 calculated over the previous three years of production. Sales values in the regulation written in 2011 must be adjusted upward each year to account for inflation (see the calculation tool on the FDA website).

2. Likely to be eaten raw (e.g., leafy greens, cucumbers, tomatoes, summer squash, and most fruits). Raw produce is considered riskier than cooked fruits and vegetables where any harmful microorganisms are likely to be destroyed.

Put another way, produce not covered under the regulation includes those commodities that are:
• Grown on farms with average annual produce sales less than $25,000 (increased each year to account for inflation).
• Rarely eaten raw (e.g., potatoes, winter squash, pumpkins, and some root crops). FDA has an exhaustive list of produce that is rarely consumed raw, and thus not covered under the regulation.

Qualified and processing exemptions are available wherein all parts of the rule are not required and only certain modified requirements are in place. These will be discussed later in this article. Keep in mind that even if you think your produce is not covered, you are still required to do all that you can to prevent contamination with harmful microorganisms.

“The regulation states that only produce likely to be eaten raw that is grown on farms with at least $25,000 in produce sales is covered.”

Key Requirements in the Produce Safety Rule
The Produce Safety Rule is divided into key requirements that are intended to prevent contamination of produce during production, harvesting, and after harvesting. Each of these will be discussed separately in detail:

1. Worker Health, Hygiene, and Training
2. Agricultural Water for Pre- and Postharvest Uses
3. Biological Soil Amendments
4. Domesticated and Wild Animals
5. Equipment, Tools, Buildings, and Sanitation
6. Required Records

Worker Health, Hygiene, and Training
FDA requires that all personnel who harvest or handle fresh produce covered under the regulation, and those who supervise them, receive food safety training that is appropriate to their assigned duties. Training must be offered upon hiring and periodically thereafter, and it must be presented in a language that all workers can understand.

Specific training outcomes required for harvesters and handlers include:

1. Recognizing the importance of health and personal hygiene for all personnel and visitors, including knowing symptoms of a health condition that is reasonably likely to result in contamination of produce or food-contact surfaces with harmful microorganisms.

2. Knowledge of appropriate hygienic practices when handling produce or food-contact surfaces. This includes washing and drying hands when necessary, especially after using the toilet, and removing or covering jewelry that could fall into the product.

3. The ability to recognize produce that should not be harvested because it is likely to be contaminated with harmful microorganisms.

4. Understanding the importance of inspecting harvest containers and equipment prior to harvest so that they are functioning properly, clean, and maintained.

In addition to these requirements, at least one supervisor or responsible person on a covered farm must have completed food safety training at least equivalent to that received under a standardized curriculum recognized by FDA. The Produce Safety Alliance (PSA), in association with FDA, has created a seven-hour training curriculum. Grower training courses are offered throughout the country and can be found on the Produce Safety Alliance website. In Pennsylvania, Penn State Extension offers regular produce safety certification courses. Visit the Penn State Extension FSMA website for a list of upcoming courses in Pennsylvania.

"Harvesters, handlers, and supervisors must receive training appropriate to their assigned duties.”

Agricultural Water for Pre- and Postharvest Uses
Water is used extensively in farming operations. Preharvest uses include irrigation, chemical crop sprays, cooling, and frost control. Postharvest uses include washing or cooling harvested produce or cleaning food-contact surfaces. Handwashing and drinking water are also important uses of water on the farm. In the Produce Safety Rule, FDA only regulates the safety of pre- and postharvest “agricultural water,” a term FDA has defined as water that is intended to, or likely to, contact the harvestable part of the growing crop, the harvested produce, or surfaces that can come into contact with the product.

The source from which agricultural water is obtained is strongly associated with its potential to become contaminated. Surface water has the highest level of risk because it is a shared resource that may be subject to sudden and unexpected contamination from animal intrusion, manure runoff from neighboring livestock operations, or wastewater septic tank discharge. Groundwater is considered safer, although shallow, improperly constructed or located wells may be subject to surface water contamination from runoff or during flooding events. Municipal water is the safest because it is regularly monitored and usually treated to eliminate harmful bacteria. Indirect irrigation methods, such as drip systems, are considered to have the lowest risk for produce contamination because the water is unlikely to contact the harvestable part of the crop. On the other hand, overhead spray systems are at a higher risk because the water will likely contact the harvestable part of the crop.

"Only water that is intended to, or likely to, contact the harvestable part of the crop is regulated.”

Microbiological Testing Requirements
FDA initially required growers to periodically monitor the quality of pre- and postharvest agricultural water through microbiological testing. However, in 2024, FDA revised its requirements for evaluating the safety of agricultural water.
Testing pre-harvest agricultural water for generic E. coli concentration is no longer required, although it is a regulatory option for some situations and can be helpful in identifying trends. FDA’s new approach is that water test results are not to be used as the sole factor when making use decisions for pre-harvest agricultural water. Instead, the new ruling places more emphasis on considering factors such as the location and nature of the water source, how it is applied, and surrounding the environment. A pre-harvest agricultural water assessment must now to be at least once a year. Compliance dates start April 07, 2025 for farms that sell more than $500,000 total food per year (three-year rolling average) and are staggered by business size class, as in other parts of the Produce Safety Rule. FDA indicates there may updates to this revision as they obtain more data.

Sanitizers may continue to be used as long as the product is labeled for crop contact and used according to label directions. Other treatments such as ozone or UV irradiation can be used as long as scientific evidence that proves its effectiveness is presented. Microbial testing of treated water is not required, although treatment variables (e.g., concentration, pH, and application method) must be monitored and documented for each use.

FDA resources on the new ruling include a summary of factors to consider are online and an "Agricultural Water Assessment Builder" decision making tool. Visit the FDA FSMA Final Rule on Pre-Harvest Agricultural Water page for more information.

**Biological Soil Amendments**

Biological soil amendments are materials of animal or plant origin that are intentionally added to the soil to improve its chemical or physical properties (e.g., compost and manure). Animal manures are often added to soil because they are a rich source of nutrients that support plant growth. However, untreated animal manure is a potential food safety hazard if it comes into contact with the harvestable part of the crop. For this reason, the Produce Safety Rule establishes farm food standards for the application of biological soil amendments of animal origin. The regulation forbids the use of human waste except for sewage sludge biosolids that have been treated according to applicable federal or state regulations.

FDA has established standards in the Produce Safety Rule for the use of raw animal manure and compost prepared from raw animal manure as soil supplements.

“Only raw or composted animal manure that can come into contact with the harvestable part of the crop is regulated.”

**Raw Manure**

FDA states that it is highly likely that raw animal manure contains one or more microbial species that can cause human illness. However, scientific studies have shown that once human pathogens are no longer within the protective environment of the animal colon, they begin to die in response to the destructive effects of sunlight and less favorable temperature and humidity conditions. FDA is currently sponsoring studies to measure the rate at which pathogens die as affected by climatological conditions, application methods, and soil type. Of particular interest is determining the number of days needed between field application and harvest to reduce pathogens to safe levels.

FDA has stated that this will require several years of research under actual farming conditions. Until these studies are complete, FDA does not object to farmers adhering to the raw manure application standards described in the USDA National Organic Program, which call for a 120-day interval between the application of raw manure for crops likely to come in contact with the soil amendment, and 90 days for crops that do not contact the soil. They further state that all untreated biological soil amendments of animal origin, including raw manure, must be applied in a manner that does not contact produce during application, and minimizes the potential for contact with covered produce after application. FDA advises that adherence to these standards is a prudent step toward minimizing the likelihood of contamination while the issue continues to be studied.

**Compost Containing Materials of Animal Origin**

FDA has established microbial reduction targets for processes used to treat biological soil amendments, including manure. Safe compost must have no detectable levels of Listeria monocytogenes, Salmonella spp., and E. coli O157:H7. Alternatively, if only Salmonella species are tested, they must be absent in a 4-gram dried sample, and fecal coliforms must be fewer than 1,000 colony-forming units per gram (CFU/gm).

The Produce Safety Rule provides two examples of scientifically valid composting methods that will meet these standards:

1. Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55°C) for three consecutive days and followed by adequate curing
2. 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 followed by adequate curing

There is no restriction on the number of days between application of compost and harvesting for either of these two methods. Any composting method that deviates from these protocols must follow the application intervals for raw manure. In addition to compost preparation requirements, FDA requires that preventive measures be taken to minimize the potential for contact of the compost with produce during and after application. Research will continue to develop and validate alternative composting methods that can meet the microbial reduction standards, and further guidance will become available in the future.
Domesticated and Wild Animals

The Produce Safety Rule addresses concerns about the potential for grazing animals (e.g., livestock and dairy cattle), working animals used in fields for various purposes (e.g., mules or horses), and intrusion by wild animals (e.g., birds, deer, or feral swine) into fields. Growers must take measures to prevent entry of domesticated animals such as cattle, swine, and poultry into fields. Control measures include confining them to designated areas that are not accessible to fields, and being aware of potential routes for contamination, such as wind-blown dust or water runoff.

During the growing season, fields must be inspected for evidence of fecal contamination and measures must be taken as necessary to ensure that contamination cannot occur during harvesting. For example, placing brightly colored flags or cones around a contamination site is a recommended way to notify harvesters that they should not harvest produce within the designated perimeter.

FDA recognizes the challenges associated with preventing wildlife intrusion and does not expect growers to completely eliminate this potential hazard, such as by surrounding fields with fences. FDA also acknowledges that unwarranted killing or trapping of animals is not recommended if they threaten protected species. Instead, all reasonable and practical nonlethal methods, such as noise cannons, decoys, or netting, are appropriate.

“FDA requires that reasonable and practical measures be taken to ensure that wild and domesticated animals do not become a source of contamination.”

Equipment, Tools, Buildings, and Sanitation

Sanitation standards for equipment and tools that are likely to contact produce during harvesting and postharvest handling are written into the Produce Safety Rule. Knives, implements, mechanical harvesters, hydro-coolers, grading belts, sizers, and equipment used to store or convey harvested, covered produce (e.g., containers, bins, food-packing material, dump tanks, flumes, and transport vehicles) are examples of equipment with produce-contact surfaces.

Equipment and tools must be designed and constructed so they can be easily cleaned and, when necessary, properly sanitized. They must be stored and maintained to protect produce from becoming contaminated and to prevent them from attracting and harboring pests.

Postharvest packing or storage facilities must be suitable in size, construction, and design to facilitate maintenance and sanitary operations that reduce the potential for produce contamination. Packing buildings must have adequate space for efficient operation, pest intrusion must be monitored and controlled, and overhead drip or condensate minimized. There must be adequate drainage to prevent accumulation of water and waste liquids on the floor. Readily accessible toilet facilities must be provided that are designed, located, equipped, and maintained so they cannot become a source of contamination.

FDA has no objection to packing or sorting activities that are conducted outdoors or in buildings with open walls, as long as measures are taken to prevent pests from becoming established and to trap or otherwise remove them when necessary.

“Postharvest equipment, containers, tools, and the packing environment must not be potential sources of contamination.”

Exemptions to the Rule and Modified Requirements for Exempt Farms

Discussed above are the full requirements for growers who are covered under the regulation. However, some produce farms covered under the regulation may be eligible for certain exemptions and may not have to comply with all parts of the Produce Safety Rule. Two types of exemptions are available for some growers: the qualified exemption and the processing exemption. These two exemptions are discussed below, in addition to a brief review of the mixed-type facility exemption that falls under another FSMA regulation. The following discussion should help you decide if you are eligible for either of these exemptions.

Qualified Exemption

Determination of Eligibility

In an attempt to further lighten the regulatory burden on smaller farms, Congress wrote into the law that produce farms with average annual food sales of less than $500,000 over the previous three years may be eligible for a qualified exemption (QE). Again, note that because of inflation, this number is increased each year.

It is important to understand that, in contrast to criteria for coverage, which is based on average annual gross produce sales, QE eligibility is based on three-year average annual farm food sales. This means that in addition to gross receipts for fruits and vegetables, sales of grains for human or animal consumption, animals raised for human food, dairy products, and farm-processed food products are also factored in. This may be a particularly important factor for highly diversified farms where a variety of agricultural food and feed products are produced. A further requirement for QE eligibility is that more than half of the average annual food sales must be made directly to qualified end users (QEU). FDA defines QEUs in either of the following ways:

1. Consumers who purchase food directly from a farmer such as at a farmers market or farm stand, over the Internet, or at a community-supported agriculture (CSA) operation
2. Retail grocery stores or food service establishments (restaurants) that are located in the same state as the farm where the produce was grown or within 275 miles of the farm (note that indirect sales where the produce is resold, such as to distributors, warehouses, and fresh-cut
processors, do not fall into this category)

"Eligibility for a qualified exemption is based on average annual total food sales."

**Modified Requirements**

Farms that have attained qualified exemption status are not subject to the full standards and recordkeeping requirements in the areas of worker health, hygiene, and training; the use of biological soil amendments containing animal manure; sampling and testing of agricultural water; exclusion of domesticated and wild animals; and sanitation of equipment, tools, and buildings. However, compliance with these farm food safety standards is still highly recommended since FDA may withdraw an exemption if at any time they determine that your farming practices could put consumers at risk of illness.

Qualified exempt growers are subject to the following modified requirements:

- If the produce is displayed and sold in unpackaged form, such as at a farmers market, the name and complete business address of the farm where the produce was grown must be prominently displayed on a label, poster, sign, or placard at the point of purchase. This information must include the street address or post office box, city, state, and Zip code.
- If the produce is packaged for retail display and sale, the same type of name and business address information must be prominently displayed on the label.

**Processing Exemption**

**Determination of Eligibility**

As mentioned above, the Produce Safety Rule only applies to produce that is likely to be eaten raw. However, some fruits and vegetables could be grown for either the fresh market or further processing. For instance, a tomato grower might sell at least some of the crop to a grocery store where it would be displayed and sold in its fresh form. On the other hand, at least some portion of the harvest might be sold to a commercial cannery where the tomatoes would be subjected to high temperatures that are sufficient to kill harmful microorganisms. Other examples of processes with "kill steps" include blanching prior to freezing, fermenting, or distilling. If evidence can be presented that proves the process is adequate to reduce harmful microorganisms to safe levels, then that portion of the crop destined for further processing would be eligible for this exemption. The rest of the crop would not be eligible, although it is possible that the qualified exemption could apply.

"Covered produce that is further processed may not be subject to all parts of the rule."

**Modified Requirements**

Farms claiming a processing exemption are not subject to all parts of the Produce Safety Rule. However, the following modified requirements apply:

1. You must disclose in documents accompanying shipment of the produce, whether directly to the processor or to an intermediary broker or distributor, that it has not yet been adequately processed.
2. You must obtain annual written assurance from either the processor that adequate processing procedures are followed or a broker or distributor that "not yet adequately processed" documents must accompany further shipments and adequate processing was performed before the final product was sold to consumers.

**Mixed Type Facility Exemption**

There is another type of exemption that some growers might be interested in. It is not written in the Produce Safety Rule but instead to another FSMA regulation, the Preventive Controls for Human Food Rule. This is for mixed-type facilities (MTF) where both growing and processing activities take place. MTF exemptions to the Preventive Controls Rule are available, but only for certain products and processes that FDA has determined to be "low risk." For instance, in addition to growing fresh produce, a farmer might also have an on-farm side business where baked goods are cooked, packaged, and sold to customers. If your farm is a MTF, see the article on the Preventive Controls for Human Food Rule to learn more about this exemption.

**Required Records**

Unlike third-party audits mandated by many wholesale produce buyers, the FDA Produce Safety Rule does not require a written food safety plan. However, in order to remain compliant with the regulation, certain records must be kept for at least two years past the date the record was created. Records used to satisfy the criteria for a qualified exemption must be kept as long as necessary to support the farm’s status during the applicable calendar year.

"FDA has a list of required records that must be kept to document compliance with food safety standards."

**Personnel Qualifications and Training**

You must keep a record that proves at least one supervisor or responsible person on your farm has successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA. Training information was provided in the "Coverage under the Produce Safety Rule" section above.

**Agricultural Water**

Recordkeeping is relatively simple but can become more burdensome if you choose to use treatments or methods not specifically provided in the regulation. You must keep records showing the following:

1. The findings of the required inspection of the agricultural water system.
2. Results of any analytical tests conducted on agricultural water. Laboratory results must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made.

3. You must document any corrective measures you have taken if agricultural water does not meet the geometric mean and statistical threshold water quality criteria.

4. If you are treating your agricultural water with chemical sanitizers or physical treatments such as UV irradiation, you must keep treatment monitoring records and scientific data or information that proves the adequacy of the water treatments.

5. If public municipal water is used, annual documentation of testing results or certificates of compliance provided by the public water system must be kept on file.

6. If you are claiming a specific microbial die-off reduction during washing or storage, you must have on hand the results of scientific studies that support your claim.

7. If you use microbial water quality criteria sampling frequencies or laboratory testing methods other than those stated in the regulation, you must provide the results of scientific studies supporting your claim that your water is safe for its intended use.

Biological Soil Amendments of Animal Origin

If compost is prepared on the farm, records must be kept documenting that proper time, temperature, and number of turnings were achieved. Records related to on-farm soil amendment treatment must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made.

When soil amendments are purchased from outside vendors, growers must document annually that:

1. The method used to treat or compost the biological soil amendment of animal origin is a scientifically valid process that was carried out with appropriate process monitoring.

2. Upon receipt on the farm, the soil amendment has been handled, conveyed, and stored in a manner and location that minimizes the risk of contamination from untreated or incompletely composted biological soil amendments of animal origin.

Equipment, Tools, Buildings, and Sanitation

Records must be kept showing the date and method that food-contact equipment used during harvesting, packing, or holding was cleaned and sanitized. The records must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after they are made.

Qualified Exemption Requirements

Qualified exemption status is not automatic. You must keep at least three years of records, such as receipts, demonstrating that your farm meets the average annual food sales criteria. Receipts must be dated, but no signature is required. You must review your eligibility for the qualified exemption each year and keep a written record of the annual review that verifies your continued eligibility for the exemption. The annual review record must be dated and signed by a supervisor or responsible party within a reasonable time after the records are made. Growers are encouraged to begin keeping records from previous and upcoming years so they will be ready to claim the exemption once the enforcement date occurs.

Processing Exemption Requirements

To claim a processing exemption, you must obtain written assurance from the business that processes your product that it has adequate processes in place to reduce microorganisms of public health significance to safe levels. Processors are required by other state or federal regulations to prove the adequacy of their processing methods, so they should be able to provide this to you. These records must be updated annually.

Deadlines for Compliance with the Rule

Compliance dates are based on three-year average annual produce sales as shown in the table below. The deadline for larger growers with sales greater than $500,000 is January 26, 2018. Small businesses with sales between $250,000 and $500,000 have until January 28, 2019. Very small businesses with sales between $25,000 and $250,000 have until January 27, 2020. For each category, an additional two years are given for compliance with the agricultural water standards issued in the regulation. In 2017, FDA proposed additional extensions for the agricultural water compliance deadline. Readers can keep up to date on any changes to the regulation at any of the websites listed in the Additional Resources section of this article.

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<th>Business Category</th>
<th>Produce Sales Criteria*</th>
<th>General Compliance Deadline</th>
<th>Ag Water Related Deadline</th>
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*Sales values are in 2011 dollars.
As you can tell by now, the definitions and criteria for coverage and exemptions are complex. For a further explanation of coverage and exemption options, watch the video from Penn State Extension.

**Additional Resources**

*Produce Safety. Pennsylvania Department of Agriculture* State implementation of the FDA Produce Safety Rule, documents and forms, contacts

*The Produce Safety Alliance.* Cornell University. Information on training opportunities, farm food safety resources, and the latest news on the Produce Safety Rule.

*FDA Food Safety Modernization Act (FSMA).* U.S. Food and Drug Administration (FDA). Official site for all the regulations under FSMA including "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (the Produce Safety Rule). Contains the complete regulation, fact sheets, and regular updates on Guidance Documents.

*The Penn State Extension FSMA Website.* Interpretative videos, decision trees, and fact sheets explaining coverage and exemption criteria and a list of upcoming FSMA Produce Safety certification training opportunities in Pennsylvania.


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