



Agricultural Water Proposed Rule

PROPOSAL OVERVIEW

If finalized, this proposal would replace the pre-harvest microbial quality criteria and testing requirements in the Produce Safety Rule for covered produce (other than sprouts) with requirements for systems-based pre-harvest agricultural water assessments.

Agricultural Water Assessment

- covered farms would be required to conduct pre-harvest agricultural water assessments once annually, and whenever a change occurs that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto produce or food contact surfaces.
- assessments would be 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 corrective or mitigation measures are needed to minimize the risks associated with pre-harvest agricultural water

Agricultural Water Assessment

The following are factors that farms would be required to assess as part of the agricultural water assessment.

Agricultural water system(s):

- Location and nature of the water source
- Type of distribution system
- The degree to which the system is protected

Agricultural water practices:

- The type of application method
- Time interval between direct application and harvest

Crop Characteristics:

- Susceptibility of the produce to surface adhesions or internalization of hazards

Agricultural Water Assessment (factors), continued



Environmental conditions

- Frequency of heavy rain or extreme weather events
- Air temperatures
- Sun (UV) exposure

Other Relevant Factors

- Such as testing results that could inform assessment

Outcomes of Agricultural Water Assessment

- Farms would use their assessments to make written determinations about whether corrective or mitigation measures are needed
- This could include 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.

Summary of outcomes and actions that would be required



If you determine	Then you must
<p>that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)</p>	<ul style="list-style-type: none"> • Immediately discontinue use (s) And • Take corrective measures before resuming use of the water for pre-harvest activities
<p>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</p>	<ul style="list-style-type: none"> • Implement mitigation measures promptly, and no later than the same growing season,
<p>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</p>	<ul style="list-style-type: none"> • 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
<p>that there are no known or reasonably foreseeable hazards for which mitigation is reasonably necessary</p>	<ul style="list-style-type: none"> • Inspect and adequately maintain the water system(s) regularly, and at least once each year

Exemptions

- The proposed rule would exempt 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 (such as the microbial quality criterion and 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 rule

Additional Changes

- reorganize subpart E to more clearly delineate which provisions apply based on how the water is used.
 - This means that some requirements may be renumbered. However, FDA is not proposing to alter the requirements in subpart E for sprouts; for water used during harvest, packing and holding activities; or for treatment of agricultural water.
- Add definitions for “agricultural water assessment” and “agricultural water system” to provide additional clarity.

Engagement

The FDA is looking forward to hearing from stakeholders about this proposal.

- Comments should be submitted to docket FDA-2021-N-0471 on Regulations.gov.
- The comment period will be open for 120 days.
- The FDA will be announcing two virtual public meetings.



More to
come

- The FDA is developing an online tool to assist farms in evaluating potential risks posed by their water sources and in determining potential management options.
- **Compliance Dates NPRM:** The FDA recognizes that the current agricultural water compliance dates are set to begin in January 2022 for some farms. The agency intends to exercise enforcement discretion for the agricultural water requirements for covered produce (other than sprouts) while proposing to extend the compliance dates for all subpart E provisions applicable to such produce, with the goal of completing the compliance date rulemaking as quickly as possible. More information on the proposed compliance dates will be announced in a forthcoming notice in the *Federal Register*.

