
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

In response to feedback received from stakeholders, the FDA announced in March 2017 the intent to review Subpart E of the Produce Safety Rule (PSR) to consider how these requirements for agricultural water might be simplified.

The current proposal published in December 2021 does not include changes to the harvest and post-harvest requirements for agricultural water. In July 2022, the FDA [issued](#) a supplemental notice of proposed rulemaking to extend the compliance dates for the pre-harvest agricultural water requirements for non-sprout covered produce. In this same notice, the agency also announced end dates for the intended enforcement discretion provided for the harvest and post-harvest agricultural water requirements, to begin on January 26, 2023, for the largest farms.

This fact sheet is intended to highlight the requirements for agricultural water used for harvest and post-harvest activities under the PSR.

1. What is agricultural water?

Agricultural water is 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 and in harvesting, packing, and holding activities.

- **“Harvest and post-harvest agricultural water”** refers to water used in harvesting, packing, and holding activities, such as water used to prevent dehydration, for transport, cooling, and washing. This includes water used to make ice that contacts covered produce or food contact surfaces and water used for handwashing.
- **“Pre-harvest agricultural water”** refers to water used during growing activities, such as irrigation and crop protection sprays. Note: FDA intends to continue to exercise enforcement discretion for the pre-harvest water requirements (for covered produce other than sprouts) in the Produce Safety Rule during rulemaking. Additional information is included in the final question and answer below.

(see [§ 112.3](#) for complete definition)

2. Who is covered by the agricultural water requirements?

Covered farms are subject to the requirements of Subpart E if they use water during the growing, harvesting, packing, or holding of covered produce in a way that meets the definition of “agricultural water.”

3. What dates should farms be aware of when the intended enforcement discretion period for the harvest and post-harvest requirements in Subpart E end?

In July 2022, the FDA issued a supplemental notice of proposed rulemaking that [announced](#) dates for the end of the intended enforcement discretion period for the harvest and post-harvest agricultural water requirements for covered produce other than sprouts. These dates, as listed below, are staggered by farm size:

- January 26, 2025, for very small businesses;
- January 26, 2024, for small businesses; and
- January 26, 2023, for all other businesses.

In the same announcement, FDA also proposed staggered compliance dates for the pre-harvest agricultural water requirements that would begin with largest farms, 9 months after the effective date of a final rule. See also the final question and answer below.

4. When will routine inspections that include an assessment of the Subpart E harvest and post-harvest agricultural water requirements begin, and what will they look like?

The end of period of FDA's intent to exercise enforcement discretion for the harvest and post-harvest requirements for covered produce other than sprouts in Subpart E of the Produce Safety Rule for large farms covered by the rule is January 26, 2023.

As has been done with other FSMA rules, the FDA plans to take an educational posture for the harvest and post-harvest agricultural water requirements as the enforcement discretion period ends. During the first year after the end of the intended enforcement discretion policy, FDA will work closely with state and industry partners to advance training, technical assistance, educational visits, and on-farm readiness reviews to prepare both farmers and state regulators for implementing these provisions.

5. What are the Produce Safety Rule (PSR) requirements for harvest and post-harvest agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use (see § 112.41). Specifically, [Subpart E](#)* (and related provisions in Subparts N and O) include requirements for agricultural water, including harvest and post-harvest agricultural water, such as:

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| § 112.41: Quality standard | § 112.47: Who may test |
| § 112.42: Inspections and maintenance | § 112.48: Additional management and monitoring |
| § 112.43: Treatment | § 112.50: Records |
| § 112.44(a): Microbial quality criterion | § 112.151: Test methods |
| § 112.45(a): Measures | § 112.161: Records requirements |
| § 112.46(a, c): Testing | |

Some of the requirements from Subpart E are discussed below.

*Relevant requirements in Subpart E include those sections that apply specifically to water used during harvest and post-harvest activities, as well as those requirements pertaining to all agricultural water used.

6. What requirements apply to agricultural water sources and water distribution systems?

Subpart E includes requirements for inspecting and maintaining agricultural water sources and distribution systems, which can be found in § 112.42. These include inspecting agricultural water systems to the extent they are under the farm's control to 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 the covered produce, practices, and conditions. These also include requirements for maintaining agricultural water sources and distribution systems.

7. What specific microbial quality criteria apply to agricultural water used for certain intended uses? (See 21 CFR 112.44(a))

When agricultural water is used for any one or more of the purposes described in § 112.44(a), then the farm must ensure there is no detectable generic *E. coli* per 100 ml of agricultural water and must not use untreated surface water for any of those purposes.

[\(See § 112.44\(a\)\)](#)

8. What measures must be taken if the harvest or post-harvest agricultural water is not safe and of adequate sanitary quality for its intended use, or does not meet the requirements of § 112.44(a)?

If a covered farm has determined, or has reason to believe, that the water used during and after harvest does not meet these criteria, **the farm must immediately discontinue use of that water**. Before using the water source and/or distribution system again for this intended use(s), certain steps must be taken as described in § 112.45(a). These include, but are not limited to, reinspecting the entire affected agricultural water system, to the extent it is under the farm's control, and making necessary changes; or treating the water as described in that section.

[\(See § 112.45\(a\)\)](#)

9. What are the requirements for treating harvest and post-harvest agricultural water?

Requirements for treatment of agricultural water in accordance with § 112.45 are found in § 112.43. If the harvest or post-harvest agricultural water is treated to comply with § 112.45, then:

- Any method used (including physical treatment, an EPA-registered antimicrobial pesticide product, or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the microbial criterion of no detectable generic *E. coli* per 100 mL of water, as applicable
- Treatment must be delivered in a manner, and monitored at a frequency adequate, to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the microbial criterion of no detectable generic *E. coli* per 100 mL of water, as applicable

[\(See § 112.43\)](#)

10. What are the requirements for testing harvest and post-harvest agricultural water subject to the requirements of § 112.44(a)?

There is no requirement to test agricultural water that is subject to the requirements of § 112.44(a) when certain additional requirements are met. Those additional requirements are found in § 112.46(a). Section 112.46(a) includes additional requirements for when:

- water is received from a Public Water System,
- water is received from a public water supply, or
- water is treated in accordance with the requirements of § 112.43.

More information about those requirements can be found in § [112.46\(a\)](#)(1), (2), and (3), respectively.

For harvest and post-harvest agricultural water, if untreated ground water is used for the purposes that are subject to the requirements of § 112.44(a), there are testing requirements for that water, which are found in § 112.46(c). Those testing requirements include frequency of testing and how those results are used. These requirements include, but are not limited to:

- initially testing the untreated ground water at least four times during the growing season or over a period of one year;
- testing the water once annually thereafter; and
- if any annual test fails to meet the microbial quality criterion in § 112.44(a), resuming testing of water at least four times per growing season or year.

(See § [112.46](#))

11. If agricultural water is tested, who must test the agricultural water?

Agricultural water test results must be collected by the covered farm, by a person or entity acting on the covered farm's behalf, or by a third party provided that third party data adequately represents the covered farm's agricultural water source(s) and meets all other applicable requirements of this part.

(See § [112.47](#))

12. How must harvest and post-harvest agricultural water quality samples be collected and analyzed?

- Samples must be aseptically collected and tested using a method in accordance with § 112.151
- Under §112.151, you must test the quality of water using
 - (a) the method of analysis published by the U.S. Environmental Protection Agency (EPA), "Method 1603: *Escherichia coli* (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-09-007)" (EPA Method 1603); or
 - (b)(1) a scientifically valid method that is at least equivalent to the method of analysis in (a) in accuracy, precision, and sensitivity.

(See § [112.47](#))

We have provided a list of various quantification methods and presence/absence methods that are scientifically valid and at least equivalent in accuracy, precision, and sensitivity to EPA Method 1603 when used to test agricultural water subject to the requirements in § 112.44(a). These methods can be found at: <https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water>.

13. What other measures must be taken for harvest and post-harvest agricultural water?

There are other requirements for harvest and post-harvest agricultural water found in § 112.48. Those include measures related to:

- management of water
- monitoring the quality of water, and
- maintaining and monitoring the temperature of water.

(See § 112.48)

14. What are the recordkeeping requirements for harvest and post-harvest agricultural water?

Subpart E includes recordkeeping requirements for agricultural water. For harvest and post-harvest agricultural water, those requirements include, but are not limited to,

- records pertaining to agricultural water system inspections,
- test results,
- water treatment,
- methods,
- corrective actions, and
- public water systems (if applicable).

All records required under Subpart E are also subject to the general requirements for records in Subpart O of the Produce Safety Rule.

(See § 112.50)

15. What about the pre-harvest agricultural water requirements in the Produce Safety Rule?

In December 2021, FDA published a notice of proposed rulemaking to propose changes to some of the requirements for pre-harvest agricultural water. FDA intends to continue to exercise enforcement discretion for pre-harvest agricultural water during rulemaking.

In the supplemental proposed rule that we issued in July 2022, we proposed compliance dates for pre-harvest agricultural water for produce other than sprouts:

- 2 years and 9 months after the effective date of a final rule for very small businesses;
- 1 year and 9 months after the effective date of a final rule for small businesses; and
- 9 months after the effective date of a final rule for all other businesses.

Additional Information

- Subpart E - Agricultural Water: <https://www.ecfr.gov/current/title-21/chapter-1/subchapter-B/part-112/subpart-E>
- FSMA Final Rule on Produce Safety: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- FSMA Produce Safety Rule, Subpart E- Agricultural Water: <https://www.ecfr.gov/current/title-21/chapter-1/subchapter-B/part-112#subpart-E>
- FSMA Proposed Rule on Agricultural Water: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water>
- Constituent Update 2022: FDA Proposes Compliance Date Extension for Pre-Harvest Agricultural Water Requirements: <https://www.fda.gov/food/cfsan-constituent-updates/fda-proposes-compliance-date-extension-pre-harvest-agricultural-water-requirements>
- Contact for the Produce Safety Network: ProduceSafetyNetwork@fda.hhs.gov
- FSMA PSR Proposed Rule: <https://www.federalregister.gov/documents/2021/12/06/2021-26127/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-relating>
- Constituent Update 2021: <https://www.fda.gov/food/cfsan-constituent-updates/fda-proposes-changes-agricultural-water-requirements-produce-safety-rule>
- Constituent Update 2019: <https://www.fda.gov/food/cfsan-constituent-updates/fda-finalizes-new-compliance-dates-agricultural-water-requirements>
- Announcement on Agricultural Water 2017: <http://wayback.archive-it.org/org-1137/20180908124905/https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm546089.htm>
- Equivalent Testing Methodologies for Agricultural Water: <https://www.fda.gov/files/food/published/Equivalent-Testing-Methodologies-for-Agricultural-Water-%28PDF%29.pdf>

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