

FSMA Produce Safety Rule Pre-Harvest Agricultural Water Inspection & Assessment How-To

*Tips are highlighted in gray

1. The Agricultural Water Rule, Subpart E of the Produce Safety Rule, is finalized.
 - a. Read the regulation by searching “21 CFR 112”, www.ecfr.gov is recommend
 - b. The finalized subpart E has different section numbers than the original/proposed Subpart E. The workshop packet contains a conversion table that can be used for resources like the On-Farm Readiness Review manual published before Subpart E was finalized in 2024.
 - c. Compliance Dates: Additional year of enforcement discretion for harvest and post-harvest water testing requirements

Farm Size:	Harvest and post-harvest water inspection & testing	Pre-harvest water inspection & assessment
Large (greater than \$500,000 gross produce sales)	January 26, 2023 2024	April 7, 2025
Small (\$250,000 to \$500,000 gross produce sales)	January 26, 2024 2025	April 6, 2026
Very Small (\$25,000 to \$250,000 gross produce sales)	January 26, 2025 2026	April 5, 2027

2. Summary of Subpart E:
 - a. Agricultural water must be safe for intended use
 - b. Inspection & maintenance of agricultural water system (pre-harvest, harvest, post-harvest water)
 - c. Agricultural water assessment (pre-harvest water)
 - d. Harvest/post-harvest water testing requirements
 - e. Agricultural water assessment corrective actions
 - f. Agricultural water treatment
 - g. Agricultural water required records
3. Workshop relevance to farms:
 - a. Farms not subject to the PSR might be required to do and ag water inspection/assessment for a third-party audit.
 - b. All farms should be aware of potential hazards related to their agricultural water use.
 - c. Farms exempt from PSR ag water assessment still need to inspect their ag water system.
4. Assessment Exemptions are listed in:
 - a. Produce Safety Rule section 112.43(b)
 - b. FDA Ag Water Assessment Builder Tool Table B
 - i. Exempt if farm is not subject to Produce Safety Rule
 - ii. Exempt if the water does not touch the edible portion of the crop
 - iii. Exempt if the crop is not subject to the Produce Safety Rule (potatoes)
 - iv. Exempt if source is ground or municipal water with 0 E. coli or treated surface water and the water quality is unlikely to change prior to use.
5. Inspection vs Assessment *Commonalities highlighted in yellow.
 - a. **Inspection**, 112.42: Go look at it!

- i. Pre-harvest, harvest, and post-harvest ag water
- ii. Inspect physical system under farm's control
- iii. Consider conditions that may pose a risk including adjacent/nearby lands: *These considerations don't seem to apply to harvest/post-harvest water so read the definition of agricultural water system in section 112.3 and it will make more sense.

1. Nature of the source

2. Extent of control over the source

3. Degree of protection of the source *See cheat sheet from assessment builder sections C-7, C-11, D-7, D-11.

4. Use of adjacent and nearby land

5. Likelihood of introduction of hazards by another user before the farm

b. **Assessment**, 112.43: Think about what you saw during the inspection

- i. Pre-harvest water only
- ii. Based in part of inspection findings and maintenance
- iii. Evaluate conditions that may pose a risk
- iv. Elements of an assessment:
 1. Agricultural water system *Split into several assessment tool tables resulting in more tables than assessment elements.
 - a. Location and nature of the source
 - b. Type of water distribution system
 - c. Degree of protection from possible sources of contamination (other water users, adjacent/nearby land uses related to animal activity, soil amendments of animal origin, human waste).
 2. Agricultural water use (application method, interval between application and harvest)
 3. Crop characteristics
 4. Environmental conditions
 5. Other relevant factors such as testing

c. **Inspection & Assessment** commonalities

- i. Intent of both is to "identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto **produce** or **food contact surfaces**."
- ii. Both can trigger repairs, maintenance, or other actions to control identified hazards.
- iii. Both are annual and require documentation.
- iv. Inspection tasks are in the FDA Assessment Builder paper-based tool (C-6, C-10, D-6, D-10, E-3). You can't have Assessment without Inspection. *Take the assessment template and cheat sheet with you to take notes when you do the inspection.

6. Let's Inspect Lindsay's Well with pictures:

- a. *Use the DACF cheat sheet for evaluating the degree of protection and other considerations when conducting an inspection.
- b. 1st photo is standing in the horse pasture on the edge of the leach field marked with rocks. Manure pile with sloping land down to the dug well behind the little white house.

- c. 2nd photo is the well cap. Pictures taken when raking leaves away. Out of sight to the left is the old windmill. This well used to supply the old school.
- d. 3rd photo a closeup of the well cover. Made a cement cover to replace the wood one that was rotted. Submersible pump suspended by the rope tied to the pipe that serves no other function. No seal between the cement cover and pad but no large open gap either.
- e. 4th photo is standing on the cement pad looking up to manure pile. About 10 feet between edge of cement pad and fence line. About 225 feet between fence line and manure pile.
- f. 5th photo is the stone-lined inside of the well.
- g. 6th photo is the grass not grazed by the horse due to them being well fed enough not to eat grass contaminated with manure runoff. Runoff pattern from the side.
- h. 7th Photo shows the runoff pattern from below. About 33-36 feet between the bottom edge of runoff and the manure pile. Manure pile hauled off every spring.









7. Inspection Findings:

- a. Source = dug well with possible surface water influence?
- b. Distribution system = closed, pipes intact
- c. Extent of control = full control, Lindsay's land
- d. Degree of protection = partial
 - i. Not sealed, stone lined so no casing
 - ii. Regularly monitored while doing horse chores
 - iii. 2 horses, fencing for 10-foot vegetation buffer
 - iv. Backflow prevention device installed in the house
 - v. Uphill manure pile about 235 feet away.
- e. Use of adjacent land = woods, 2 residences, horse pasture/manure pile
- f. Prior use = none
- g. Is the water safe? Maybe, let's do an assessment... 112.43(a)
 - i. What is this water being used for?
 - 1. Pre-harvest, need to do assessment
 - 2. Harvest/post-harvest, testing results show 0 generic *E. coli*

8. Testing as part of assessment, 112.43(d)

- a. Testing is one way to get to know your water source better
- b. Let's follow Lindsay's water testing journey...

2007 purchased house, full residential test

Date Received	July 31, 2007	Time Received	9:00 AM	Date Reported	August 02, 2007
Client Information	[REDACTED]			Temperature Upon Arrival	22°C
Property Tested	[REDACTED]			Sample Point	Kitchen
This water is rated as:		Satisfactory			
<u>PARAMETERS</u>	<u>METHOD NO.</u>	<u>LIMITS</u>	<u>RESULTS</u>	<u>DATE/TIME ANALYZED</u>	
Total Coliform	9222*	ABSENT [0/100ML]	Absent	7/31/2007 12:30:00 PM	
E coli	9222*	ABSENT [0/100ML]	Absent	7/31/2007 12:30:00 PM	
Nitrite-N	4500-NO2D*	1.0 mg/L	<0.10 mg/L	7/31/2007 4:50:00 PM	
Nitrate-N	4500-NO3B*	10.0 mg/L	<1.0 mg/L	7/31/2007 4:20:00 PM	
pH	4500-H+B*	6.5-8.5	7.2 pH Units	7/31/2007 3:40:00 PM	
Copper	3111B*	1.3 mg/L	0.87 mg/L	N/A	
Manganese	3111B*	0.05 mg/L	<0.02 mg/L	N/A	
Iron	3111B*	0.30 mg/L	0.07 mg/L	N/A	
Chloride	4500-ClB	250 mg/L	20 mg/L	N/A	
Hardness (EDTA)	2340C*	500 mg/L	91 mg/L	N/A	
Sodium	3111B*	100 mg/L	9.1 mg/L	N/A	
Lead <i>Source</i>	3113B*	0.015 mg/L	<0.005 mg/L	N/A	
Arsenic	3113B*	0.010 mg/L	<0.005 mg/L	N/A	

2009 re-check full residential test

Date Sampled June 18, 2009 Time Sampled 10:45 AM Sample ID 160650
 Date Received June 18, 2009 Time Received 11:30 AM Date Reported June 22, 2009
 Client Information Lindsay Werner Temperature Upon Arrival 22 °C

Property Tested Same as Above Sample Point Bath

This water is rated as: Satisfactory

PARAMETERS	METHOD NO.	LIMITS	RESULTS	DATE/TIME ANALYZED
Total Coliform	9222*	ABSENT [0/100ML]	Absent	6/18/2009 12:00:00 PM
E coli	9222*	ABSENT [0/100ML]	Absent	6/18/2009 12:00:00 PM
Nitrite-N	4500-NO2D*	1.0 mg/L	<0.10 mg/L	6/18/2009 4:45:00 PM
Nitrate-N	4500-NO3B*	10.0 mg/L	<1.0 mg/L	6/18/2009 4:20:00 PM
pH	4500-H+B*	6.5-8.5	8.1 pH Units	6/18/2009 3:40:00 PM
Copper	3111B*	1.3 mg/L	0.51 mg/L	N/A
Manganese	3111B*	0.05 mg/L	<0.02 mg/L	N/A
Iron	3111B*	0.30 mg/L	0.07 mg/L	N/A
Chloride	4500-CIB*	250 mg/L	35 mg/L	N/A
Hardness (EDTA)	2340C*	500 mg/L	63 mg/L	N/A
Sodium	3111B	100 mg/L	2.0 mg/L	N/A
Lead Source	3113B*	0.015 mg/L	<0.005 mg/L	N/A
Arsenic	3113B*	0.010 mg/L	<0.005 mg/L	N/A

2014 basic water safety test Positive for Coliform Bacteria Shocked well

fails EPA Proposed Limit X

CERTIFICATE OF ANALYSIS FOR DRINKING WATER

SAMPLE ID#: 1410-00108-001 DATE AND TIME COLLECTED: 10/02/2014 8:20 AM
 SAMPLED BY: Lindsay Werner DATE AND TIME RECEIVED: 10/02/2014 9:31 AM
 ANALYSIS PACKAGE: A & L Set C-ME
 SAMPLE LOCATION: [REDACTED] RECEIPT TEMPERATURE: 17 CELSIUS

Test Description	Results	Test Units	Pass /Fail	EPA Limit	Method	Analyst	Date & Time Analyzed
Coliform Bacteria*	Present	P-A/100mL	⊗	Absent	SM 9223 B	RL	10/02/14 12:30 PM
E. coli Bacteria*	Absent	P-A/100mL	✓	Absent	SM 9223 B	RL	10/02/14 12:30 PM
pH*	7.06(H)	SU	✓		SM4500-H+ B	RL	10/02/14 1:20 PM
Nitrite as N*	<0.10	mg/L	✓	1 mg/L	SM4500-NO2 B	RL	10/02/14 2:00 PM
Nitrate as N*	1.85	mg/L	✓	10 mg/L	SM4500-NO3	RL	10/02/14 2:40 PM

D

2023 Coliform and E. coli only, quantified

Annual rake leaves away from well



A & L LABORATORY

A DIVISION OF GRANITE STATE ANALYTICAL SERVICES, LLC.

155 Center Street, Building C, Auburn, Maine 04210
 Phone (207) 784-5354 website www.allaboratory.com

CERTIFICATE OF ANALYSIS FOR DRINKING WATER

DATE PRINTED:	10/07/2023	<table border="1"> <thead> <tr> <th colspan="2">Legend</th> </tr> </thead> <tbody> <tr> <td>Passes</td> <td>✓</td> </tr> <tr> <td>Fails EPA Primary</td> <td>⊗</td> </tr> <tr> <td>Fails EPA Secondary</td> <td>⊗</td> </tr> <tr> <td>Fails State Guideline</td> <td>✕</td> </tr> <tr> <td>Attention</td> <td>⚠</td> </tr> </tbody> </table>	Legend		Passes	✓	Fails EPA Primary	⊗	Fails EPA Secondary	⊗	Fails State Guideline	✕	Attention	⚠
Legend														
Passes	✓													
Fails EPA Primary	⊗													
Fails EPA Secondary	⊗													
Fails State Guideline	✕													
Attention	⚠													
CLIENT NAME:	Lindsay Werner													
CLIENT ADDRESS:	[REDACTED]													
SAMPLE ID #:	2310-01558-001	DATE AND TIME COLLECTED:	10/06/2023 10:25AM											
SAMPLED BY:	Lindsay	DATE AND TIME RECEIVED:	10/06/2023 12:20PM											
SAMPLE ADDRESS:	Werner	ANALYSIS PACKAGE:	A & L MPN-ME											
MORE LOC INFO:	Kitchen	RECEIPT TEMPERATURE:	20° CELSIUS											
		CLIENT JOB #:												

Test Description	Result	Test Units	Pass /Fail	DQ Flag	RL	Limit	Method	Analyst	Date - Time Analyzed
Coliform MPN*	<1	MPN/100mL	✓		1	No Limit	SM 9223 B	RL-ME	10/07/2023 09:30AM
E. coli MPN*	<1	MPN/100mL	✓		1	0	SM 9223 B	RL-ME	10/07/2023 09:30AM

Total Coliform / E.coli Bacteria Preparation (Colilert®-18 Quanti-Tray®) 20th ED SM 9223 B JR-ME 10/06/2023 01:50PM

- c. Notice how Coliform dropped back to <1 after start raking leaves away annually.
- d. How do we feel about Lindsay’s well after seeing the testing results?
 - i. Could this water be used for harvest/post-harvest water? Sure, unless you get an inspector that considers it surface water.
 - ii. What would Lindsay need to do if she was a farm subject to the Produce Safety Rule and this water source was being used to wash harvest bins? Test 4 times in 1 year to build water profile. Annual testing thereafter if all 4 tests are 0 generic *E. coli*.

9. Assessment Tool/Template Findings, 112.43(a):

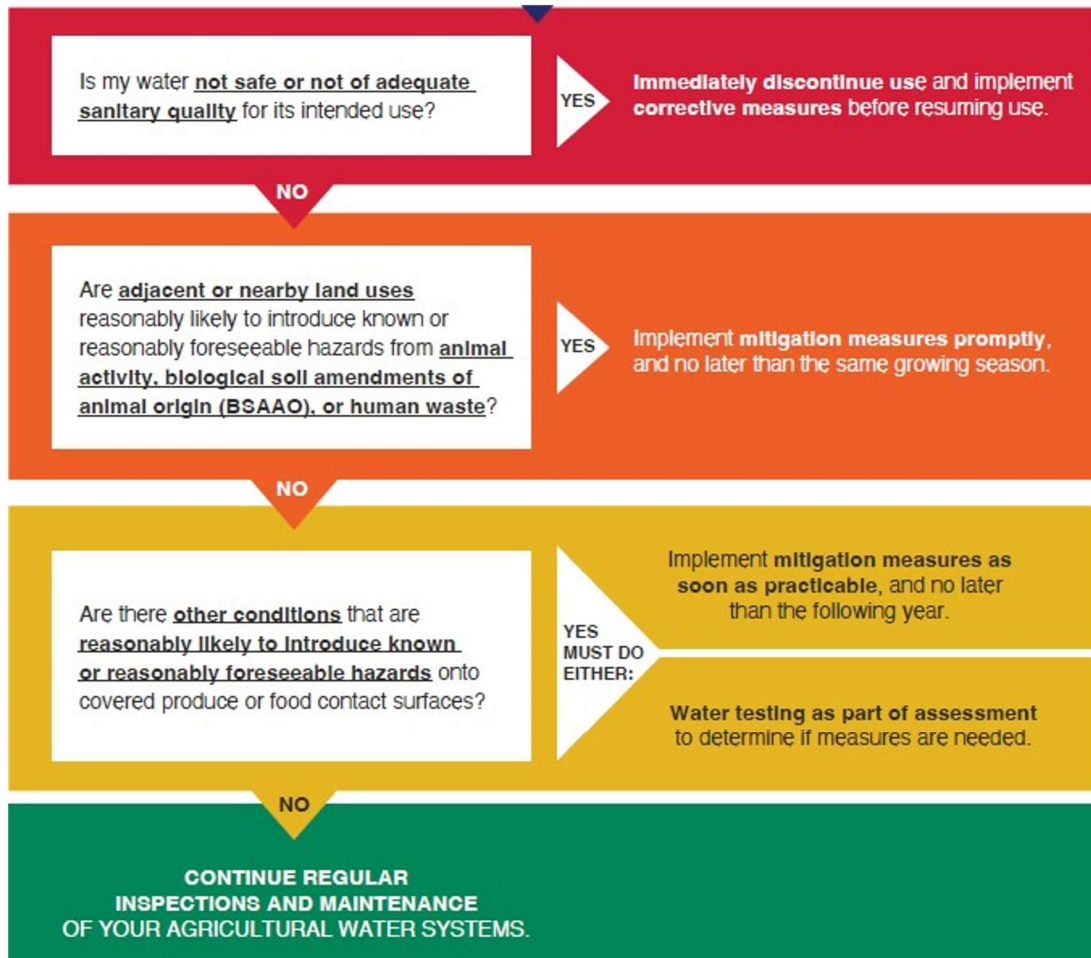
- a. Table C. Description of water source: Dug well, stone lined, 20’ deep, 8’ wide, unsealed cement cover, under Lindsay’s control, partially protected.
- b. Table D. Description of distribution system: Closed, copper pipes into residence, under Lindsay’s control, protected via backflow prevention device.
- c. Table E. Equipment, buildings, structures: Well house doesn’t seem to have a purpose other than electrical access. Partial roof replacement 2023, door repair 2024 to keep rodents out.
- d. Table F. Animals: 2 horses, 1 can, probably some field rodents but not many due to grazing, wildlife minimal.
- e. Table G. Biological Soil Amendments of Animal Origin: Manure pile about 235’ from well, hauled off every spring.

- f. Table H. Human waste systems: Leach field next to manure pile about 250' from well, pumped 2024, in good condition, no indication neighbors leach field about 200' from well is having issues.
- g. Table I. Land application of human waste: None
- h. Table J. Other water users: None
- i. Table K. Other potential sources of known or reasonably foreseeable hazards: None
- j. Table L. Crop characteristics: Lettuce/cantaloupe susceptible to surface adhesion but soils grain well, not prone to pooling.
- k. Table M. Ag water use practices: Overhead irrigation up to day of harvest with well source.
- l. Table N. Environmental conditions: Manure pile is far enough away from the well so runoff from more frequent heavy rain events is not an issue. No crop damage to date from weather events. Water quality does not necessitate a microbial die-off period.
- m. Table O. Other relevant factors: None

10. Assessment Outcome for Lindsay's Well:

- a. Is the water safe for intended use?
 - i. Pre-Harvest = YES *FDA builder tool note 33
 - ii. Harvest/Post-Harvest: Maybe
- b. Are there one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated/improperly treated human waste? No, it's been mitigated with a vegetation buffer and distance between manure and water source.
- c. Are there one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated/improperly treated waste? No.

11. Assessment Outcomes, 112.43(c): FDA Flow Chart



12. What If Scenarios for Lindsay’s Well:

- a. Manure pile within 100 feet of the well? ORANGE
- b. Manure pile within 20 feet of the well? RED
- c. Dead deer next to well? RED/ORANGE
- d. Dead deer 20 downhill from the well? Not sure, ask a hydrogeologist
- e. Neighbor’s septic fails? RED/ORANGE.
- f. Increased heavy rain events? GREEN

13. Assessment Corrective Measures, 112.45

- a. RED, 112.45(a) – Unsafe or inadequate quality:
 - i. Examples: Sewage overflow or leak upstream from where you pull water, dead deer in farm pond, septic system fail near water source, significant amount of animal waste introduced into water source.
 - ii. Immediately discontinue use. Re-inspect the water system, fix the issue or treat the water, determine if changes were effective before using water again.
- b. ORANGE or YELLOW, 112.45(b) – Conditions reasonably likely or foreseeable to introduce hazards: Take mitigation measures within the timeline specified in the FDA Flow Chart. Examples are making necessary changes such as repairs, berm to reduce runoff, install windbreak, increase time between last direct application and harvest, change the method of application, treat the water. Farms must have a study specific to their farm if relying on

the time between harvest and end of storage and/or commercial washing to reduce hazards.

- c. GREEN, 112.43(e) – No hazards identified or hazards mitigated: Regularly inspect and maintain the agricultural water system and reassess whenever a significant change occurs.

14. Approved pesticide treatment: Sanidate 12.0 is the first EPA approved pesticide to control microorganisms of public health significance with labeling instructions for pre-harvest water use. Treatment options may include physical treatment such as filtration, UV, etc.

15. Die-off Refresher:

- a. The science behind using die-off between last direct application and harvest is in the Produce Safety Alliance Grower Training manual. Farms can use this science.
- b. The manual gives a percentage equivalent to the daily 0.5 log reduction that can be expected during good weather. 68% reduction or 32% remaining each day.
- c. Using the recreational water standard (126 MPN generic *E. coli*/100mL) as a guide, here's the math:
 - i. 1 day die-off adequate for up to 394 *E. coli* (126 divided by .32)
 - ii. 2 days die-off adequate for up to 1231 *E. coli* (394 divided by .32)
 - iii. 3 days die-off adequate for up to 3847 *E. coli* (1231 divided by .32)
 - iv. 4 days die-off adequate for up to 12022 *E. coli* (3847 divided by .32)
 - v. The science for die-off cannot be used for water with more than 12022 *E. coli*.

16. Resources:

- a. FDA website: search "FDA finalized ag water rule"
 - i. Assessment Builder: Paper-based version used to design workshop and resources.
 - ii. Other FDA website resources: Online Assessment Builder, May 2024 Webinar recording link, Ag Water Assessment Fact Sheet, Expanded Table on Factors to Consider, Corrective and Mitigation Measures, Assessment Outcomes.
- b. Produce Safety Alliance website:
 - i. Resources > General Resources > scroll to water
 - ii. Resources > Trainer Resources > Module 5-1 (updated) & 5-2
- c. Western Growers, CA & AZ Leafy Greens Marketing Agreements
 - i. Appendix A: Ag Water System Assessments
 - 1. Table 2 – Assessing Well Components
 - 2. Table 3 – Assessing the Area Surrounding the Well
 - 3. Table 4 – Guidelines for Assessing Surface Water
 - 4. Table 5 – Guidelines for Assessing Reservoirs
 - 5. Table 6 – Risk factors related to the presence of microbial hazards in ag water sources
 - 6. Table 8 – Ag Water System Assessment of Distribution System
 - ii. Appendix F: Considerations for Addressing the Effects of Weather Conditions on Environmental Sources of Human Pathogens
- d. Michigan State University, Risk Prioritization Tool for Agricultural Water
 - i. Scenarios with videos, online risk calculator

- e. DACF Cheat Sheet, considerations for evaluating the degree of protection and other considerations. 1 page prompt for inspection.

17. Template Options – links in DACF Produce Safety Rule website Library of Resources:

- a. Ag Water System Inspection:
 - i. Missouri Dept. of Ag – Water Distribution System Inspection Log from their Produce Growers FSMA Record Keeping Guide
 - ii. Produce Safety Alliance – Agricultural Water System Inspection Record
 - iii. Community Alliance with Family Farmers – Annual Water System Inspection Log
 - iv. None of these are perfect! Make your own! It needs to have the name/location of the farm, date of inspection, what was inspected, inspection findings, initials/signature of person conducting the inspection.
- b. Pre-Harvest Assessment:
 - i. DACF Template
 - ii. DACF Water Assessment Exercise: for considering water testing results, crops, application method.

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