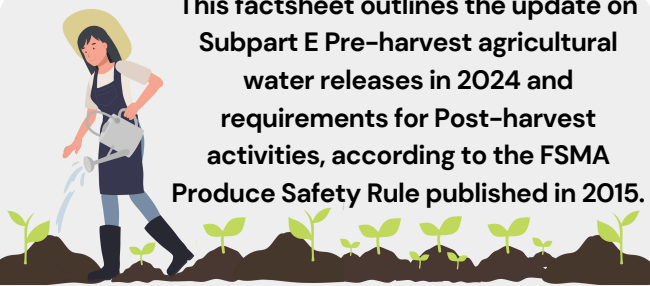


This factsheet outlines the update on Subpart E Pre-harvest agricultural water releases in 2024 and requirements for Post-harvest activities, according to the FSMA Produce Safety Rule published in 2015.

On May 6, 2024, the FDA published a final rule regarding pre-harvest agricultural water provisions for covered produce (other than sprouts) in Subpart E of the FSMA Produce Safety Rule.



Pre-harvest agricultural water refers to water used during growing activities, such as for irrigation and crop protection sprays.

The new rule introduces systems-based assessments, at least once annually, to identify hazards and make informed risk management decisions aimed at minimizing potential risks associated with pre-harvest agricultural water, replacing previous microbial quality criteria and testing requirements.

The requirements for pre-harvest and post-harvest uses of agricultural water and the agricultural water requirements for sprouts have not changed. Sprouts are subject to specific pre-harvest agricultural water requirements, and the compliance dates for sprouts requirements have passed.

Agricultural Water Assessment

As part of pre-harvest agricultural water assessments, covered farms are required to evaluate certain factors, once annually or on any occasion in the event of a significant change that could elevate risk due to known or reasonably foreseeable hazards into or onto produce or food contact surfaces.

- **Agricultural water system(s):** Location and nature of the water source (groundwater, surface water, etc); The type of water distribution system (open or closed to the environment); the degree to which the system is protected from possible sources of contamination, including other users of water system, animal impacts (grazing, working or animal intrusion), adjacent land use, application of biological soil amendments of animal origin (BSAAO), untreated or improperly treated human waste.
- **Agricultural water practices:** The type of application method (overhead sprinkler, drip irrigation, farrow, etc); The time between last application of agricultural water and harvest of the covered produce.
- **Crop characteristics:** Aspects that make covered produce vulnerable to contamination, such as susceptibility to surface adhesion or internalization of microbial hazards. (physical damage from weather events, biological damage, physical characteristics of the produce, growth characteristics, etc).
- **Environmental conditions:** Frequency of heavy rain or extreme weather events and their impact on the water system or that may impact per damage produce. Damage can increase susceptibility to contamination; Air temperature; UV exposure (sun).
- **Other relevant factors:** If applicable, test results to inform the assessment.

Outcomes

Based on assessments findings, covered farms must evaluate and determine if mitigation or corrective actions need to be implemented to reduce potential contamination of covered produce or food contact surfaces.

If you determine	Then you must
That your agricultural water is not safe or is not of adequate sanitary quality for intended use(s).	Immediately discontinue use AND take corrective measures before resuming use of the water.
There is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land for which mitigation is reasonably necessary.	Implement mitigation measures promptly, and no later than the same growing season.
There is one or more known or reasonably foreseeable hazards NOT related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land, for which mitigation is reasonably necessary.	Implement mitigation measures as soon as practicable and no later than the following year OR test water as part of the assessment, and implement measures if needed based on outcome of assessment.
There are not any known or reasonably foreseeable hazards for which mitigation is reasonably necessary.	Regularly (at least once each year) inspect and adequately maintain the water system(s).

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Exemptions

The final rule exempts covered farms from conducting a pre-harvest agricultural water assessment if they demonstrate:

- Their pre-harvest agricultural water meets requirements that apply for harvest and post-harvest agricultural water (microbial quality criterion and testing requirements, prohibition of untreated surface water, and if applicable, the testing requirements for untreated groundwater);
- If agricultural water is received from a public water system or supply that meets requirement established in the rule (provided that the farm has public water system results or certificates of compliance demonstrating that the water meets relevant requirements);
- Agricultural water is treated in accordance with the standards outlined in the Produce Safety Rule.
- Reasonably likely that the quality of the water will not change prior to the use of the agricultural water (how the water is held, stored or conveyed).

Compliance Dates

The rule is effective 60 days after publication of the final rule, and establishes compliance dates for pre-harvest agricultural water provisions for non-sprout covered produce as follows. **The effective date was July 5, 2024.**

Large farms	9 months after effective date	April 7, 2025
Small farms	1 year, 9 months after effective date	April 6, 2026
Very small farms	2 years, 9 months after effective date	April 5, 2027

**Final Rule does not change harvest/post-harvest water requirements.*



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.

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.

- 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?

These dates, as listed on the right chart, are staggered by farm size:

All other businesses	January 26, 2023
Small farms	January 26, 2024
Very small farms	January 26, 2025

- What are the Produce Safety Rule requirements for harvest and post-harvest agricultural water?

Water specifically used for harvest and post harvest **must** meet the requirements in Subpart E - Agricultural water § 112.44 (a) **Microbial quality criterion**. When you must ensure there is no detectable generic *E. coli* in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:

1. used as sprout irrigation water.
2. used during or after harvest activities in a manner that directly contacts covered produce.
3. used to contact food contact surfaces or to make ice that will contact food contact surfaces.
4. used for washing hands during and after harvest activities.

More information is available regarding the requirements applied to agricultural water use in harvesting, packing, and holding covered produce. Please scan a QR code.



References

1. Food and Drug Administration (FDA). 2024. 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>
2. Food and Drug Administration (FDA). 2023. Requirements for Harvest and Post-Harvest Agricultural Water in Subpart E for Covered Produce Other than Sprouts. <https://www.fda.gov/food/food-safety-modernization-act-fsma/requirements-harvest-and-post-harvest-agricultural-water-subpart-e-covered-produce-other-sprouts>