

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

Food and Drug Administration

February 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



Standards for the Produce Safety Rule

- 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)



July 22, 2022 - SNPRM

- 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.*

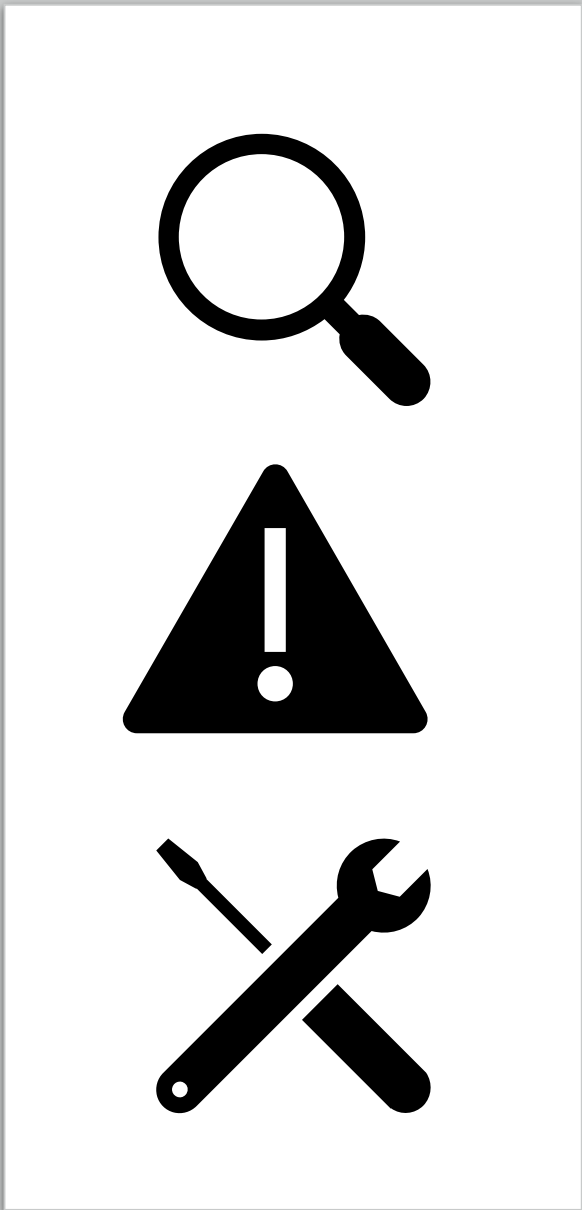
Water Quality Standard (112.41)

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)

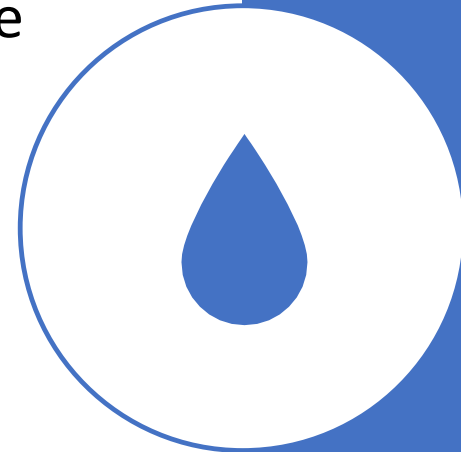


- Farms are required to do inspections at least annually, on [\[H/PH Ag Water\]](#) systems that are under their control:
 - ID and correct conditions that may introduce hazards
 - Conduct maintenance as needed based on the findings of the inspection

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

Educational Materials and Resources

Educational materials:

- PSA Grower Training
- PSA resource docs
- OFRR

- Updated Webinar for FD226

New Resource:

- Factsheet



PSA Grower Training- Agricultural Water

- Existing curriculum in **Module 5** covers **harvest/post-harvest agricultural water**:
 - Provides growers and regulators with information for PSR compliance
 - If previously attended PSA training, no requirement for additional training prior to compliance dates (**beginning January 26, 2023**)
- **PSA Training Curriculum will remain the same until Ag Water rule is finalized**



On-Farm Readiness Reviews

On-Farm Readiness Review Partners



Material based on the final PSR (2015)

- OFRR Resource Manual
- WAQ
- NASDA/Rutgers Post Survey

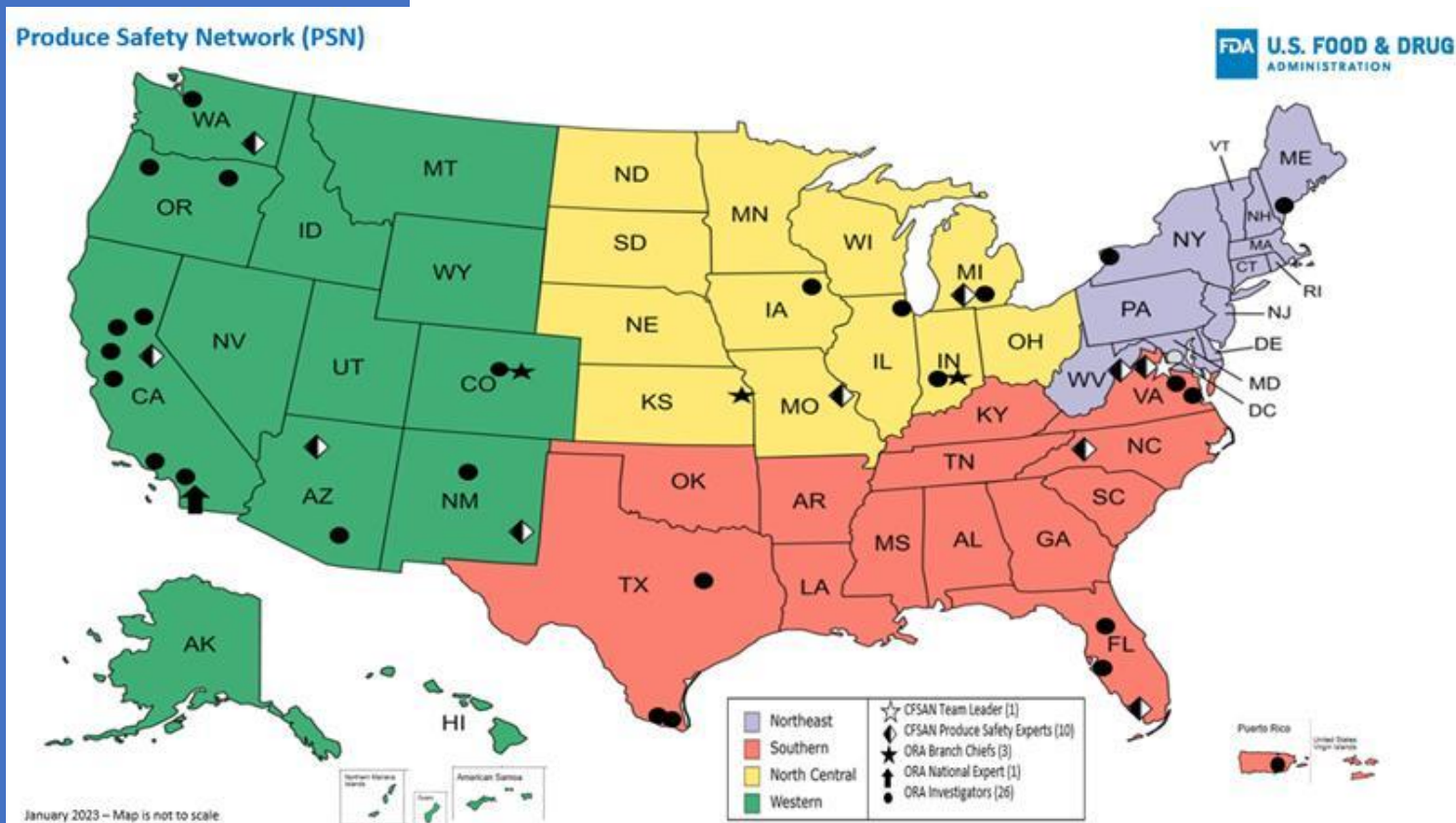
Fact Sheet:

Harvest/Post-harvest Ag Water

- Directed to farms and the PSR covered produce industry
- Focused on requirements for harvest and post-harvest ag water as referenced in the 2015 final PSR
- Information about compliance dates, inspection approach, applicable requirements, corrections such as measures to take if not meeting “no detectable generic *E. coli*/100 ml”) are a few of the items included.



Produce Safety Network



- PSN Directory: <https://www.fda.gov/media/105420/download>

Resources for Harvest and Post-harvest Ag Water

Webpages:

- [Federal Register :: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#)
- [FSMA Proposed rule on Agricultural Water](#)
- [FDA Proposes Compliance Date Extension for Pre-Harvest Agricultural Water Requirements | FDA](#)

Factsheet:

- [Harvest and Post-harvest Agricultural Water Fact Sheet](#)



Gracias!

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Questions?

