Ag Water Assessment: How to Fill Out & Promote on Farms

Sarah (Cope) Avery
Outreach Coordinator
Produce Safety Program
Food & Drug Protection Division
North Carolina Department of Agriculture and Consumer Services

FSMA Final Rule on Pre-Harvest Agricultural Water

- Pre-harvest agricultural water: water used in contact with produce during growth
  - Irrigation
  - Fertigation
  - Crop sprays
  - Cooling
  - Frost protection
  - Dust abatement
  - Other uses where water directly contacts produce
- All agricultural water must be safe and of adequate sanitary quality for its intended use

Definition: Agricultural Water Assessment

- An evaluation, conducted by a covered farm, of 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) to:
  - (1) Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces

  AND
  - (2) Determine whether corrective or mitigation measures for pre-harvest agricultural water are necessary to reduce the potential for contamination with such known or reasonably foreseeable hazards

Definition: Agricultural Water System

- A source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities

FSMA Final Rule on Pre-Harvest Agricultural Water

Covered farms would be REQUIRED to:

1. Conduct pre-harvest agricultural water assessments once annually
2. Conduct pre-harvest agricultural water assessments 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
3. Evaluate certain factors (listed below) that could impact produce safety
    a. Agricultural water system(s)
    b. Agricultural water practices
    c. Crop characteristics
    d. Environmental conditions
    e. Other relevant factors

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A covered farm may be exempt if it can demonstrate that 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

OR

- 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

Pre-Harvest Agricultural Water Treatment

SaniDate 12.0

- BioSafe Systems' SaniDate 12.0 is the First EPA-Registered Product to Reduce and Control Foodborne Bacterial Pathogens in Agricultural Irrigation Water
  - After years of collaborative work with industry and university researchers, BioSafe Systems announces that SaniDate® 12.0 has been approved by the EPA for the reduction of foodborne bacterial pathogens in pre-harvest agricultural irrigation water
  - SaniDate 12.0 is currently the only EPA-registered product labeled for the reduction and control of Shiga Toxin-producing Escherichia coli (STEC), including 0157:H7 and Salmonella enterica in preharvest irrigation water

FSMA Final Rule on Pre-Harvest Agricultural Water

What does this mean for produce growers?

- If not exempt, produce growers will need to conduct pre-harvest agricultural water assessments once annually and whenever a change occurs to determine if their pre-harvest water is of safe and adequate sanitary quality to use

Agricultural Water Assessment Builder

A user-friendly tool designed to help farms understand the proposed requirements in the FSMA Final Rule on Pre-Harvest Agricultural Water

- Prompts users to answer questions and/or fill in information specific to their unique conditions

Agricultural Water Assessment Builder

- Online tool
  - Information entered in the tool is not shared with the FDA and will not be saved
  - Users can save their responses as a PDF or print their responses when complete
    - The online tool won't save your place online if you close out of the browser
  - The tool can be used on a phone or tablet in the field if you have internet access
- Paper based tool
  - Downloadable PDF that you can print and write on or type into without internet access

It is NOT a requirement to use this tool

Agricultural Water Assessment Builder

- A. Optional user info
- B. Applicability & exemptions
- C. Ag water source
- D. Ag water distribution system
- E. Related equipment, buildings, and structures
- F. Animal impacts & activities
- G. BSAAOs
- H. Systems for collection/disposal of human waste
- I. Application of human waste to land
- J. Other water users
- K. Other potential sources of known or reasonably foreseeable hazards
- L. Crop characteristics
- M. Ag water use practices
- N. Environmental conditions
- O. Other relevant factors
- P. Outcomes without testing
- Q. Ag water testing
- R. Outcomes after testing
- S. Additional information

Elements of a Pre-Harvest Agricultural Water Assessment

C. Agricultural water source
D. Agricultural water distribution system
E. Related equipment, buildings, and structures
F. Animal impacts and activities
G. Biological soil amendments of animal origin
H. Systems for the collection and/or disposal of human waste
I Application of human waste to land
J. Other water users
K. Other potential sources of known or reasonably foreseeable hazards
L. Crop characteristics
M. Agricultural water use practices
N. Environmental conditions
O. Other relevant factors

Factors to Conducting an Assessment

Agricultural water systems

- The location and nature of the water source
  - Including whether it is ground water or surface water
- The type of water distribution system
  - Such as whether it is open or closed to the environment
- The degree to which the system is protected from possible sources of contamination, including:
  - 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, or the presence of untreated or improperly treated human waste

Factors to Conducting an Assessment

Agricultural water practices

- The type of application method
  - Such as overhead sprinkler or spray, drip, furrow, flood, and seepage irrigation
- The time interval between the last direct application of agricultural water and harvest of the covered produce
  - Other than sprouts

Factors to Conducting an Assessment

Crop Characteristics

- Susceptibility of the covered produce to surface adhesion or internalization of hazards
- There is currently research being done on this topic by academic institutions
  - Colonization and Internalization of Salmonella enterica and Its Prevalence in Cucumber Plants
    - DOI: 10.3389/fmicb.2020.01135
  - Salmonella enterica Colonization and Fitness in Pre-harvest Cantaloupe Production
    - DOI: 10.1016/j.fm.2020.103612

Factors to Conducting an Assessment

Environmental conditions

- Seasonal rainfall patterns, the frequency of extreme weather events (such as heavy winds or rain)
    - By stirring sediments that may contain human pathogens
    - Impact or damage produce
        - Damage can increase the susceptibility of produce to contamination
- Air temperatures
    - In general, the survival of pathogens in water sources decreases with increasing temperatures
- Sun (UV) exposure

Factors to Conducting an Assessment

Other relevant factors

- Including, if applicable, results of testing that could inform the assessment

Site Navigation

Factors Progress
12 %

Agricultural Water Source

Water Source Name

Provide a short name for your water source.

Water Source Description

Provide a brief description of this source.

Water Source Location

Where is this water source located?

Water Source Type
Ground Water

Is this a ground water source or a surface water source?

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Site Navigation

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Ground Water

Control - To what extent is this water source under your control?

Enter Response

Inspection - To the extent that it is under your control, do you inspect the water source at the beginning of the growing season, as appropriate, but at least once annually, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? Please provide a brief explanation of your practices.

Select Response

Selected Response:

Enter Response

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Site Navigation

Factors Progress
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Ground Water - Degree of Protection

Please consider the following factors in evaluating the degree of protection of the water source from potential sources of known or reasonably foreseeable hazards. Please choose Yes, No, or Not Applicable.

Element Question	Response Selection
Water source is regularly monitored for significant deficiencies, which if observed, are corrected (such as control of cross-connections and repairs to well caps, well casings, sanitary seals, piping tanks, and treatment equipment).	Yes No Not Applicable
Water source and surrounding area are kept free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.	Yes No Not Applicable
Regular maintenance activities occur to prevent the water source from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity.	Yes No Not Applicable
Barriers such as earthen diversion berms or ditches are present that may help minimize the influence of discharges or runoff from adjacent or nearby lands.	Yes No Not Applicable
Water source is subject to discharges or runoff from surrounding lands.	Yes No Not Applicable

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Site Navigation

Factors Progress
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Ground Water - Degree of Protection

Based on this information, do you consider this water source to be protected from potential sources of known or reasonably foreseeable hazards? Please explain.

Select Answer
Yes

- Yes
- No

Enter Response

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Site Navigation

Factors Progress
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Water Distribution System

Water Distribution System Name

Please provide a short name for your water distribution system:

Water Distribution System Description

Provide a brief description of this distribution system (For example, unlined laterals, piped distribution system, etc.).

Water Distribution System Location

Where is this distribution system located?

Water Distribution System Type

What kind of distribution system is this?

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Outcomes of a Pre-Harvest Agricultural Water Assessment

P. Outcomes without testing
Q. Agricultural water testing
R. Outcomes after testing

Outcomes of a Pre-Harvest Agricultural Water Assessment

Agricultural Water Assessment:

Outcomes follow a risk-based tiered approach

If…	*Then…*
Ag water not safe or not of adequate sanitary quality	Immediately discontinue use **AND** Take corrective measure(s) before use at pre-harvest
Condition(s) on adjacent or nearby land uses pose risk related to animal activity, BSAAO, or human waste	Implement mitigation measures promptly, and no later than the same growing season
Other conditions that may introduce known or reasonably foreseeable hazards, not related to animal activity, BSAAO, or human waste on adjacent or nearby lands	Implement mitigation measures as soon as practicable, and no later than the following year **OR** Test water as part of the agricultural water assessment and implement measures as needed
No known or reasonably foreseeable hazards for which mitigation is necessary	Inspect and maintain water system regularly and at least once a year

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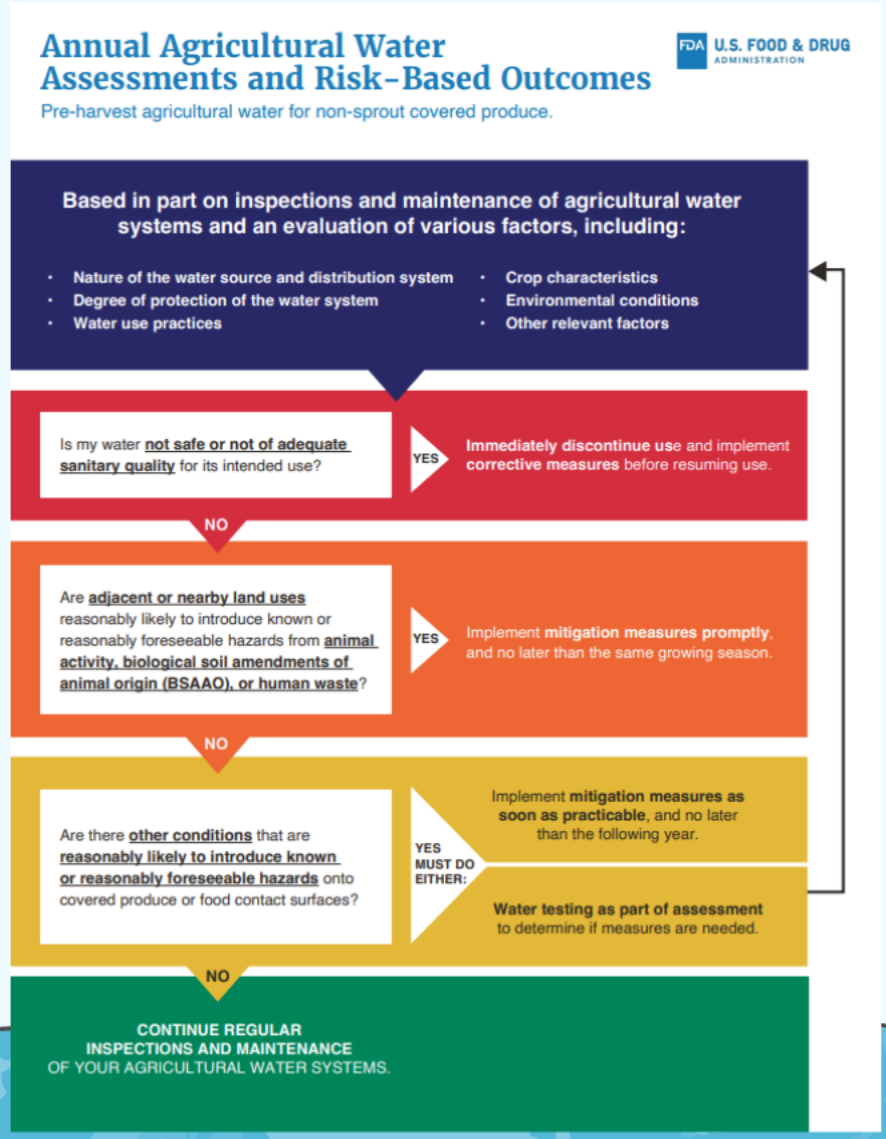


Assessment Outcomes

- If you determine that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)
- Then you must:
  - Immediately discontinue use(s)

  AND
  - Take corrective measures before resuming use of the water for pre-harvest activities

Assessment Outcomes

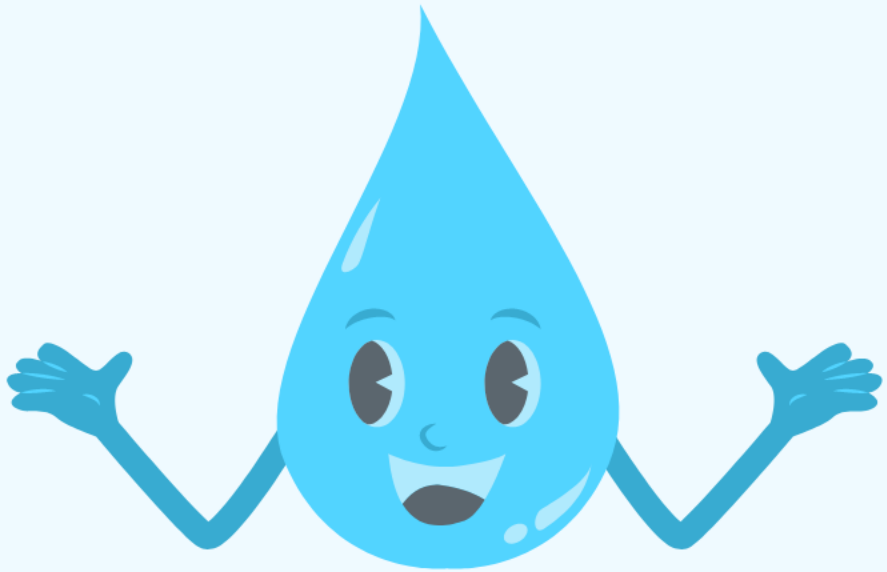
- If you determine there is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste, for which mitigation is reasonably necessary
    - Then you must implement mitigation measures **promptly**, and no later than the **same growing season**
- If you determine 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
    - Then you must:
        - 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

Assessment Outcomes

- If you determine that there are no known or reasonably foreseeable hazards for which mitigation is reasonably necessary
- Then you must inspect and adequately maintain the water system(s) regularly, and at least once each year



Corrective Measures vs. Mitigation Measures

- Corrective measures are put in place when the water is not safe or of adequate sanitary quality for its intended use
- Mitigation measures may be used to reduce the potential for contamination from pre-harvest agricultural water

Corrective Measures vs. Mitigation Measures

Agricultural Water Assessment: Corrective and Mitigation Measures

Corrective measures	• Re-inspecting the entire affected agricultural water system under the farm's control and, among other steps, making necessary changes **OR** • Treating the water in accordance with the standards in FSMA PSR
Mitigation measures	• Making necessary changes such as repairs • Increasing time interval between last direct application and harvest (microbial die-off) • Increasing time interval between harvest and end of storage (microbial die-off) • Other activities that result in die-off or removal • Changing water application method • Treating water (PSR standards) • Taking alternative mitigation measures supported by scientific information

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Corrective Measures

- If the pre-harvest agricultural water is not safe or of adequate sanitary quality for its intended use(s), it would be required to immediately discontinue such use
- Corrective measures refer to actions that covered farms must implement in order to resume use of water
    - Use in circumstances where it is necessary to take immediate action to protect public health

Corrective Measures

- Corrective measures a farm could take in order to resume use include:
  - Re-inspecting the entire affected agricultural water system under the farm's control and, among other steps, making necessary changes and taking adequate measures to determine if the changes were effective

  OR

  - Treating the water in accordance with the standards outlined in the Produce Safety Rule

Mitigation Measures

- Mitigation measures may be used to reduce the potential for contamination of produce or food contact surfaces with hazards associated with their pre-harvest agricultural water
- Examples of mitigation measures include:
  - Making necessary changes such as repairs
    - Ex) Repairing a well-head to ensure it is protected from hazards
  - Increasing the time interval between last direct application of agricultural water and harvest of the covered produce to allow for microbial die-of
    - Ex) Consider the timing of water applications vs environmental conditions

Mitigation Measures

- Additional examples of mitigation measures include:
  - Increasing the time interval between harvest and the end of the storage period and/or conducting other activities during or after harvest to allow for microbial die-off or removal
    - Ex) Commercial washing or controlled atmosphere storage (among others), if supported by scientific data and information
  - Changing the method of water application to reduce the likelihood of produce contamination
    - Ex) Change from use of overhead spray to subsurface drip irrigation for certain crops

Mitigation Measures

- Additional examples of mitigation measures include:
  - Treating the water in accordance with the standards outlined in the Produce Safety Rule
    - Ex) Physical treatment, an EPA-registered antimicrobial pesticide product, or other suitable method
  - Taking alternative mitigation measures supported by scientific data and information
    - Ex) Covered farms are not required to notify or seek approval from FDA regarding use of an alternative mitigation measure

Reassessment

A covered farm would be required to conduct a reassessment each year in which the farm applies preharvest agricultural water to covered produce (other than sprouts), and anytime there is a significant change in its agricultural water systems, agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that make it reasonably likely that a hazard will be introduced into or onto produce or food contact surfaces through direct application of pre-harvest agricultural water

Records

- Covered farms are required to maintain written records of their pre-harvest agricultural water assessments, including descriptions of factors evaluated and their written determinations
- Farms that test their pre-harvest agricultural water as part of their assessments are required to maintain certain documentation related to their sampling and testing procedures
- Supervisors are required to review the written pre-harvest agricultural water assessments and the determinations made based on the outcomes of the assessments

Frequently Asked Questions

- So, what are the water testing requirements under the FSMA Final Rule on Pre-Harvest Agricultural Water?
  - Test results and analysis can be utilized as one factor when conducting an assessment
- Can you use untreated surface water for irrigation?
  - Yes, if you have conducted an assessment and you determine that the water is safe or of adequate sanitary quality for its intended use(s)
- Can you download and save the assessment once you're done?
  - Yes, you can save as a PDF or print the assessment when you are complete
- Does every farm have to conduct an assessment under the FSMA Final Rule on Pre-Harvest Agricultural Water?
  - No, only covered farms that are not exempt must comply with the requirements

So, what do inspectors need to be looking for regarding pre-harvest ag water on an inspection?

- Record review of the pre-harvest agricultural water assessments, including descriptions of factors evaluated and their written determinations, reviewed and signed off by a supervisor
- If applicable, review of certain documentation related to their sampling and testing procedures
- If applicable, corrective measures and mitigation measures are documented
- The water source, distribution, and application align with what is documented on the assessment

Citing the Produce Safety Rule

112.40 What requirements of this subpart apply to my covered farm?

112.41 What requirements apply to the quality of my agricultural water?

112.42 What requirements apply to inspecting and maintaining my agricultural water systems?

112.43 What requirements apply to assessing agricultural water used in growing covered produce (other than sprouts)?

112.44 What requirements apply to agricultural water used as sprout irrigation water and in harvesting, packing, and holding covered produce?

Citing the Produce Safety Rule cont…

112.45 What measures must I take for agricultural water to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards?

112.46 What requirements apply to treating agricultural water?

112.47 Who must perform the tests required under this subpart?

112.48–112.49 [Reserved]

112.50 Under this subpart, what requirements apply regarding records?

Compliace Dates

Large farms: April 7, 2025
Small farms: April 6, 2026
Very small farms: April 5, 2027

So, all in all, what changed since the proposed rule?

- Clarification that an exemption only applies if water quality is unlikely to change prior to use
- Revisions to certain mitigations to better allow for future science and advancements in post-harvest handling, such as:
  - In field die off
  - Post-harvest storage and other post-harvest activities that could influence die off/potential microbial reduction

Produce Safety Alliance Resources

- Revised Module 5-1 Slide Availability:
- Fill out the form at this page and you will be able to download the PowerPoint slides with notes and a printable PDF handout containing the slides and notes:

https://cals.cornell.edu/produce-safety-alliance/psa-curriculum/revised-module-5-1

- PSA collects contact information upon download so they can share any updates to the materials.
    - Please do not share the Power Point and printable PDF directly.

Thank You

For more information and to view all of the factsheets, visit:

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-pre-harvest-agricultural-water

Other resources:

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

To teach growers in your state about the new requirements:

Reach out to your state's FDA Produce Safety Network contact to inquire about hosting an FDA/State Joint Water Systems Workshop. The content focuses on water equipment and risks. FDA is developing additional educational opportunities that will focus on assessments.

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