QUICK REFERENCE GUIDE

New Modified FSMA PSR Agricultural Water Requirement Proposal

In December 2021, the United States Food and Drug Administration (FDA) proposed a revision to Subpart E of the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) that would change the pre-harvest agricultural water requirements for covered produce, other than sprouts.

What is the proposed change?

The proposed revision to Subpart E modifies the previous requirement for produce growers to **replace the microbial criteria and testing requirements** for pre-harvest agricultural water with new provisions for **conducting pre-harvest agricultural water assessments**, providing more flexibility to produce growers in evaluating risks.

These aim for hazard identification (including consideration of agricultural water sources, distribution systems, and practices, as well as adjacent and nearby land uses, and other relevant factors), and using the results of the assessment to determine whether **corrective or mitigation measures** are needed to reduce the potential for contamination of produce or food contact surfaces with hazards associated with pre-harvest agricultural water.

What is an "agricultural water assessment"?

It refers to an **evaluation**, conducted by a covered farm, of factors in its agricultural water system used during growing activities for non-sprout covered produce, its agricultural water practices for such pre-harvest water, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate).

Factors	Description
Agricultural water systems	• Location and nature of the water source (including whether it is ground or surface water). • Water distribution system type (such as whether it is open or closed to the environment). • Degree to which the system is protected from possible sources of contamination.
Agricultural water practices	• Water application method (overhead sprinkler, spray, drip, furrow, flood, seepage, etc.). • Time interval between the last direct water application and harvest of the covered produce.
Crop characteristics	• Susceptibility of the covered produce to surface adhesion or internalization of hazards.
Environmental conditions	• Frequency of heavy rain or extreme weather events may impact the agricultural water system or damage produce that can increase the susceptibility of produce to contamination. • Air temperatures. • Sun (UV) exposure.
Other relevant factors	• Including, if applicable, results of water testing that could inform the assessment.

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Corrective and mitigation measures

The proposed rule does **NOT** change the requirements for harvest and post-harvest water, but only impacts pre-harvest water. Under this proposed rule, a covered farm would **make a determination under the requirements, based on the outcome of its agricultural water assessment**, as to whether mitigation measures would be reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with its pre-harvest agricultural water.

Based on the assessment, 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(s). **AND** • 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 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, 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, as needed, based on the outcome of the assessment.
that there are no known or reasonably foreseeable hazards for which mitigation is reasonably necessary,	• inspect and adequately maintain the water system(s) regularly, and at least once each year.

Exemptions

A covered farm would be exempt from the requirement to conduct an assessment for pre-harvest agricultural water if the farm can demonstrate that the agricultural water meets these requirements, including:

- It meets certain requirements that apply for **harvest and post-harvest agricultural water** (such as the microbial quality criterion and testing requirements for untreated ground water).
- It 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
- It is treated in accordance with the standards outlined in the Produce Safety Rule.

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