

FSMA Produce Safety Rule: Agricultural Water Systems Inspection is Different from the Agricultural Water Assessment

*Don Stoeckel, Donna Clements, Thais Ramos, Tommy Saunders, Mariana Villarreal Silva, Elizabeth A. Bihn
February 2025*

This fact sheet provides information about the differences between an agricultural water systems inspection (§ 112.42) and the agricultural water assessment (§ 112.43) from the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR)¹. Subpart E of the FSMA PSR can be grouped into requirements related to:

1. **Pre-harvest agricultural water** used for growing covered produce other than sprouts
2. **Harvest/Postharvest agricultural water** used during harvesting and packing covered produce other than sprouts

The *PSA Records Required by the FSMA Produce Safety Rule* fact sheet ² provides templates to aid in recordkeeping.

Agricultural Water Systems Inspection and Agricultural Water Assessment Explained

The **agricultural water systems inspection** includes all agricultural water systems (i.e., pre-harvest agricultural water, harvest/postharvest agricultural water) at covered farms to the extent that they are under the farm's control. The agricultural water systems inspection requires consideration of potential influences from prior users of the water as well as adjacent and nearby land uses. The inspection must be done at least once per year, to identify conditions that may introduce hazards (e.g., human pathogens) to covered produce or food-contact surfaces through water.

Observations made during the inspection are used to guide the implementation of practices such as system repairs, maintenance, or other actions that reduce the identified risks. Findings of the inspection must be documented in the farm's record. The information in the agricultural water systems inspection (i.e., water source(s), conveyance(s), equipment) can be used in the agricultural water assessment, but the agricultural water systems inspection and the agricultural water assessment are different things requiring different records.

The **agricultural water assessment** requirement applies to pre-harvest agricultural water that is used to grow covered produce. The agricultural water assessment must be completed at least once per year, to identify conditions that may result in contamination of the water source or otherwise increase the likelihood of human pathogens being in the water. The agricultural water assessment requires consideration of how the water is used, crops being grown, environmental impacts, adjacent land uses, and other things that can influence the risk of fruits and vegetables being contaminated through water. Observations made during the assessment allow a farm to reduce risks by deciding what uses are appropriate for the water source, and any measures that might be needed to reduce produce safety risks. The findings of the assessment, and any corrective measures or mitigation measures applied as an outcome of the assessment, must be documented in the farm's record.

The table on the following page provides a more detailed comparison of the two requirements.

Agricultural water system means a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities ¹.

Characteristic	Agricultural Water System Inspection	Agricultural Water Assessment
Regulatory requirement	Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) 21 Code of Federal Regulations (CFR) 112.42	§ 112.43
Compliance date	First compliance date: January 26, 2022 <ul style="list-style-type: none"> Phased in by business size class 	First compliance date: April 07, 2025 <ul style="list-style-type: none"> Phased in by business size class
Scope of requirement	For all agricultural water systems on covered farms, to the extent under the farm's control. Applies to water used during growing (pre-harvest), harvest, and postharvest activities	Applies only to agricultural water used during growing activities (pre-harvest water) on covered farms
Frequency	§ 112.42: <i>"At the beginning of a growing season, as appropriate, but at least once annually ..."</i>	§ 112.43: <i>"... at the beginning of the growing season, as appropriate, but at least once annually ..."</i>
Evaluation parameters	Abridged quote from § 112.42: <i>"... identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, including consideration of the following:</i> <i>(1) The nature of each agricultural water source (for example, whether it is ground water or surface water);</i> <i>(2) The extent of your control over each agricultural water source;</i> <i>(3) The degree of protection of each agricultural water source;</i> <i>(4) Use of adjacent and nearby land; and</i> <i>(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm."</i>	Paraphrased from § 112.43(a): <ul style="list-style-type: none"> Water system characteristics: include information collected as part of the agricultural water systems inspection Agricultural water practices: include a description of how the water is applied and timing of application Crop characteristics: examples include characteristics related to adhesion or internalization of hazards Environmental conditions: examples include the frequency of heavy rain or extreme weather events that may impact the agricultural water system (such as by stirring sediments) or covered produce (such as damage to harvestable leaves) during growing activities, air temperatures, and sun exposure Other factors: include water analysis results, if water is tested
Outcome	Paraphrased from § 112.42(a): Identify conditions that could increase the potential for introduction of pathogens into the water system	Paraphrased from § 112.43(c): <ul style="list-style-type: none"> Determine whether either of the following is reasonably necessary based on findings of the assessment: (a) immediately discontinue use and take corrective measures because water is not safe, or not of adequate sanitary quality for its intended use, or (b) implement mitigation measures, within the timeframe defined for the condition, to reduce risk Record the determination Follow through with necessary and appropriate action
Documentation required	§ 112.50(b)(1): <i>"You must establish and keep the following records, as applicable: The findings of inspections of your agricultural water systems in accordance with the requirements of § 112.42(a)"</i>	Abridged quote from § 112.50(b)(2): <i>"Your written agricultural water assessments, including descriptions of factors evaluated and written determinations, in accordance with § 112.43"</i> Abridged quote from § 112.50(b)(7): <i>"Documentation of actions you take in accordance with § 112.45"</i> (e.g., discontinue use pending corrective measures, or implementation of mitigation measures)

Compliance Dates According to Agricultural Water Use

Business Size Class	Harvest and Postharvest Use ³	Pre-Harvest Use ¹
All other businesses (> \$500,000 annual produce sales*)	January 26, 2022	April 07, 2025
Small businesses (\$250,000 to \$500,000 annual produce sales)	January 26, 2023	April 06, 2026
Very small businesses (< \$250,000 annual produce sales)	January 26, 2024	April 05, 2027

*Annual produce sales are calculated on a rolling three-year average basis and are not adjusted for inflation.

Exemptions and exclusions

Water that is not used as agricultural water is excluded from all requirements in Subpart E, including the agricultural water systems inspection and the agricultural water assessment.

Agricultural water systems inspection requirement

There are no exemptions from the agricultural water systems inspection requirement for any covered farms that use agricultural water.

Agricultural water assessment requirement

Three exemptions from the pre-harvest agricultural water assessment requirement are described in § 112.43(b):

1. Water that meets quality and testing requirements for postharvest water quality, with records from § 112.50(b)(5) and (if relevant) § 112.50(b)(12).
2. Water that meets requirements for water from a public water system or public water supply, with records from § 112.50(b)(6).
3. Water that is treated according to § 112.46, with records from § 112.50(b)(10) and § 112.50(b)(11).

Each of the three exemptions also requires that the quality of the water does not change prior to being used as agricultural water.

Supporting Guidance and Fact Sheets

The preamble to each FSMA published rule ^{1,3} can help to understand the reasoning behind requirements. FDA also summarized the requirements that apply to various uses of agricultural water in § 112.40. In addition, FDA described Subpart E pre-harvest requirements in a series of fact sheets ⁴ and an *Agricultural Water Assessment Builder* tool ⁵ which provide insight into what compliance with the requirement may look like. PSA has created an agricultural water systems inspection and agricultural water assessment templates in the required records document ².

PSA will continue updates and the creation of additional resources as FDA publishes new guidance and tools so check the website often or [sign up](#) to receive our newsletter.

References

1. U.S. Food and Drug Administration 2024. [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water](#). Federal Register May 06, 2024 89(88): 37448-37519. Accessed October 2024.
2. K. Woods, D. Pahl, D. Stoeckel, B. Fick, G. Wall, and E.A. Bihn 2024. Water System Inspection Record Template and Agricultural Water Assessment Template. Page 2 in [Records Required by the FSMA Produce Safety Rule](#). Fact Sheet. Produce Safety Alliance, Cornell University. Accessed October 2024.
3. U.S. Food and Drug Administration 2019. [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E](#). Federal Register March 18, 2019. 84(52) 9706-9714. Accessed October 2024.
4. U.S. Food and Drug Administration 2024. [FSMA Final Rule on Pre-Harvest Agricultural Water](#). Web page. Accessed October 2024.
5. U.S. Food and Drug Administration 2024. [Agricultural Water Assessment Builder](#). Online tool. Accessed October 2024.