

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

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This fact sheet provides information about the differences between an Agricultural Water System Inspection (§ 112.42) and the proposed Agricultural Water Assessment (AgWA) from the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). This information is based on the current FSMA PSR requirements for agricultural water¹ as well as proposed revisions to the current requirements that were published in 2021².

Subpart E of the FSMA PSR for fruit and vegetables producers can be grouped into requirements related to:

- Growing covered produce other than sprouts (production/ pre-harvest water)
- Harvesting and packing covered produce other than sprouts (harvest/ postharvest water)

Differences between FSMA PSR Requirements for Agricultural Water System Inspection and Agricultural Water Assessment

The **Agricultural Water System Inspection** is a requirement in the FSMA PSR¹, with enforcement dates phased in (according to business size class) beginning in January 26, 2023 for harvest/ postharvest water. This requirement will eventually include all agricultural water systems at covered farms, including those used for production/ pre-harvest and harvest/ postharvest agricultural water, but currently only apply to harvest/ postharvest water until the final production/pre-harvest standards are published. The requirement covers agricultural water systems to the extent that they are under the farm's control, but requires consideration of off-site influences that could introduce human pathogens to water and the use of practices that reduce these risks.

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. The findings of the inspection must be documented in the farm's record. The PSA [Records Required by the FSMA Produce Safety Rule](#) fact sheet³ provides a template to aid in recordkeeping.

The **Agricultural Water Assessment (AgWA)** is a proposed requirement², subject to change until it is finalized. This requirement would be in addition to the Agricultural Water System Inspection. The AgWA is specific to production/ pre-harvest agricultural water that is used to grow covered produce. The AgWA is proposed to 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. In contrast to the Agricultural Water System Inspection which focuses on the physical agricultural water system, the AgWA requires consideration of crops being grown, weather impacts, adjacent land uses, and other things that can influence risks to fruits and vegetables being produced. Observations made during the AgWA enable a farm to reduce risks by determining what uses are appropriate for the water source, including application of measures that may be necessary to reduce produce safety risks. The findings of the AgWA, 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 activities².

Characteristic	Agricultural Water System Inspection	Agricultural Water Assessment (proposed)
Regulatory requirement	FSMA Produce Safety Rule 21 Code of Federal Regulations (CFR) 112.42	Proposed revision to 21 CFR Subpart E
Compliance date	Started January 26, 2022 <ul style="list-style-type: none"> Initially under enforcement discretion Phased in by business size class 	Proposed to begin 9 months after the effective date of the final revised 21 CFR Subpart E <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, harvest, and postharvest activities	Applies to agricultural water used during growing activities (production/ pre-harvest water) on covered farms
Frequency	FSMA PSR § 112.42: "At the beginning of a growing season, as appropriate, but at least once annually"	Proposed § 112.43: "Based in part on the results of any inspections and maintenance you conducted under § 112.42, at least once annually you must prepare a written agricultural water assessment for water that you apply to covered produce (other than sprouts) using a direct application method during growing activities."
Evaluation parameters	Abridged quote from FSMA PSR § 112.42: "... Identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following: (1) The nature of each agricultural water source (for example, ground water or surface water); (2) The extent of your control over each agricultural water source; (3) The degree of protection of each agricultural water source; (4) Use of adjacent and nearby land; and (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."	Paraphrased from proposed § 112.43(a): <ul style="list-style-type: none"> Water system characteristics: mostly information carried over from the Agricultural Water System Inspection Agricultural water practices: how the water is used Crop characteristics: such as those related to adhesion or internalization Environmental conditions: including potential for water source contamination related to runoff Other factors: including testing results
Outcome	Maintain water sources and distribution systems to reduce the potential for pathogens in the water.	Paraphrased from proposed § 112.43(c): <ul style="list-style-type: none"> Determine whether either of the following is reasonably necessary based on findings of the AgWA: <ul style="list-style-type: none"> (a) discontinuation of use pending corrective measures, or (b) implementation of mitigation measures Record the determination Take necessary and appropriate action
Documentation required	FSMA PSR § 112.50(b)(1): "You must establish and keep the following records: The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a)"	Abridged quote from proposed § 112.50(b)(2): "Your written agricultural water assessments, including descriptions of factors evaluated and written determinations..." Abridged quote from proposed § 112.50(b)(7): "Documentation of actions you take in accordance with § 112.45..." (e.g., discontinuation of use pending corrective measures, implementation of mitigation measures)

Compliance and Enforcement Dates

The FSMA PSR was published in its final form in December, 2015¹. Farms growing covered produce other than sprouts were not inspected against the agricultural water requirements in Subpart E up until January 2023. This is because FDA both [extended relevant compliance dates](#)⁴ and announced policies to exercise enforcement discretion (i.e., inspectors do not enforce those requirements) in order to [“allow time for the agency to consider how best to address stakeholder concerns while protecting public health.”](#)⁵

In December 2021, FDA published a proposed rule in the Federal Register to revise Subpart E². FDA followed up in July 2022 with a [proposed rule for production/ pre-harvest water compliance dates](#)⁶ and in January 2023 with a [fact sheet](#)⁷, both stating that the policy to exercise enforcement discretion for requirements related to harvest/ postharvest water would end in January 2023. The updated policy results in enforcement for covered farms selling more than \$500,000 of produce per year (3-year average) first, with enforcement dates that are phased in for other business size classes.

Business Size Class	Compliance dates (enforcement dates) for harvest/ postharvest water ⁷	Compliance dates for production/ pre-harvest water (proposed) ⁶
All other businesses (> \$500,000 annual produce sales*)	January 26, 2022 (January 26, 2023)	9 months after effective date of final revised rule
Small businesses (\$250,000 to \$500,000 annual produce sales)	January 26, 2023 (January 26, 2024)	1 year, 9 months after effective date of final revised rule
Very small businesses (< \$250,000 annual produce sales)	January 26, 2024 (January 27, 2025)	2 years, 9 months after effective date of final revised rule

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

What Subpart E Requirements Apply Now?

- Covered farms that use agricultural water in covered activities **during and after harvest** (i.e., harvesting, packing, holding) must follow the relevant **2015 Produce Safety Rule** requirements in Subpart E⁷ including the **Agricultural Water System Inspection** when their business becomes subject to the rule (see table to the left).
- Requirements for agricultural water used during production/pre-harvest are currently (Spring 2023) at the proposed stage, and do not apply until publication of the final rule and compliance dates arrive.

Supporting Guidance and Fact Sheets

The preamble to the FSMA PSR¹ is valuable for understanding the basis for current requirements. FDA also summarized the requirements for harvest/ postharvest agricultural water in a fact sheet released in January 2023⁷.

The preamble to the proposed revision to Subpart E² provides a basis for understanding what is currently proposed for production/ pre-harvest agricultural water. In addition, FDA has described proposed revisions to Subpart E production/ pre-harvest requirements in a fact sheet⁸ and an Agricultural Water Assessment Builder tool⁹ which provide insight into what compliance with the future requirement may look like.

The PSA Team used these FDA documents along with insights from collaborating subject matter experts to create a template for the required record of the Agricultural Water System Inspection³. PSA also created a fact sheet and a decision tree to aid in filling out the record and navigating the Agricultural Water System Inspection process¹⁰.

PSA plans to update this fact sheet with future versions as FDA publishes new guidance and tools, and as the finalized Subpart E revision arrives.



References

1. U.S. Food and Drug Administration 2015. [*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*](#). (Final Rule). Federal Register November 27, 2015. 80(228):747354-74568. Accessed March 2023.
2. U.S. Food and Drug Administration 2021. [*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water*](#). (Proposed Revisions to Subpart E). Federal Register December 06, 2021 86(231): 69120-69155. Accessed March 2023.
3. K. Woods, D. Pahl, D. Stoeckel, B. Fick, G. Wall, and E.A. Bihn 2020. *Water System Inspection Record Template*. Page 2 in [*Records Required by the FSMA Produce Safety Rule*](#). Fact Sheet. Produce Safety Alliance, Cornell University. *Revision in preparation* March 2023. Accessed March 2023.
4. 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 March 2023.
5. U.S. Food and Drug Administration 2021. [*FDA Proposes Changes to Agricultural Water Requirements in the Produce Safety Rule*](#). Constituent Update. Accessed March 2023.
6. U.S. Food and Drug Administration 2022. [*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water*](#). (Proposed Compliance Dates for Subpart E Revisions). Federal Register July 19, 2022. 87(137):42937-42979. Accessed March 2023.
7. U.S. Food and Drug Administration 2023. [*End of Intended Enforcement Discretion for Subpart E Requirements for Harvest and Post-Harvest Agricultural Water for Covered Produce Other than Sprouts - Beginning January 26, 2023*](#). Fact Sheet. Accessed March 2023.
8. U.S. Food and Drug Administration 2021. [*Agricultural Water Proposed Rule*](#). Fact Sheet. Accessed March 2023.
9. U.S. Food and Drug Administration 2021. [*Agricultural Water Assessment Builder*](#). Online tool. Accessed March 2023.
10. Produce Safety Alliance *In Preparation*. *Agricultural Water System Inspection Fact Sheet and Decision Tree*.