

Agricultural Water Final Rule



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Agenda

- Overview of the Final Rule
- Summary of Comments Received
- Rule Requirements
- Compliance Dates
- Supporting Materials

Overview of Final Rule

- Requires comprehensive, systems-based assessments at least once per year that focus on key factors for contamination by pre-harvest agricultural water:
 - Agricultural water systems
 - Water use practices
 - Crop characteristics
 - Environmental conditions
 - Other factors (including testing in certain circumstances)
- Requires timely action based on risk and includes new requirement for expedited mitigation for certain hazards
- Reflects new science demonstrating limitations of the previous testing requirements and findings from several produce-related outbreaks
- No changes for sprouts or harvest/post-harvest ag water

Comments

- Received 180 comments from farms, trade organizations, academia, consumer groups, and state and foreign government agencies, among others
- Commentary varied and included:
 - Support, noting appreciation for flexible, risk-based approach compared to the previous “one-size-fits-all” testing requirements
 - Requests for clarity on how farms can mitigate hazards that are outside their control
 - Requests for additional guidance on the requirements for assessments and outcomes

Changes in Final Rule

- Finalizing as proposed with minor changes:
 - Clarifying that an exemption only applies if water quality unlikely to change prior to use
 - Revising certain mitigations to better allow for future science and advancements in post-harvest handling
 - In-field die-off
 - Post-harvest storage / other post-harvest activities

Agricultural Water Assessment



At the beginning of the growing season, but at least once annually, farms are required to evaluate various factors as part of their assessments:

Agricultural water system(s):

- Location and nature of the water source
- Type of distribution system
- The degree to which the system is protected, including from other water users, animal impacts, and certain uses of adjacent and nearby land

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, cont'd

Environmental conditions

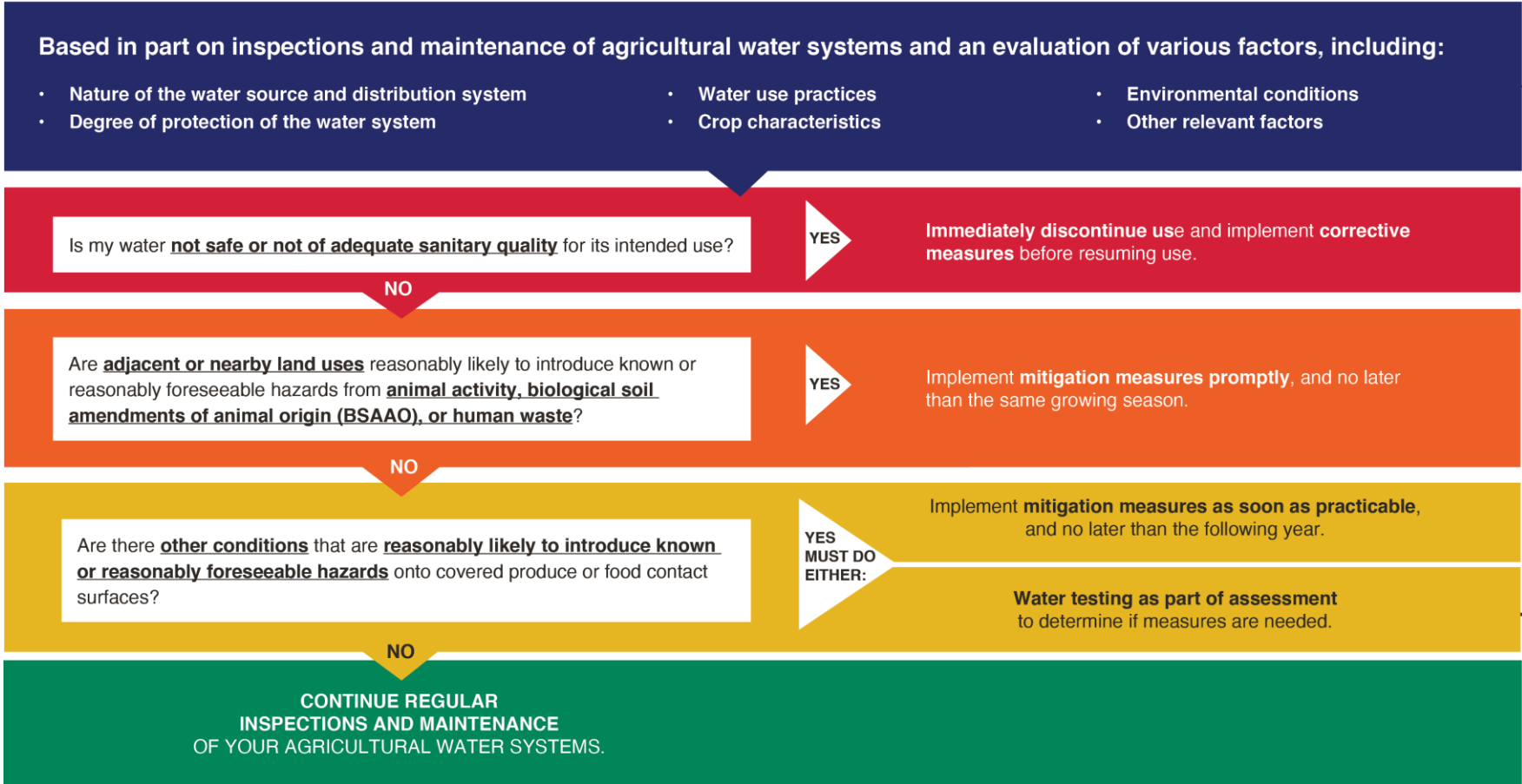
- Frequency of heavy rain or extreme weather events that impact water systems or covered produce
- Air temperatures
- Sun (UV) exposure

Other Relevant Factors

- For example, test results to inform an assessment

The pre-harvest agricultural water assessment must be written, and supervisors must review of assessments and determinations

Outcomes: Flow Chart



Adjacent and Nearby Land Uses



- Farms are required to consider land uses related to animal activity, BSAAOs, and untreated or partially treated human waste
- Along with other factors evaluated as part of an assessment, farms can consider:
 - The nature of the water system, proximity of land uses 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



Adjacent and Nearby Land Uses, Cont'd

- If mitigation measures are necessary in response to adjacent and nearby land uses, they must be implemented on an expedited basis
- The rule includes measures that can be used even if a source of hazards is outside the farm's control

Testing as Part of the Assessment

- Requirements are flexible to account for future science:
 - **Test organism:** samples must be tested for generic *E. coli* or other scientifically valid indicator organism, index organism, or other analyte
 - **Sampling frequency and microbial criteria:** must be appropriate to assist in determining, alongside other factors assessed, whether mitigation is needed



Testing as Part of the Assessment, cont'd

- While not required, farms may choose to use the sampling framework and microbial criteria for pre-harvest ag water in the 2015 Produce Safety Rule
 - If a farm has data or information more reflective of its unique conditions, it is required to use that in establishing a sampling frequency and microbial criteria
- Test results are to be considered as part of the assessment, not as standalone basis for decision-making

Corrective and Mitigation Measures



- Corrective measures:
 - Refers to measures farms must implement in order to resume use of water if the water is not safe and adequate
 - Used in circumstances where it is necessary to take immediate action to protect public health
- Mitigation measures:
 - Provide more flexibility in the timing of actions
 - Must be applied:
 - Promptly, and no later than the same growing season, for certain uses of adjacent or nearby lands
 - As soon as practicable and no later than one year after the assessment for other hazards

Corrective Measures

- Farms applying corrective measures can:
 - Re-inspect the ag water system, identify conditions that may introduce hazards, make necessary changes, and determine if those changes were effective
 - Treat the water in accordance with the requirements in the rule

Mitigation Measures

- Farms applying mitigation measures can:
 - Make necessary changes, such as repairs
 - Increase the time interval between last direct water application and harvest (with scientific justification)
 - Increase the time interval between harvest and end of storage and/or conduct other activities during or after harvest (with scientific justification)
 - Change the water application method
 - Treat the water
 - Take alternative measures

Reassessment

- Farms must conduct an assessment at least once annually, and whenever a significant change occurs
- Examples of significant changes:
 - Change from ground water to surface water
 - Changes in water use practices
 - Growing a different type of covered produce
 - Some environmental conditions (e.g., unexpected flooding that may introduce hazards to a water source)
- Reassessment must evaluate factors and conditions affected by the change

Exemptions

- An exemption may apply if a farm can demonstrate that its water:
 - Meets certain requirements for harvest/post-harvest water, including the microbial criterion, prohibition on the use of untreated surface water, and relevant testing requirements;
 - Meets certain requirements for water from a public water system or supply (including that farm has results or certificate of compliance that requirements are met); or
 - Is treated in accordance with the rule.
- It must be reasonably likely that the quality of water will not change prior to use of the water (e.g., due to the manner in which the water is held, stored, or conveyed)



Pre-harvest Compliance Dates (Non-sprout covered produce)

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

- Effective Date – July 5, 2024
- FDA is committed to taking an “educate before and while we regulate” approach to supporting compliance

Supporting Materials

- Information available on the rule's website (e.g. fact sheets)
- Agricultural Water Assessment Builder v2.0
 - Tool designed to help farms understand requirements in the final rule
 - Can be accessed at:
<https://agwaterassessment.fda.gov/>

Other resources

- FSMA Technical Assistance Network
- FDA Produce Safety Network
- Reach out to AgWater@fda.hhs.gov



