

FSMA Final Rule on Pre-Harvest Agricultural Water

Federal Register Notice

(<https://www.federalregister.gov/public-inspection/2024-09153/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-relating>)

Introduction

The FDA published a final rule that revises certain pre-harvest agricultural water provisions for covered produce (other than sprouts) in Subpart E of the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule (</food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>). Specifically, this rule replaces the previous pre-harvest water microbial quality criteria and testing requirements for covered produce (other than sprouts) with requirements for systems-based, pre-harvest agricultural water assessments for hazard identification and risk management decision-making purposes.

These assessments are used to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto produce or food contact surfaces, and to determine whether, and how soon, corrective or mitigation measures must be implemented to minimize risks associated with pre-harvest agricultural water.

These requirements reflect recent science, findings from investigations of several produce-related outbreaks, and information and feedback from a variety of stakeholders. The requirements are designed to achieve improved public

health protections, while also being more feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to future advancements in agricultural water quality science.

Requirements for [harvest and post-harvest \(/food/food-safety-modernization-act-fsma/requirements-harvest-and-post-harvest-agricultural-water-subpart-e-covered-produce-other-sprouts\)](/food/food-safety-modernization-act-fsma/requirements-harvest-and-post-harvest-agricultural-water-subpart-e-covered-produce-other-sprouts) uses of agricultural water, and the agricultural water requirements for sprouts, have not changed. Sprouts are subject to specific pre-harvest agricultural water requirement, and the compliance dates are for sprouts requirements have passed.

Overview

1. Agricultural Water Assessment

[Agricultural Water Assessment Fact Sheet \(/media/178221/download?attachment\)](/media/178221/download?attachment)
(PDF: 104KB)

[Agricultural Water Assessment Builder \(https://agwaterassessment.fda.gov/\)](https://agwaterassessment.fda.gov/)

[May 2024 Webinar \(/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-fsma-final-rule-pre-harvest-agricultural-water-05202024\)](/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-fsma-final-rule-pre-harvest-agricultural-water-05202024)

The final rule establishes requirements for systems-based pre-harvest agricultural water assessments for hazard identification and risk management decision-making. Covered farms - those that are subject to the requirements in the [Produce Safety Rule \(/food/food-safety-modernization-](/food/food-safety-modernization-act-fsma-final-rule-pre-harvest-agricultural-water)

act-fsma/fsma-final-rule-produce-safety) – that use pre-harvest agricultural water for covered produce (other than sprouts) are required to conduct agricultural water assessments once annually, and whenever a significant change occurs that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto produce or food contact surfaces. As part of their pre-harvest agricultural water assessments, farms are required to evaluate certain factors (overview below) that could impact produce safety as a result of the use of pre-harvest agricultural water.

Table 1. Summary of Factors Evaluated as Part of a Pre-Harvest Agricultural Water Assessment

Factor	Description
Agricultural water system(s)	<ul style="list-style-type: none"> • The location and nature of the water source (for example, whether it is ground water or surface water) • The type of water distribution system (for example, whether it is open or closed to the environment) • The degree to which the system is protected from possible sources of contamination, including: <ul style="list-style-type: none"> ◦ other users of the water system ◦ animal impacts (such as from grazing animals, working animals, and animal intrusion) ◦ adjacent and nearby land uses related to animal activity, the application of biological soil amendments of animal origin (BSAAOs), or the presence of untreated or improperly treated human waste
Agricultural water practices	<ul style="list-style-type: none"> • The type of application method (such as overhead sprinkler or spray, drip, furrow, flood, and seepage irrigation)

	<ul style="list-style-type: none"> • The time interval between the last direct application of agricultural water and harvest of the covered produce (other than sprouts)
Crop characteristics	<ul style="list-style-type: none"> • Susceptibility of the covered produce to surface adhesion or internalization of hazards
Environmental conditions	<ul style="list-style-type: none"> • Frequency of heavy rain or extreme weather events that may impact the agricultural water system (such as by stirring sediments that may contain human pathogens) or that may impact or damage produce. Damage can increase the susceptibility of produce to contamination. • Air temperatures • Sun (UV) exposure
Other relevant factors	<ul style="list-style-type: none"> • Including, if applicable, results of testing to inform the assessment

[Expanded Table on Factors for Agricultural Water Assessment to Consider \(/media/178227/download?attachment\)](/media/178227/download?attachment)
 (PDF: 115KB)

[Corrective and Mitigation Measures for Pre-harvest Agricultural Water for Non-Sprout Covered Produce \(/media/178228/download?attachment\)](/media/178228/download?attachment)
 (PDF: 129KB)

2. Outcomes

Based on findings of their agricultural water assessments, covered farms are required to determine if corrective or mitigation measures are reasonably necessary to reduce the potential for contamination of covered produce (other than

sprouts) or food contact surfaces with hazards associated with pre-harvest agricultural water. This includes expedited mitigation measures to address known or reasonably foreseeable hazards in agricultural water systems associated with animal activity, biological soil amendments of animal origin (BSAAOs), or untreated or improperly treated human waste on adjacent and nearby land. The following chart summarizes the actions covered farms are required to take based on the outcomes of their agricultural water assessments:

If you determine	Then you must
that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)	<ul style="list-style-type: none"> • immediately discontinue use(s) <p>AND</p> <ul style="list-style-type: none"> • take corrective measures before resuming use of the water for pre-harvest activities
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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • implement mitigation measures as soon as practicable and no later than the following year <p>OR</p> <ul style="list-style-type: none"> • test water as part

	<p>of the assessment and implement measures, as needed, based on the outcome of the assessment</p>
<p>there are not any known or reasonably foreseeable hazards for which mitigation is reasonably necessary</p>	<ul style="list-style-type: none"> • regularly (at least once each year) inspect and adequately maintain the water system(s)

[Annual Agricultural Water Assessments and Risk-Based Outcomes \(/media/178219/download?attachment\)](/media/178219/download?attachment) (PDF: 141KB)

3. Required Management Review of Pre-harvest Agricultural Water Assessments

The final rule includes a requirement for supervisory review of the written pre-harvest agricultural water assessment and the determinations that were made based on the outcomes of the assessment.

Exemptions

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

- demonstrate that their pre-harvest agricultural water for covered produce (other than sprouts):
 - meets certain requirements that apply for harvest and post-harvest agricultural water (including the prohibition on the use of untreated surface water, the microbial quality criterion, and, if applicable, the testing requirements for

- untreated ground water),
 - is received from a public water system or supply that meets requirements established in the rule (provided that the farm has public water system results or certificates of compliance demonstrating that the water meets relevant requirements), or
 - is treated in accordance with the standards outlined in the Produce Safety Rule, and
- it is reasonably likely that the quality of the aforementioned water will not change prior to the water being used as agricultural water (for example, due to the manner in which the water is held, stored, or conveyed).

4. Compliance Dates

The rule establishes compliance dates for the pre-harvest agricultural water provisions for covered produce (other than sprouts) as follows:

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

The effective date is July 5, 2024.

Additional Resources

- [Webinar on the FSMA Final Rule on Pre-Harvest Agricultural Water – May 20, 2024 \(/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-fsma-final-rule-pre-harvest-agricultural-water-05202024\)](https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-pre-harvest-agricultural-water-05202024)

- [Factsheet on the Final Rule \(/media/178221/download?attachment\)](/media/178221/download?attachment)
- [FSMA Final Rule on Pre-harvest Agricultural Water: Corrective and Mitigation Measures for Pre-harvest Agricultural Water for Non-Sprout Covered Produce \(/media/178228/download?attachment\)](/media/178228/download?attachment)
- [FSMA Final Rule on Pre-harvest Agricultural Water: Equivalent Testing Methodology for Agricultural Water Produce Safety Rule \(21 CFR 112\) \(/media/178224/download?attachment\)](/media/178224/download?attachment)
- [FSMA Final Rule on Pre-harvest Agricultural Water: Factors for Agricultural Water Assessment to Consider \(/media/178227/download?attachment\)](/media/178227/download?attachment)
- [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 \(/media/178226/download?attachment\)](/media/178226/download?attachment)
- [FSMA Final Rule on Pre-harvest Agricultural Water: Annual Agricultural Water - Assessments and Risk-Based Outcomes \(/media/178219/download?attachment\)](/media/178219/download?attachment)

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