



Factsheet, Series: 2021

Produce Safety Rule Highlights

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This fact sheet serves as a primer on some of the major topics covered in the Produce Safety Rule. There are several important definitions, exemptions and key requirements which are outlined below. FDA has produced detailed guidance documents that are linked at the end of this document with more information.

Produce Safety Rule Overview

With the enactment of the Food Safety Modernization Act of 2011 (FSMA), the U.S. Food and Drug Administration (FDA) established science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.¹ FSMA's intent was carried out under 21 U.S.C. § 350(h) of the Food Drug and Cosmetic Act which requires FDA to establish minimum science-based standards for raw agricultural commodities which may have a history of foodborne illness outbreaks. Known as the FSMA final rule on Produce Safety (Produce Safety Rule or PSR), the PSR "requires covered farms to take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated."² The PSR originally went into effect on January 26, 2016. Currently, a majority of its parts are in effect, but due to concern with compliance requirements and deadlines, the agricultural water

¹ Pub. L. 111-353.

² U.S. FDA, *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Guidance for Industry*, <https://www.fda.gov/media/117414/download> (last visited Dec. 9, 2021).

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requirements for covered produce other than sprouts will not be enforceable until 2022-2024 depending on farm size.³

This factsheet first explains the main definitions used in the PSR, then discusses the different subparts of the PSR. For each Subpart, it will cover the main topics addressed and briefly explains what the regulation says and requires.

Definitions - Covered Farm, Produce, and Activities

In general, the PSR applies to “covered farms” that grow, harvest, pack, or hold “covered produce”. “Covered produce” is produce that is a raw agricultural commodity which is defined as produce that is washed, colored, or otherwise treated in its unpeeled natural form prior to marketing.⁴ Produce that is not covered by the PSR includes produce that is rarely consumed raw (such as beans, beets, or corn); produced for personal or on-farm consumption; or produce that falls within the commercial processing exemption.⁵

A “covered farm” encompasses both primary production and secondary activity farms.⁶ A covered farm grows, harvests, packs, or holds covered produce and annually has on average of the previous three years more than \$25K in sales of all produce. Certain covered farms may qualify for exemptions. First, small or very small farms qualify for certain exemptions and modified requirements. A farm is considered small or very small if the farm annually made less than \$500K in food sales on average in the previous three years, and sells a majority of its food directly to “qualified end-users.”⁷ Qualified end-users are consumers, local restaurants or local retail food establishments. Second, covered farms that sell produce to commercial processors are eligible for a commercial processing exemption.⁸ Details on these exemptions can be found in the guidance, Standards for Produce Safety – Coverage and Exemptions/Exclusions for 21 PART 112, linked at the end of the article.

“Covered activities” include growing, harvesting, packing, or holding covered produce, as well as certain other types of activities as defined in the regulations.⁹

Personnel Qualification and Training

³ U.S. FDA, *FDA Finalizes New Compliance Dates for Agricultural Water Requirements*, <https://www.fda.gov/food/cfsan-constituent-updates/fda-finalizes-new-compliance-dates-agricultural-water-requirements> (last visited Dec. 9, 2021).

⁴ 21 C.F.R. § 112.3, 21 U.S.C. § 321(r).

⁵ 21 C.F.R. § 112.1.

⁶ 21 C.F.R. § 112.3.

⁷ 21 C.F.R. § 112.5.

⁸ *Id.*

⁹ 21 C.F.R § 112.3.

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Subpart C outlines personnel qualification and required training for all farm personnel, including supervisors and responsible parties.¹⁰ Subpart C requires farming operations to have supervisors or responsible parties who ensure compliance with the requirements of the PSR. A supervisor or responsible party oversees the conduct of personnel on a covered farm that handles covered produce or food contact surfaces during covered activities.¹¹ Supervisors and responsible parties also ensure compliance with the training requirements of the PSR.¹² Supervisors and those they oversee must receive adequate training upon hire before handling covered produce.¹³ Additionally, supervisors and farm workers must receive periodic training to stay up to date on best practices as well as when needed as a corrective action.¹⁴

Although training must be conducted in a manner that is easily understood,¹⁵ Subpart C requires training to cover many topics. Training must explain the principles of food hygiene and food safety including the relevant sources of foodborne pathogens, routes of contamination, potential for cross-contamination, preventive measures, and corrective measures.¹⁶ Training must also include the importance of health and personal hygiene for personnel and visitors, including recognizing and reporting applicable health conditions and hygienic practices to avoid contamination.¹⁷

For workers who conduct harvest activities, additional training is required. Persons who conduct harvest activities must be trained to recognize covered produce that is not harvestable due to contamination.¹⁸ These persons must also receive training on how to inspect harvest containers and equipment to ensure that they are functioning properly, clean, and maintained to avoid contamination.¹⁹ Lastly, these persons must receive training on performing corrective actions.²⁰

As for recording keeping, covered farms must establish and keep records of trainings. The records must document required training of personnel, including the date of the training, topics covered, and the persons trained.²¹

Worker Health and Hygiene

People can contaminate covered produce and food contact surfaces with pathogens by failing to maintain proper hygiene. The PSR defines food contact surfaces as the surfaces that contact human

¹⁰ 21 C.F.R. § 112.21 et seq.

¹¹ 21 C.F.R. § 112.23.

¹² *Id.*

¹³ 21 C.F.R. § 112.21(a).

¹⁴ 21 C.F.R. § 112.21(d).

¹⁵ 21 C.F.R. § 112.21(c).

¹⁶ 21 C.F.R. § 112.22.

¹⁷ 21 C.F.R. § 112.22(a)(2).

¹⁸ 21 C.F.R. § 112.22(b)(1).

¹⁹ 21 C.F.R. § 112.22(b)(2).

²⁰ 21 C.F.R. § 112.22(b)(3).

²¹ 21 C.F.R. § 112.30.

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food including the surfaces on equipment and tools that contact food.²² The requirements of Subpart D establish minimum requirements to reduce the likelihood that personnel and visitors will contaminate covered produce or food contact surfaces.²³ Specifically, the section covered farms to prevent ill or infected persons from contaminating covered produce; implement hygienic practices to minimize the risk of contamination; and minimize the risk of contamination by visitors.

Subpart D requires covered farms to prevent any person who is ill from doing any work that may contaminate covered produce or food contact surfaces while the person's health condition presents a risk to public health.²⁴ Covered farms must instruct personnel to notify their supervisors or other responsible party if they are or may be sick.²⁵

Subpart D also lays out a list of hygienic practices farm workers must implement. These practices include avoiding contact with animals; washing hands often and thoroughly with soap and water and drying hands thoroughly; ensuring gloves are sanitary; removing jewelry that cannot be sanitized; and not eating, drinking, or chewing gum while working.²⁶ Additionally, covered farms must make visitors aware of the farm's health and hygiene policies and ensure the visitors follow the policies.²⁷ Farms must also make bathrooms and hand washing facilities accessible to visitors.²⁸

Agricultural Water

Subpart E of the PSR regulates agricultural water which is water that is intended or likely to contact covered produce or food contact surfaces.²⁹ The PSR establishes two sets of "microbial quality criteria", both based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination. Under the first set of criteria, water cannot have any detectable generic *E. coli* present.³⁰ The first set of criteria apply to agricultural water that directly or indirectly contacts produce (such as water used for hand washing, water used on food contact surfaces, and water that directly contacts produce during harvest, packing, or holding).³¹ The first set of criteria also apply to water used for sprout irrigation.³²

The second set of criteria apply to agricultural water that is used in growing produce, other than sprouts.³³ Agricultural water applied to growing produce must not exceed specific thresholds of *E. coli*. Under the second set of criteria, Farmers must calculate the "geometric mean" and "statistical threshold value" of *E. coli* in their irrigation water. If agricultural water, whether used in the growing process

²² 21 C.F.R. § 112.3

²³ 21 C.F.R. § 112.31 et seq.

²⁴ 21 C.F.R. § 112.31.

²⁵ 21 C.F.R. § 112.31(b)(2).

²⁶ 21 C.F.R. § 112.32.

²⁷ 21 C.F.R. § 112.33(a).

²⁸ 21 C.F.R. § 112.33(b).

²⁹ 21 C.F.R. § 112.41 et seq.

³⁰ 21 C.F.R. § 112.44(a).

³¹ 21 C.F.R. § 112.44(a)(2)-(4).

³² 21 C.F.R. § 112.44(a)(1).

³³ 21 C.F.R. § 112.44(b).



(including growing sprouts) or during post-harvest activities, contains excessive *E. coli*, corrective actions must be taken before continuing use of that water source.

Subpart E of the PSR also sets out how frequently testing for the second set of criteria must occur. The rule bases testing frequency on the type of water source, either surface or ground water. For untreated surface water used for growing produce, covered farms must conduct an initial survey using a minimum of 20 samples taken over two to four years.³⁴ Following the initial survey, farmers must annually take at least five test samples.³⁵ For untreated ground water, Subpart E requires farmers to take an initial survey using four test samples during the growing season over a period of one year.³⁶ For untreated ground water, farmers must follow the initial survey with at least one annual test sample.³⁷ If a farm sources its water from a public water system or public water supply, then the farm is not required to conduct any water quality tests.³⁸

However, since the PSR was finalized in 2015, FDA has received feedback from producers and other stakeholders expressing concern about the second set of criteria and the testing requirements. Specifically, these stakeholders find the criteria and tests:

- inflexible because the current rule attempts to apply a “one-size-fits-all” approach but in reality does not fit most;
- too complicated to understand, particularly the requirements that producers calculate a “geometric mean” and “statistical threshold value”; and
- difficult to implement when a farm has more than one water source.³⁹

To give the FDA more time to consider how best to approach these concerns, the FDA finalized a rule in 2019 to extend the compliance dates of Subpart E for water used to grow covered produce, except for sprouts.⁴⁰ On December 6, 2021, FDA published a proposed rule that, if finalized, will change the agricultural water requirements for farmers growing covered produce other than sprouts.⁴¹ For farmers who grow covered produce, the proposed rule, if finalized, will replace the second set of criteria and the testing requirements and instead require farmers to prepare an annual written agricultural water assessment.⁴² The proposed rule will not change the first set of criteria. Meaning the requirements for water used during harvest, packing, and holding, and water used to grow sprouts will not change.

Biological Soil Amendments of Animal Origin and Human Waste

³⁴ 21 C.F.R. § 112.46(b)(1)(i)(A).

³⁵ 21 C.F.R. § 112.46(b)(2)(i)(A).

³⁶ 21 C.F.R. § 112.46(b)(1)(i)(B).

³⁷ 21 C.F.R. § 112.46(b)(2)(i)(B).

³⁸ 21 C.F.R. § 112.46(a).

³⁹ 86 F.R. 69120.

⁴⁰ 84 F.R. 9706.

⁴¹ 86 F.R. 69120.

⁴² *Id.*

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Subpart F of the PSR regulates the use of biological soil amendments of animal origin and human waste. Soil amendments are any chemical, biological, or physical material intentionally added to soil to improve the condition of soil in relation to plant growth or capacity to hold water.⁴³ *Biological* soil amendments are soil amendments containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings alone or in combination.⁴⁴

Biological soil amendments of animal origin (BSAAO) consist in whole or in part of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination.⁴⁵ BSAAOs have the potential to be a route of on farm contamination of produce due to their composition. Therefore, Subpart F sets out minimum standards for BASSOs to minimize the risk of contamination and help prevent produce adulteration. The minimum application intervals for BSAAOs, the time between application of BSAAOs to covered produce and harvest of the produce, are linked to whether the BSAAOs are treated and how they were treated.

A treated BSAAO is one that has been treated by a scientifically valid controlled process or combination of scientific processes to meet the regulatory microbial standards. The PSR does not require testing for treated BSAAOs.⁴⁶ However, the PSR requires treated BSAAOs to meet microbial standards for many types of bacteria.⁴⁷ For example, *Listeria monocytogenes* must not be detectable in treated BSAAOs using a method that can detect one colony forming unit (CFU) per 5 gram testing sample.⁴⁸ To ensure treated BSAAOs do not become contaminated, covered farms must handle, convey, and store untreated BSAAO so they do not become a potential source of contamination.

Although Subpart F does not require farmers to treat BSAAOs, farmers may choose to do so because treated BSAAOs are easier to use. If a farmer uses untreated BSAAOs, the farmer must ensure they are applying the BSAAO in a manner that does not contact the produce during or after the BSAAO is applied.⁴⁹ If the untreated BSAAO contacts the produce during or after application, the farmer may face a lengthy minimum application interval or risk being in violation of the regulation. If a farmer chooses to use treated BSAAOs, the farmer will likely have no restriction in how they choose to apply the BSAAO and will not have a minimum application interval.⁵⁰

Although Subpart F discusses untreated BSAAOs and interval periods, organic farmers must also be aware of the requirements laid out in the organic regulations. FDA does not object to compliance with the organic standards, which allow for 90 or 120 day interval periods.⁵¹ FDA is currently working to

⁴³ 21 C.F.R. § 112.3.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ 21 C.F.R. § 112.51(a).

⁴⁷ 21 C.F.R. § 112.54.

⁴⁸ 21 C.F.R. § 112.54(a).

⁴⁹ 21 C.F.R. § 112.56.

⁵⁰ 21 C.F.R. § 112.56, 21 C.F.R. § 112.54.

⁵¹ 7 C.F.R. § 250.203(c)(1).

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conduct a risk assessment to evaluate the risk of human illness associated with the consumption of produce grown in areas where untreated BSAAOs have been applied.⁵²

Domesticated and Wild Animals

The regulations contained in Subpart I of the PSR address science-based minimum standards regarding the potential for domesticated or wild animals to contaminate covered produce.⁵³ Domesticated and wild animals are sources of pathogens that can transmit foodborne disease through produce contamination. Subpart I therefore only applies to covered activities that take place outside or in a partially enclosed building where there is a reasonable probability that animals will contaminate produce.⁵⁴ This subpart does not apply to indoor facilities or to aquaculture operations.⁵⁵

To comply with Subpart I, covered farms must search relevant areas for evidence of potential contamination of covered produce during the growing season. If evidence such as the presence of animals or observation of animal excreta is found, covered farms must determine whether the covered produce can be harvested under in accordance with Subpart K.⁵⁶ If the covered produce cannot be harvested, the covered farm must ensure that the contaminated produce will be identified throughout the rest of growing season as not harvestable.⁵⁷

Although covered farms must avoid animal contamination, Subpart I does not authorize the “taking” of endangered or threatened species; nor does it require covered farms to take measures to destroy animal habitats or exclude animals from outdoor growing areas.⁵⁸

Growing, Harvesting, Packing and Holding Activities

Subpart K addresses proper separation of covered and excluded produce, identifying and not harvesting contaminated covered produce, handling harvested covered produce, handling dropped covered produce, packaging covered produce, and the use of proper food-packing material.⁵⁹ If a farm grows, harvests, packs, or holds covered produce and excluded produce, then the farm must take measures

⁵² U.S. FDA, Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin, <https://www.fda.gov/food/cfsan-risk-safety-assessments/risk-assessment-foodborne-illness-associated-pathogens-produce-grown-fields-amended-untreated> (last visited Dec. 10, 2021).

⁵³ 21 C.F.R. § 112.81 et seq.

⁵⁴ 21 C.F.R. § 112.81(a).

⁵⁵ 21 C.F.R. § 112.81(b).

⁵⁶ 21 C.F.R. § 112.83.

⁵⁷ *Id.*

⁵⁸ 21 C.F.R. § 112.84.

⁵⁹ 21 C.F.R. § 112.111 et seq.

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during covered activities to keep covered and excluded produce separate.⁶⁰ Such farms must also adequately clean and sanitize any food contact surfaces as necessary to avoid excluded produce from contaminating covered produce.⁶¹ However, if all produce is treated as covered produce, these extra cleaning and sanitizing measures are not necessary.

Immediately before and during harvesting, covered farms must take all reasonably necessary measures to identify and not harvest covered produce that may be contaminated.⁶² Once harvested, covered produce must be handled in a manner that protects against contamination.⁶³ However, if covered produce drops to the ground before harvest—and it is produce that does not grow underground (like carrots), on the ground (like cantaloupe), or intentionally dropped as part of harvesting (like almonds)—it may not be sold to consumers.⁶⁴ Covered farms must also ensure they package covered produce in a way that prevents the formation of *Clostridium botulinum* toxin where the risk exists.⁶⁵ Finally, food-packing must be cleanable or designed for single use and unlikely to support growth or transfer of bacteria.⁶⁶

Equipment, Tools and Buildings

Subpart L outlines appropriate construction, maintenance, cleaning, and sanitizing requirements for equipment, tools, and buildings.⁶⁷ Subpart L groups equipment and tools together, and separately lays out regulations for buildings.

Subpart L requires covered farms to use equipment and tools that are constructed in a way that allows for proper maintenance and cleaning to prevent contamination of covered produce.⁶⁸ FDA recommends that equipment and tools be made from non-porous materials to allow for proper cleaning, maintenance and prevention of accumulation of moisture or organic material.⁶⁹ All equipment and tools that are food contact surfaces must be inspected, cleaned and sanitized as frequently as reasonably necessary to protect against contamination of covered produce.⁷⁰ Further, any equipment used for transportation of covered produce should be cleaned before transporting covered produce and used in a manner that minimizes the risk of contamination.⁷¹

⁶⁰ 21 C.F.R. § 112.111(a).

⁶¹ 21 C.F.R. § 112.111(b).

⁶² 21 C.F.R. § 112.112.

⁶³ 21 C.F.R. § 112.113.

⁶⁴ 21 C.F.R. § 112.114.

⁶⁵ 21 C.F.R. § 112.115.

⁶⁶ 21 C.F.R. § 112.116.

⁶⁷ 21 C.F.R. § 112.121 et seq.

⁶⁸ 21 C.F.R. § 112.123(a).

⁶⁹ FDA, *Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (2018) at 94, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-standards-growing-harvesting-packing-and-holding-produce-human-consumption> (last visited Dec. 13, 2021).

⁷⁰ 21 C.F.R. § 112.123(d)(1).

⁷¹ 21 C.F.R. § 112.125.

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Buildings include any fully or partially enclosed structure used for covered activities, including minimal structures that have a roof but no walls.⁷² Subpart L applies to both permanent and temporary buildings.⁷³ Buildings must be suitable in size, construction, and design to allow for maintenance and sanitary operations of covered activities.⁷⁴ Buildings must also have adequate drainage in the areas where water or other liquid waste regularly ends up on the ground or floor of the building.⁷⁵ Subpart L also lays out regulations for fully enclosed buildings that conduct covered activities and also house domesticated animals.⁷⁶

Additionally, Subpart L requires bathrooms and handwashing stations to be readily accessible to the growing area.⁷⁷ Covered farms must also follow the regulations regarding pest control;⁷⁸ disposal of sewage;⁷⁹ disposal of trash, litter, and waste;⁸⁰ plumbing;⁸¹ control of domesticated animal excreta;⁸² and record keeping.⁸³

Sprouts

Subpart M of the PSR focuses on the standards for growing, harvesting, packing and holding sprouts.⁸⁴ Sprouts present a targeted food safety concern because the warm, moist and nutrient-rich conditions—under which they are produced—are ideal for the growth of potential pathogens. Importantly, Subpart M applies to all sprouts, except those grown in soil or substrates and are harvested without their roots.⁸⁵ Sprout operations that do not fall under Subpart M are still subject to all other applicable requirements of the PSR.

Covered sprout farms must take measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, and must treat the seeds or beans.⁸⁶ Treatment can be conducted either by the sprout operator or the supplier, if the supplier provides documentation that the sprouts have been treated and packaged in accordance with the regulations.⁸⁷ Subpart M also lays out

⁷² 21 C.F.R. § 112.122.

⁷³ *Id.*

⁷⁴ 21 C.F.R. § 112.126(a)(1).

⁷⁵ 21 C.F.R. § 112.126(a)(2).

⁷⁶ 21 C.F.R. § 112.127.

⁷⁷ 21 C.F.R. § 112.129-130.

⁷⁸ 21 C.F.R. § 112.128.

⁷⁹ 21 C.F.R. § 112.131.

⁸⁰ 21 C.F.R. § 112.132.

⁸¹ 21 C.F.R. § 112.133.

⁸² 21 C.F.R. § 112.134.

⁸³ 21 C.F.R. § 112.140.

⁸⁴ 21 C.F.R. § 112.141 et seq.

⁸⁵ 21 C.F.R. § 112.141.

⁸⁶ 21 C.F.R. § 112.142.

⁸⁷ 21 C.F.R. § 112.142(e).

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special regulations for spent sprout irrigation water. Before a product batch of sprouts can enter into commerce, the spent sprout irrigation water for that batch (or the sprouts themselves) must test negative for *E. coli*, *Salmonella*, and other pathogens.⁸⁸ Additionally, the sprout growing, harvesting, packing and holding areas must be tested for *Listeria monocytogenes*.⁸⁹ If any testing samples—either from the spent irrigation water or the samples taken of the general area—are positive, the covered farm must implement corrective actions.⁹⁰

Linked References and Resources

[FSMA Final Rule on Produce Safety](#)

[What's New in FSMA](#)

[Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for the Sprout Operations: Draft Guidance for Industry](#)

[Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Draft Guidance for Industry](#)

[New Protocol for the Development and Registration of Treatments for Preharvest Agricultural Water](#)

[FMSA Proposed Rule on Agricultural Water](#)

[Standards for Produce Safety – Coverage and Exemptions/Exclusions for 21 Part 112](#)

[FDA Fact Sheet – Required Training for Covered Farms](#)

[FDA Fact Sheet – Biological Soil Amendments of Animal Origin](#)

[FDA Fact Sheet – Dropped Covered Produce](#)

[FDA Fact Sheet – “Rarely Consumed Raw” Produce](#)

[NALC's Food Safety Reading Room](#)

⁸⁸ 21 C.F.R. § 112.147(b).

⁸⁹ 21 C.F.R. § 112.145.

⁹⁰ 21 C.F.R. § 112.146, 112.148.

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