

FSMA Final Rule on Pre-harvest Agricultural Water: 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 July 2022, the FDA [announced](#) end dates for the intended period of enforcement discretion for the harvest and post-harvest agricultural water requirements for non-sprout covered produce in the Produce Safety Rule. These end dates begin on January 26, 2023, for the largest farms and are staggered based on farm size.

This factsheet is intended to highlight the requirements for agricultural water used for harvest and post-harvest activities under the Produce Safety Rule. Relevant requirements can be found at [21 CFR Part 112](#).

On May 6, 2024, FDA published a [final rule](#) that revised certain agricultural water requirements in the Produce Safety Rule for pre-harvest agricultural water for non-sprout covered produce. While the rule did not revise the harvest and post-harvest agricultural water requirements, it did reorganize Subpart E to group provisions of a similar nature; therefore, the location of some of the harvest and post-harvest requirements have changed. This document reflects the changes made to the regulation with that rule.

For information on the pre-harvest agricultural water requirements for non-sprout covered produce, see [FSMA Final Rule on Pre-harvest Agricultural Water](#).

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. (See § 112.3 for full definition)

“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 during and after harvest activities.

2. What is pre-harvest agricultural water?

“Pre-harvest agricultural water” refers to water used during growing activities, such as for irrigation and crop protection sprays. Additional information on the requirements that apply for pre-harvest agricultural water for non-sprout covered produce can be found at [FSMA Final Rule on Pre-harvest Agricultural Water](#).

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 covered farms be aware of regarding the end of the intended enforcement discretion period for the harvest and post-harvest requirements in Subpart E?

In July 2022, the FDA [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.

4. What are the Produce Safety Rule 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](#)¹ (and related provisions in Subparts N and O) include requirements for agricultural water, including those that apply for harvest and post-harvest agricultural water, such as:

- § 112.41: Quality standard
- § 112.42: Inspections and maintenance
- § 112.44(a): Microbial quality criterion and prohibition on use of untreated surface water
- § 112.44(b) and (c): Testing
- § 112.44(d): Additional management and monitoring
- § 112.45(a): Measures
- § 112.46: Treatment
- § 112.47: Who may test
- § 112.50: Records
- § 112.151: Test methods
- § 112.161: Records requirements

Some of the requirements in Subpart E are discussed below.

5. What requirements apply to inspecting and maintaining agricultural water systems?

Subpart E includes requirements for inspecting and maintaining agricultural water systems, which can be found in § 112.42. These include requirements for 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 systems, to the extent they are under the farm's control, as necessary and appropriate to prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. (See § 112.42)

6. What specific microbial quality criterion applies to agricultural water used for certain intended uses listed in § 112.44(a)?

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

7. What measures must be taken if 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 harvest or post-harvest agricultural water does not meet these requirements, **the farm must immediately discontinue that use of the water** (see § 112.45(a)). Corrective measures that a farm can take in order to resume such use of the water include:

- Re-inspecting the entire affected agricultural water system under the farm's control and, among other steps, making necessary changes; or
- Treating the water in accordance with the requirements in § 112.46.

¹Relevant 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.

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

In accordance with § 112.44(c), there is no requirement to test agricultural water that is subject to the requirements of § 112.44(a) when:

- The water is received from a Public Water System or public water supply, provided certain requirements are met (including that the covered farm has public water system results or certificates of compliance demonstrating that the water meets relevant requirements), or
- The water is treated in accordance with the requirements in § 112.46.

For untreated ground water used for the purposes listed in § 112.44(a), certain testing requirements apply, which can be found in § 112.44(b). These testing requirements include the frequency of testing and how those results are used. These requirements include, but are not limited to, the following:

- Initially testing the untreated ground water at least four times during the growing season or over a period of one year and using those results to determine whether the water can be used for the intended purpose(s);
- 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 until all of the survey results collected in a year meet the microbial quality criterion.

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

Agricultural water test results may 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)

10. 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 (see § 112.47). Under § 112.151, for harvest and post-harvest water, covered farms must test the quality of water using:

- 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
- a scientifically valid method that is at least equivalent to EPA Method 1603 in accuracy, precision, and sensitivity.

The agency has 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 [Equivalent Testing Methodology for Agricultural Water](#).

11. What additional management and monitoring requirements apply for harvest and post-harvest agricultural water?

Additional management and monitoring requirements that apply for harvest and post-harvest agricultural water can be found in § 112.44(d). These include requirements related to:

- Managing the quality of water, including by establishing and following water change schedules for non-single-pass water (including recirculated water or reused water) to maintain its safe and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce),
- Visually monitoring the quality of water for buildup of organic material, such as soil and plant debris, and

- maintaining and monitoring the temperature of water at a temperature that is appropriate for the commodity and that is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

12. What are the recordkeeping requirements in Subpart E for harvest and post-harvest agricultural water?

Subpart E includes recordkeeping requirements for agricultural water in § 112.50. For harvest and post-harvest agricultural water, those requirements include, but are not limited to, the following (as applicable):

- records pertaining to agricultural water system inspections
- test results
- test methods
- corrective measures
- water treatment
- results or certificates of compliance from public water systems

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

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

Requirements related to treatment of agricultural water can be found in § 112.46 and are described below:

- Any method used to treat agricultural water (such as with 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.

Additional Information

- FSMA Final Rule on Produce Safety:
<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>
- FSMA Produce Safety Rule, Subpart E- Agricultural water (§§ 112.40-112.50)
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112#subpart-E>
- 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>
- FSMA Final Rule on Pre-harvest Agricultural Water
<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-pre-harvest-agricultural-water>
- 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>
- Equivalent Testing Methodologies for Agricultural Water
<https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water>