



Agricultural Water Assessment Builder

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Topics covered



- Background
- Overview of builder
 - Development
 - What the builder looks like
- Next steps

Background



- Feedback that 2015 testing requirements were difficult to implement across the wide variety of water sources, uses, and practices
- “Agricultural water assessments” identified by stakeholders as a promising approach
 - Many emphasized that additional educational tools would be needed

Overview

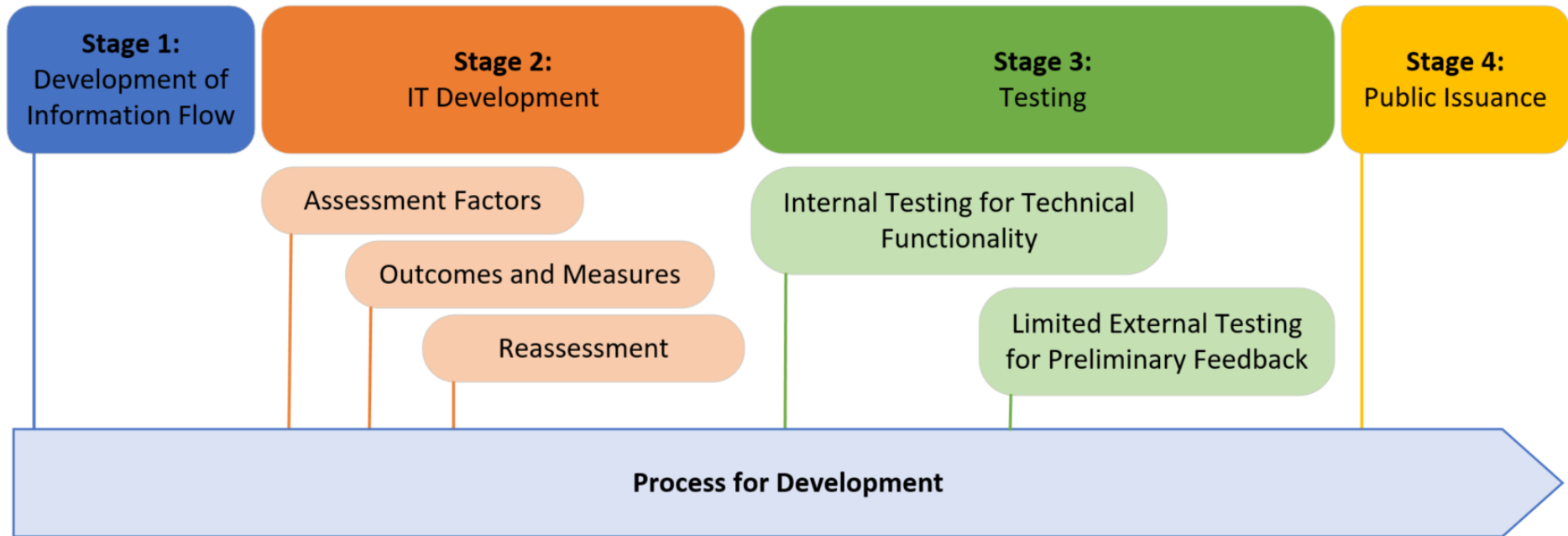
- User-friendly tool designed to help users understand the proposed requirements
- **Use of tool is OPTIONAL**, not required
- If the rule is finalized, tool would be updated to align with final requirements and feedback
- Tool NOT meant to stand alone
 - could supplement, but not replace, other technical assistance, education, training, and experience

Guiding principles/objectives



- Allow users to input information specific to conditions and practices at their individual farms
- The users' data will NOT be shared with the FDA
- Allow access to the tool across computer operating systems and across all common browsers
- Can be used on a computer or a mobile device
- Can save progress and return later to finish it, or to do a reassessment
- Can also save the information entered as a PDF for user to keep or to print it for their own records.

Development



RELEASE - V 1.0 March 21, 2022

Provided for
illustrative purposes
only, based on AW
proposed rule
codified

Constituent Updates

Center for Food Safety and Applied Nutrition

FDA Launches Agricultural Water Assessment Builder to Help Farms Understand Agricultural Water Proposed Rule Requirements

March 21, 2022

The U.S. Food and Drug Administration (FDA) released a new user-friendly online [Agricultural Water Assessment Builder](#) to help farms understand the proposed requirements for an agricultural water assessment in the [Agricultural Water Proposed Rule](#). Use of the tool is optional.

If finalized, the proposed rule would require farms to conduct systems-based agricultural water assessments to determine and guide appropriate measures to minimize potential risks associated with pre-harvest agricultural water. The assessment would include an evaluation of the water system, agricultural water use practices, crop characteristics, environmental conditions, potential impacts on source water by activities conducted on adjacent and nearby land, and other relevant factors, such as the results of optional testing. Covered farms would be required to conduct pre-harvest agricultural water assessments annually, and whenever a significant change occurs that affects the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto produce or food contact surfaces.

The Agricultural Water Assessment Builder prompts users to answer questions and/or fill in information specific to their farms. Information entered into the tool is not shared with the FDA and will not be saved. However, users have the opportunity save or print the information they provide to their local computers.

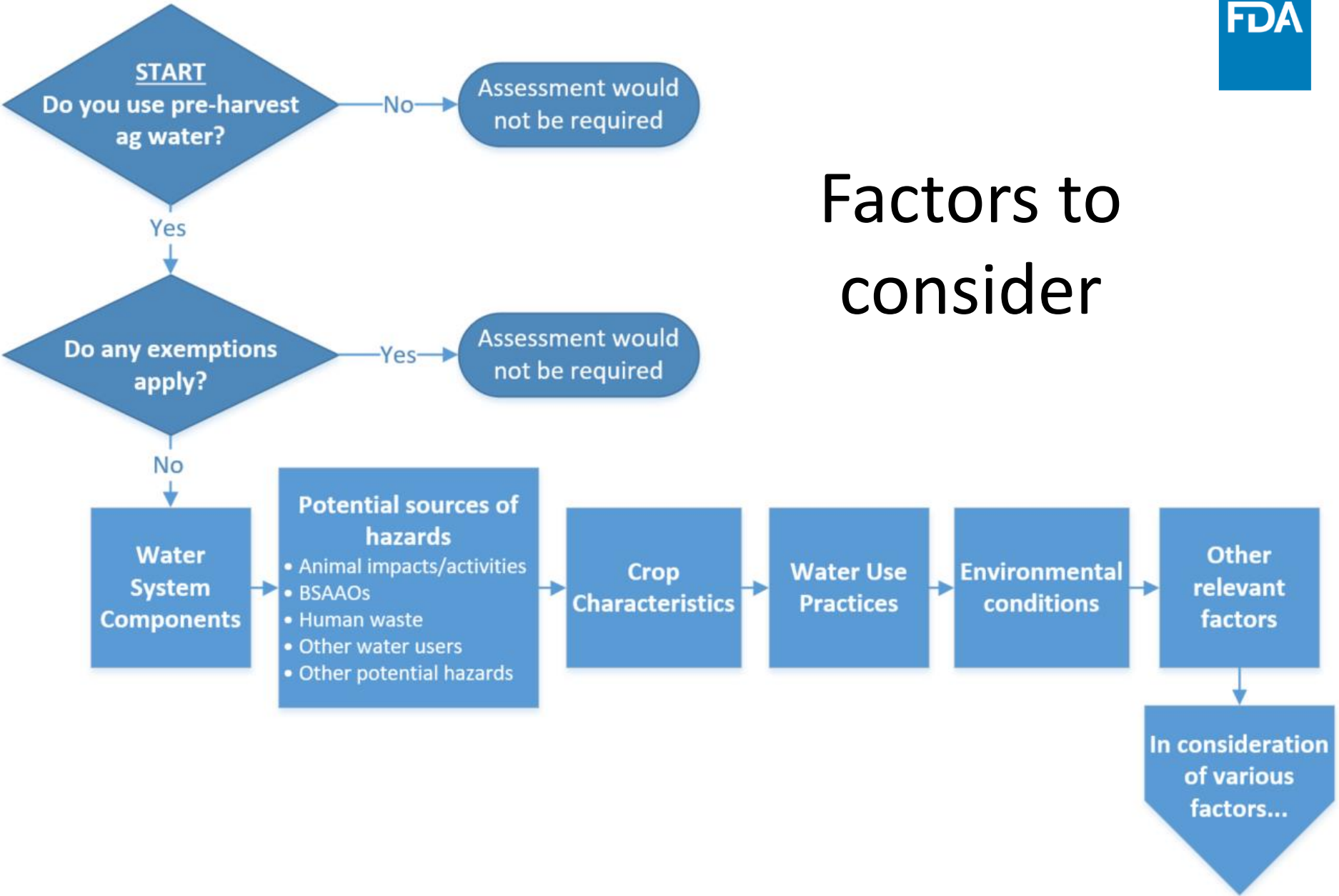
This user-friendly tool incorporates information from the Agricultural Water Proposed Rule, the Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce, and the 2015 Produce Safety Final Rule.

The development of this tool is consistent with our objectives in the [New Era of Smarter Food Safety Blueprint](#) to look for smarter tools and approaches for food safety. We welcome feedback on this optional tool, such as suggestions related to the tool's functionality and, useability. Feedback on the tool can be sent to agwaterbuilder@fda.hhs.gov.

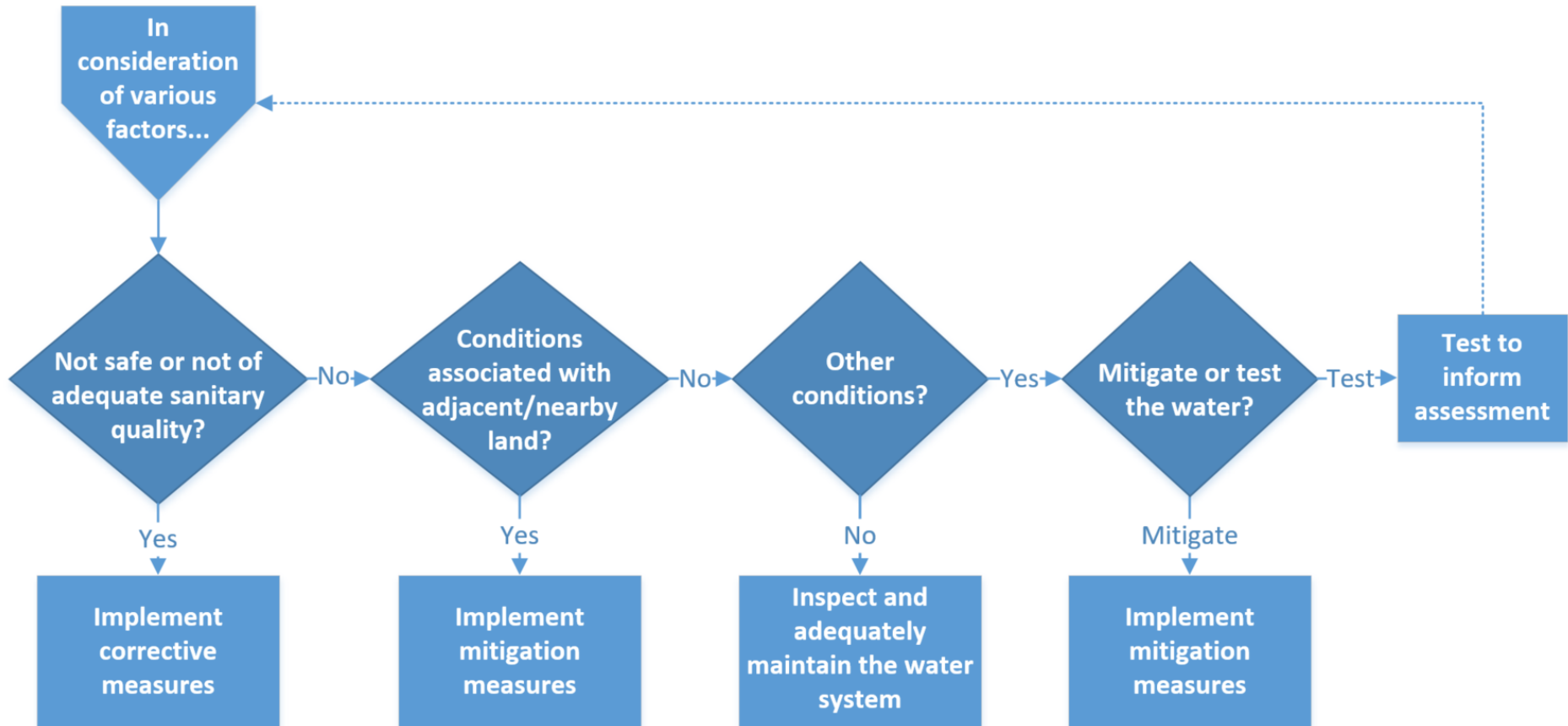
For Additional Information

- [Agricultural Water Assessment Builder Information Page](#)
- [Federal Register Notice announcing the Proposed Rule](#)
- [FSMA Proposed Rule on Agricultural Water](#)

Factors to consider



Outcomes / Measures



Landing Page Screenshot



Navigation

Supports Modern Browsers



Welcome to the Agricultural Water Assessment Builder!

  More Information

Thank you for choosing to use the Agricultural Water Assessment Builder. The Agricultural Water Assessment Builder v. 1.0 is a user-friendly tool designed to help farms understand the proposed requirements for an agricultural water assessment in the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” proposed rule (agricultural water proposed rule). If finalized, the rule would replace the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) in the 2015 Produce Safety Final Rule with provisions for systems-based agricultural water assessments. Relevant definitions and resources can be viewed by clicking the icon next to the title of this page.

We welcome feedback on v1.0 of this optional tool, such as suggestions related to the tool’s functionality and useability. Feedback on the tool can be sent to agwaterbuilder@fda.hhs.gov.

Use of this tool is not required by law (see legal disclaimer) and would not be required. If the agricultural water proposed rule is finalized, FDA expects this tool to supplement and not replace other education, training, and experience that would be needed to understand and implement the requirements of the rule.

The information entered into this page will not be shared with FDA and will not be saved. If you need to pause while entering information, we recommend that you export a copy of your data and save it to your local machine. Once the document is saved, you may resume at a later time, and upload the file to begin from where you paused. Once you have reached the end of this tool, you will be given the opportunity to print out a summary of the information entered. Remember, the data that is entered here is not saved unless your export a file to save on your computer.

This tool is being provided for illustrative purposes only because the requirements for agricultural water assessments under proposed [§ 112.43](#) have not been finalized.

Legal disclaimer: Use of the Agricultural Water Assessment Builder v. 1.0 does not constitute FDA approval of an agricultural water assessment or guarantee compliance with FDA’s requirements, if finalized. FDA has taken all reasonable precautions in creating the Agricultural Water Assessment Builder v. 1.0. However, FDA is not responsible for errors, omissions or deficiencies regarding the tool. The Agricultural Water Assessment Builder v. 1.0 is available “as is” and without warranties of any kind, either expressed or implied, including, but not limited to, warranties of performance, merchantability, and fitness for a particular purpose. FDA is not making a commitment in any way to regularly update the tool. Responsibility for the interpretation and use of the Agricultural Water Assessment Builder v. 1.0 lies solely with the user. Third parties’ use of or acknowledgment of the tool does not in any way represent that FDA endorses such third parties or expresses any opinion with respect to their statements.

CONTINUE

Navigation



Site Navigation ?

Factors

- Introduction
- Farm Information
- Applicability/Exemptions
- Elements of a Pre-harvest Agricultural Water Assessment
 - Agricultural Water System Components
 - Animal Impacts and Activities
 - BSAAs
- Human Waste
- Other Water Users
- Other Potential Sources of Hazards
- Crop Characteristics
- Agricultural Water Use Practices
- Environmental Conditions
- Other Relevant Factors

Outcomes

“More information”

More Information

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). (21 CFR 112.3).

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop. (21 CFR 112.3).

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water. (21 CFR 112.3).

As proposed, **agricultural water assessment** means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) 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 measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards. (Proposed addition to 21 CR 112.3).

As proposed, **agricultural water system** means 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. (Proposed addition to 21 CR 112.3).

Helpful resources:

- [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water \(Agricultural Water Proposed Rule\) \(86 FR 69120\), Dec. 6, 2021.](#)
- [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Final Rule" \(2015 Produce Safety Final Rule\) \(80 FR 74353\), Nov. 27, 2015.](#)
- [Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce" \(QAR\), Nov. 2015.](#)

Features Example Screenshot




U.S. Department of Health and Human Services | U.S. FOOD & DRUG ADMINISTRATION | Agricultural Water Assessment Builder | Site Optimized for Chrome, Edge, or Firefox


Site Navigation | Factors Progress: 2%


Proposed Exemptions ⓘ

Can you demonstrate one of the following for the agricultural water you apply during growing activities for covered produce (other than sprouts)? If Yes, please explain.

- Agricultural water meets the requirements in proposed [§ 112.44\(a\)](#), including the microbial quality criterion of no detectable generic E. coli per 100 mL, and if untreated ground water, also meets the testing requirements in proposed [§§ 112.44\(b\), 112.47, and 112.151](#). (This proposed exemption would not apply to untreated surface water, because proposed § 112.44(a) prohibits the use of untreated surface water for sprout irrigation or harvest or for post-harvest application on covered produce);
- Agricultural water meets the requirements in proposed [§ 112.44\(c\)](#) for water from a Public Water System or public water supply; or
- Agricultural water is treated in accordance with proposed [§ 112.46](#).

Select Answer  Drop Down

Enter Response  Comment Field

Page Controls  [< BACK](#) [NEXT >](#) [SAVE](#)

U.S. FOOD & DRUG ADMINISTRATION | ACCESSIBILITY | CAREERS | FDA BASICS | FOIA | NO FEAR ACT | NONDISCRIMINATION | WEBSITE POLICIES

Features Example Screenshot



U.S. Department of Health and Human Services Site Optimized for Chrome, Edge, or Firefox

FDA U.S. FOOD & DRUG ADMINISTRATION | **Agricultural Water Assessment Builder** ⋮

Site Navigation Factors Progress
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- Agricultural water is treated in accordance with proposed [§ 112.46](#).

Select Answer ▼

Enter Response

< BACK NEXT > SAVE **Save Functions**

ACCESSIBILITY CAREERS FDA BASICS FOIA NO FEAR ACT NONDISCRIMINATION WEBSITE POLICIES

“Save” Screenshot

The screenshot displays the 'Agricultural Water Assessment Builder' interface. At the top, it shows the U.S. Department of Health and Human Services logo and the FDA logo. The page title is 'Agricultural Water Assessment Builder'. On the left, there is a 'Site Navigation' menu, and on the right, a 'Factors Progress' indicator showing 4%. The main content area is titled 'Proposed Exemptions' and contains a question: 'Can you demonstrate one of the following for the agricultural water you apply during growing activities for covered produce (other than sprouts)? If Yes, please explain.' Below the question is a list of options, with the first one selected: 'Agricultural water meets the requirements in proposed § 112.44(a), including the microbial quality criterion of no detectable generic E. coli per 100 mL, and if untreated ground water, also meets the testing requirements in proposed §§ 112.44(b), 112.47, and 112.48, and the water is used for irrigation of covered produce;'. A 'Save Assessment' dialog box is overlaid on the page, providing instructions on how to export data. The dialog box contains the following text: 'There are two options for exporting data. Clicking the button **Save for Import** will export a JSON file that contains your current progress of the assessment to be used for continuing an assessment or conducting a re-assessment at a later time. **Do not modify this file.** Clicking the button **Save for Viewing** will export a PDF file that can be used for offline viewing of the assessment data. Feel free to click both if desired.' Below the text are two buttons: 'SAVE FOR IMPORT' and 'SAVE FOR VIEWING'. At the bottom of the page, there are navigation buttons: '< BACK', 'NEXT >', and 'SAVE'.



Next steps

- Feedback from external testing triaged for incorporation into V 1.0
- Tool reflects proposed (not final) requirements
- Long-term: update builder based on final rule and stakeholder feedback
- Considering a “paper format”
 - Potential for translation
- Question about the tool and feedback
agwaterbuilder@fda.hhs.gov
- Questions about proposed rule
AgWater@fda.hhs.gov



Compliance with Subpart E Requirements for Harvest & Post-harvest Ag Water

Food and Drug Administration

January 2023

Overview



Where we are now and how we got here



Compliance dates and inspectional approach



Existing requirements for H/PH ag water



Training, education and outreach



Resources

Seven Foundational Rules

Food Safety Modernization Act (FSMA)

- 1) **Produce Safety Rule**
- 2) Preventive Controls for Human Food
- 3) Preventive Controls for Animal Food
- 4) Foreign Supplier Verification Programs
- 5) Accredited Third-Party Certification
- 6) Intentional Adulteration
- 7) Sanitary Transportation of Food

Produce Safety Rule

- Science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables.
- Focuses on biological hazards related to growing, harvesting, packing and holding produce
- If you are a covered farm, you must comply with the PSR



- Subpart A (§112.1-112.7): General provisions
- Subpart C (§112.21-112.30): Personnel Qualifications and Training
- Subpart D (§112.31-112.33): Health and Hygiene
- **Subpart E (§112.41-112.50): Agricultural Water**
- Subpart F (§112.51-112.60): Biological Soil Amendments of Animal Origin and Human Waste
- Subpart I (§112.81-112.84): Domesticated and Wild Animals
- Subpart K (§112.111-112.116): Growing, Harvesting, Packing and Holding Activities
- Subpart L (§112.121-112.140): Equipment, Tools, Buildings and Sanitation
- Subpart O (§112.161-112.167): Records

Timeline: Ag Water Rulemaking

Nov. 2015:
Produce
Safety Rule
Published

Mar 2019:
Extended
compliance
dates for
Subpart E

July 2022:
SNPRM

Mar. 2017:
Announces
review of
Subpart E:
Ag Water

**December
2021:**
NPRM to
amend
Subpart E
(pre-harvest
water only)

- Proposed new compliance dates for pre-harvest ag water, to be applied after ag water rulemaking is final*
- Announced the end of FDA's period of intended enforcement discretion for ag water used during and after harvest

** Reminder: The December 2021 Proposed Rule to Amend Subpart E only included proposed changes for pre-harvest water*

Compliance Dates*:

Harvest and Post-harvest (H/PH) Ag Water (Covered produce other than sprouts)

- January 26, 2025 for **very small** businesses
- January 26, 2024 for **small** businesses
- **January 26, 2023 for all other businesses (large)**

**Note: These compliance dates are actually the dates that enforcement discretion ends*

Initial, routine inspections:

- *For the first year, FDA and states intend take an educational approach, ensuring farms are aware of compliance dates and working closely with partners to prepare for implementing these provisions prior to initiating routine inspections verifying compliance in the second year.*
- Exception: for-cause inspections

Definition of Ag Water and Applicability

Agricultural water - Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces. Includes water used for hand washing.

- **Pre-harvest ag water** – Water used during growing activities (including irrigation using direct water application methods and water used for preparing crop sprays).
- **Harvest, post-harvest ag water (H/PH)** - Water used in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce, making ice and water used for preventing dehydration).



PSR Requirements for H/PH Ag Water

Subpart E

- **112.41**: Quality standard
- **112.42**: Inspections and maintenance
- **112.43**: Treatment
- **112.44(a)**: Microbial quality criterion
- **112.45(a)**: Measures
- **112.46(a) and (c)**: Testing
- **112.47**: Who may test
- **112.48**: Additional management and monitoring
- **112.50**: Records

Subpart N

- **112.151**: Test methods

Subpart O

- **112.161**: Records requirements

** Note: Includes both H/PH specific requirements and requirements for “all Ag Water” from 2015 PSR. Provisions may be renumbered in final Ag Water Rule.*

(112.41)

If used for H/PH Ag Water:

- Water must be safe and of adequate sanitary quality for its intended use*
- No detectable generic *E. coli* per 100 ml of agricultural water
- Untreated ground water must be tested 4x per year initially, then 1x per year if meeting no detectable generic *E. coli* per 100 ml

**Reminder: All farms (regardless of compliance dates) should be familiar with their water sources and are required to provide reasonable assurances that produce is not adulterated under Section 402 of the FD&C Act.*

Water System Inspections and Maintenance



(112.42)

- Farms are required to do inspections at least annually, on [\[H/PH Ag Water\]](#) systems that are under their control:
 - ID and correct conditions that may introduce hazards
 - Conduct maintenance as needed based on the findings of the inspection

Water Treatment

(112.43)

- § 112.43(a): Treatment of [H/PH Ag Water] must be effective and delivered to ensure the water is consistently safe and of adequate sanitary quality for its intended use and/or meets microbial criterion of no detectable generic E. coli per 100 mL of water, as applicable
 - May be physical, chemical or a combination of treatments
- § 112.43(b): Treatment must be monitored at an adequate frequency



Corrective Measures

(112.45(a))

- Required when [H/PH Ag Water] does not meet safe and adequate requirements or microbial criterion:
 - Immediately discontinue use upon findings.
 - In order to resume use, farms must:
 - Re-inspect the system to the extent it is under your control and make changes as needed, **OR**
 - Treat the water to ensure it is of adequate sanitary quality for its intended use and/or meets the microbial criterion under treatment provisions

Testing Ag Water (112.46(c))

Testing is **NOT** required if [**H/PH Ag Water**] is:

- Sourced from a Public Water System that meets certain requirements (112.46(a)(1))
- Sourced from a public water supply that meets the microbial criterion of no detectable generic *E. coli* per 100 mL of water (112.46(a)(2)); **or**
- Treated in accordance with the requirements in 112.43

Testing **IS** required if using untreated ground water **during or after harvest.**

Additional Management & Monitoring

(112.48)



Manage the [H/PH] ag water as necessary to maintain its safety and quality and minimize the potential for it to serve as a source of contamination



Establish and follow water-change schedules for re-circulated [H/PH] ag water and visually monitor the quality of water for buildup of organic material



Maintain and monitor the temperature of [H/PH] ag water as appropriate for the commodity and operation to minimize the potential for infiltration of pathogens into covered produce

Records

(112.50,
112.161)

- ✓ Findings of [H/PH] ag water system inspections
- ✓ Analytical test results
- ✓ Documentation from public water systems such as certificates of compliance
- ✓ Documentation of corrections taken under 112.45(a)
- ✓ Scientific support to justify treatment parameters
- ✓ Treatment monitoring
- ✓ Analytical methods used in lieu of what is outlined in codified

Inspection Approach- Overview

Pre-harvest ag water: No Change

- Still subject to rulemaking, enforcement discretion continues
- Do NOT evaluate against Subpart E
- Evaluate for adulteration
 - Food, Drug and Cosmetic Act
 - General requirement in 112.11

Recommendations to farms:

- Continue to follow Good Agricultural Practices

Inspection Approach- Overview

Harvest and Post-harvest Ag Water



Staggered end of enforcement discretion

During the first year of compliance on **large farms** after enforcement discretion ends (Jan 26, 2023 – Jan 25, 2024)

- Educational engagement - helping growers prepare for implementing these provisions
- Continue to inspect under 112;
 - do NOT inspect against Subpart E, except during For-Cause Inspections

For small, very small farms (2023-2024*):

- Continue to inspect under 112;
 - do NOT inspect against Subpart E
- Continue to provide education related to Ag Water

Educate before and while we regulate

States may elect to provide OFRRs, on-farm visits and technical assistance to farms of any size during this time

Still OK if:

- Previously inspected
- Previous OFRR or EFV