

Preharvest Agricultural Water Proposed Rule



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Agenda

- Proposal overview
- Ag Water Assessment components
 - Outcomes
 - Corrective and mitigation measures
- Regulatory Impact Analysis

Proposal Overview

- Stakeholder Concerns:
 - Intended to address stakeholder concerns about complexity and practical implementation challenges with pre-harvest agricultural water testing requirements
 - Replaces the pre-harvest microbial quality criteria and testing requirements in the Produce Safety Rule with systems-based pre-harvest agricultural water assessments.



Proposal Overview (CONT'D)

- Definitions:
 - “agricultural water assessment” and “agricultural water system”
- Agricultural water assessments:
 - conducted once annually, and whenever a significant change occurs
- Outcomes:
 - Farms would be required to evaluate factors and determine which corrective or mitigation measures might need to be implemented
 - Includes expedited mitigation measures that would be required, if finalized, for hazards related to certain activities associated with adjacent and nearby lands

Agricultural Water Assessment



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

- *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



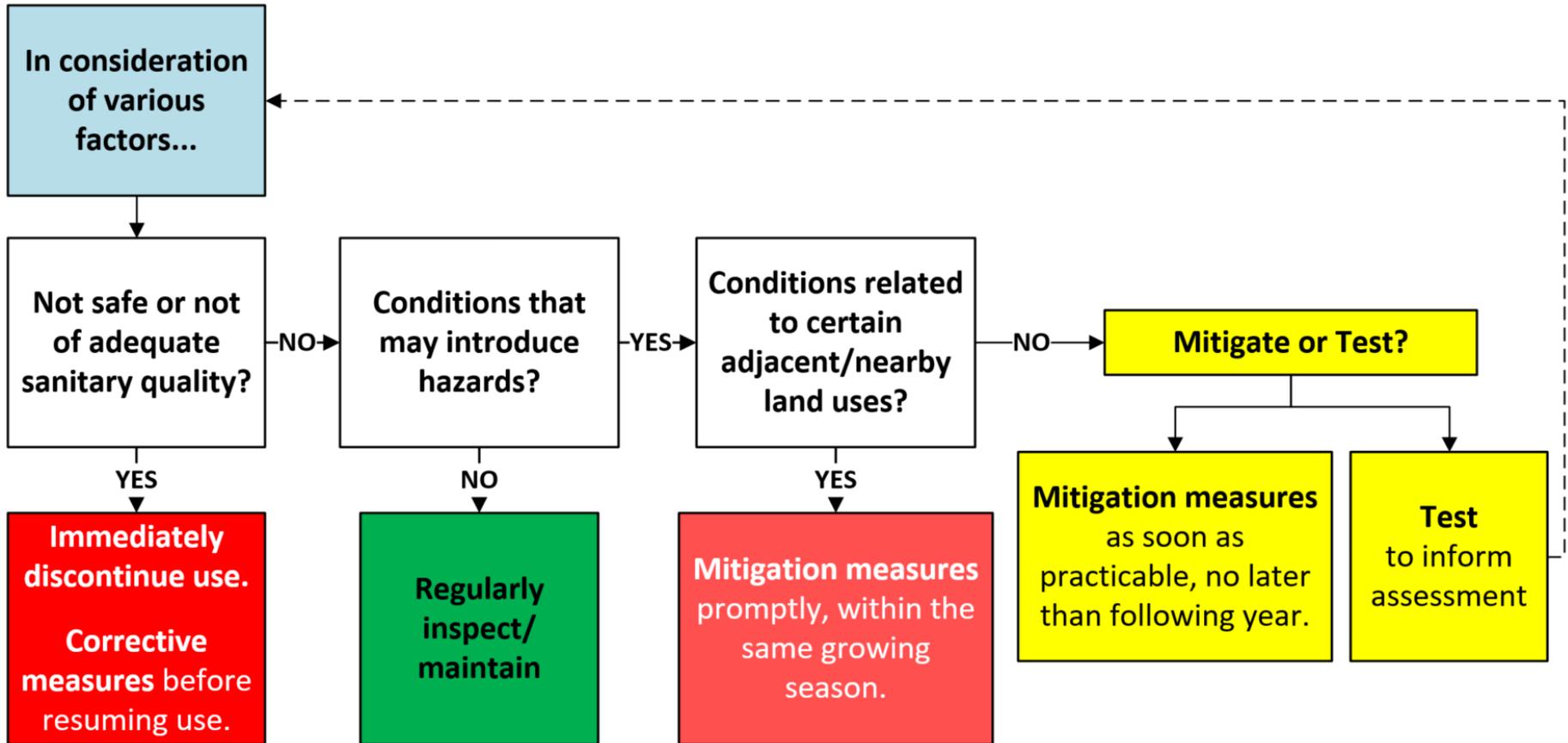
- *Environmental conditions*
 - Frequency of heavy rain or extreme weather events
 - Air temperatures
 - Sun (UV) exposure
- *Other Relevant Factors*
 - Such as testing results that could inform assessment
- **If finalized, the pre-harvest agricultural water assessment would need to be written, and supervisory review of assessments and determinations would have to occur.**

Adjacent and Nearby Land Uses



- Proposed rule reflects new information and findings from recent outbreaks
- Assessment would include adjacent and nearby land uses relating to:
 - Animal activity
 - Application of biological soil amendments of animal origin (BSAAOs)
 - Presence of untreated or partially-treated human waste
- Farms could consider:
 - The nature of the water system, proximity of adjacent and nearby land to water system, and topography of surrounding land
 - Effects of any fencing, containment, or other measures employed to prevent animal access to water sources or distribution systems
 - Earthen diversion berms, ditches, or other barriers to help minimize the influence of runoff on sources and distribution systems

Outcomes: Flow Chart



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, BSAOs, or untreated or improperly treated human waste on adjacent or nearby lands 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, BSAOs, 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

Requirements for testing option as part of the assessment

- Farms collecting samples for testing would be required to ensure that samples are...
 - Aseptically collected immediately prior to or during the growing season and be representative of their use of the water
 - Tested for generic *E. coli* or other scientifically valid indicator organism, index organism, or other analyte
- Sampling frequency and microbial criteria used would have to be appropriate to assist in determining, alongside other factors assessed, whether mitigation is needed
- Farms could choose to use the sampling framework and microbial criteria for pre-harvest ag water in the 2015 Produce Safety Rule, or other scientifically valid framework

Corrective and Mitigation Measures



- Corrective measures:
 - Applied in response to water being not safe or not of adequate sanitary quality for its intended use
- Mitigation measures:
 - Applied in response to...
 - Animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby lands
 - Other conditions not related to those above

Corrective and Mitigation Measures



- Farms applying corrective measures would have the flexibility to choose from:
 - Re-inspecting the ag water system, and, among other steps, making necessary changes
 - Treating the water
- Farms applying mitigation measures would have the flexibility to choose from:
 - Making necessary changes, such as repairs
 - Increasing the time interval prior to harvest to a minimum of 4 days (unless otherwise supported by test results or scientifically valid information)
 - Increasing the time interval between harvest and end of storage and/or conducting other activities, such as commercial washing
 - Changing the water application method
 - Treating the water
 - Taking alternative measures
- EPA has approved an FDA-developed protocol to aid in registration of chemical treatments for pre-harvest agricultural water

Additional Clarifications

- We are also proposing to reorganize subpart E in its entirety to more clearly delineate which provisions apply based on how the water is used.
- However, the proposal would not alter the requirements for sprouts; water used during harvest, packing and holding activities; or for treatment.

Exemptions

- If finalized, covered farms would be exempt from conducting a pre-harvest agricultural water assessment if they can demonstrate that their pre-harvest agricultural water:
 - 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 Produce Safety Rule

Ag Water Builder Tool

- 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

Regulatory Impact Analysis

- Quantitative benefits: Monetized value of illnesses averted
- Qualitative benefits: Increased flexibility in evaluating potential hazards associated with pre-harvest agricultural water
- Costs: Reading the rule, conducting assessments, mitigation, and recordkeeping
- Cost savings: Savings from current testing provisions replaced

Benefits, Costs of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units		Notes
					Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year	\$9.6	-\$28.0	\$48.9	7%	10 years	Benefits are illnesses averted
		\$9.9	-\$28.8	\$50.2	3%	10 years	Benefits are illnesses averted
Costs	Annualized Monetized \$millions/year	\$11.2	\$4.5	\$17.4	7%	10 years	
		\$11.3	\$4.8	\$17.4	3%	10 years	

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.
- AgWater@fda.hhs.gov



