



FSMA Produce Safety Rule Pre-Harvest Water Requirements: Revisions to PSA Grower Training Module 5.1

Produce Safety Educators'

Call #71

June 10, 2024



Instructions

- All participants are muted.
- There will be time for questions and discussion at the end of the meeting.
- Feel free to use the chat box to ask questions as well!
- This session will be recorded and the presentation will be shared via the listserv and on our website after the call.



Agenda

- Subpart E revisions recap and PSA Grower Training Course
- Train-the-Trainer presentation of Revised Module 5.1
- Policies and expectations
- Discussion



Direct link





Key Goals for Today

- Share updates to PSA GT Module 5.1
 - Educators' Call Group and PSA Trainers
- The Train-the-Trainer portion of this call will be edited for use as a training video
 - Replacement for PSA Train-the-Trainer Refresher Office Hour for Module 5.1 v1.2 from 10/29/2020



Revisions to Subpart E Recap and PSA Grower Training Course



Revised Subpart E: Agricultural Water (Pre-Harvest Uses)

- The rule to revise FSMA PSR Subpart E came out May 06, 2024
- Changes were also made to other provisions
 - Subpart A (definitions)
 - Subpart B (alternatives)
 - Subpart O (records)
 - Postharvest water requirements in Subpart E (provision #s)
 - Subpart N (methods)
- No changes to requirements for sprouts, or for agricultural water used during harvest and postharvest
- Revised Module 5.1 is a stop-gap measure
 - Quickly address incorrect information in current Module 5.1
 - Ultimately, a full revision should be completed (PSA GT Manual v2.0)
 - This will take time and funding; not currently in place so no timeframe

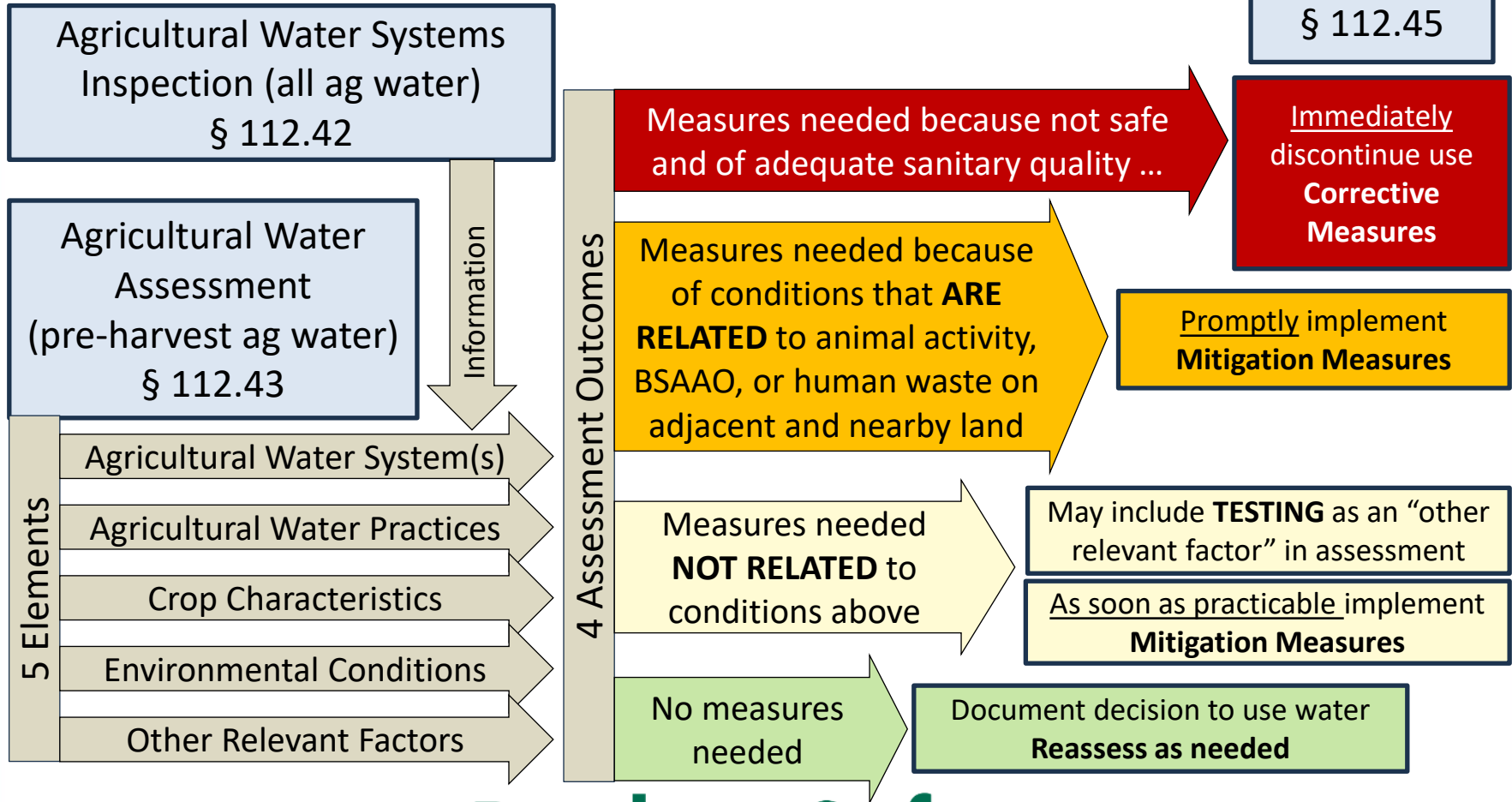


2015 Pre-Harvest Subpart E

- The focus was on creating a Microbial Water Quality Profile of generic *E. coli* data
- You should know that MWQP is no longer a focus, and in most cases testing is not required.
- It is very important that previously-trained participants understand this shift
 - PSA is working on update slides to share with previously-trained growers; these are not done yet, no timeline
 - PSA Grower Training Courses should emphasize testing as a tool and an option but not as a general requirement



Outline: Revised Subpart E Pre-Harvest Requirements





Navigation of Provisions

- FDA created a reference table in the 2024 publication

TABLE 3—SUMMARY OF CHANGES MADE TO SUBPART E REQUIREMENTS SINCE THE 2015 PRODUCE SAFETY FINAL RULE

Subpart E provisions in the 2015 produce safety final rule	Changes made with this final rule	Location of relevant provision as established with this final rule
§ 112.41: All agricultural water must be safe and of adequate sanitary quality for its intended use.	None	§ 112.41.
§ 112.42: Regularly inspect and maintain all agricultural water systems and implement measures to reduce potential for contact between covered produce and pooled water.	None	§ 112.42.
§ 112.43: If treating agricultural water, ensure that the treatment is effective and that treatment is delivered and monitored appropriately.	None	§ 112.46.
§ 112.44(a): Ensure that water used for certain purposes (for example, for sprouts and for harvest and post-harvest uses) contains no detectable generic <i>E. coli</i> per 100 mL and not use untreated surface water for such purposes.	None	§ 112.44(a).
§ 112.44(b): Ensure that water used during pre-harvest activities for covered produce (other than sprouts) meets a GM of 126 generic <i>E. coli</i> per 100 mL and a STV of 410 generic <i>E. coli</i> per 100 mL.	Replaced with provisions for pre-harvest agricultural water assessments and risk management determinations, with a requirement to test in certain circumstances.	§ 112.43.
§ 112.45(a): Immediately discontinue use (and take corrective measures prior to resuming use) if water is not safe or is not of adequate sanitary quality or if the microbial criterion of no detectable generic <i>E. coli</i> per 100 mL is not met for certain uses of water.	None	§ 112.45(a).
§ 112.45(b): Implement risk-reduction measures as soon as practicable but no later than the following year if the GM and STV microbial criteria in § 112.44(b) are not met for pre-harvest water uses for non-sprout covered produce.	Removed pre-harvest microbial criteria and revised to account for pre-harvest agricultural water assessments; expanded measures to include the flexibility to change the water application method to reduce the likelihood of contamination of covered produce or to use an alternative mitigation measure; added expedited timing for mitigation related to certain uses of adjacent and nearby lands.	§ 112.45(b).



Navigation of Provisions (Enlarged)

- FDA created a reference table in the 2024 publication

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Subpart E provisions in the 2015 produce safety final rule	Changes made with this final rule	Location of relevant provision as established with this final rule
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Subpart E provisions in the 2015 produce safety final rule		
§ 112.44(b): Ensure that covered produce (other than sprouts and for harvest and post-harvest uses) contains no detectable generic <i>E. coli</i> per 100 mL and a		
Changes made with this final rule		
§ 112.45(a): Immediately prior to resuming use) tertiary quality or if the microbial criterion of no detectable generic <i>E. coli</i> per 100 mL is not met for certain uses of water.		
§ 112.45(b): Implement risk-reduction measures as soon as practicable but no later than the following year if the GM and STV microbial criteria in § 112.44(b) are not met for pre-harvest water uses for non-sprout covered produce.	Removed pre-harvest microbial criteria and revised to account for pre-harvest water uses; expanded to change the likelihood of contamination or to use an expedited time period for certain uses of agricultural water.	§ 112.45(b)
		Location of relevant provision as established with this final rule



Changes to PSA Grower Training Course Delivery

- Short-term
 - Continue delivery using Module 5.1 from the V1.2 manual and strongly recommend using PSA supplemental slides
 - This was the recommendation sent May 03, 2024
- Mid-term (**WE ARE HERE NOW**)
 - Delivery using Revised Module 5.1
 - Today's webinar includes Train-the-Trainer information
 - A recorded demonstration will show one-way to deliver Revised Module 5.1 to participants during a PSA GT Course
- Long-term, **pending funding**
 - Creation of the V2.0 PSA Grower Training Manual and slides



Train-the-Trainer Presentation



Introduction



- Purpose of the TTT series:
To review the critical concepts from each module and share recent FDA updates, PSA resources, and tips for presenting remotely
- Intended audience: PSA Trainers and Lead Trainers



Disclaimers

- Attending these office hours or watching their recordings does not count as attendance at a PSA Train-the-Trainer or Grower Training Course, nor will you earn a PSA/AFDO certificate of completion.
- The PSA Grower Training slides are copyrighted and may not be published electronically without express permission of Cornell University nor sold in whole or in part by a third party or company for profit.



Module 5: Agricultural Water



General Layout – Module 5 Introduction

- Slides 3-7 describe revised Subpart E and Revised Module 5.1
- Slides 8-14 introduce the general water quality standard for agricultural water, and zero in on the definition

The grid contains 15 slide thumbnails, numbered 1 through 15. The content of the slides is as follows:

- Slide 1:** Module 5: Agricultural Water
- Slide 2:** Two Sections on Water
 - Part I: Production Water
 - Water used in contact with produce during growth
 - Irrigation, fertigation, foliar sprays, frost protection
 - Part II: Postharvest Water
 - Water used during or after harvest
- Slide 3:** Introduction
 - The FSMA FSP, including Subpart E (Agricultural Water), was published in 2015 and is printed in your PSA Grower Training Manual 5.2
 - Subpart E was revised in 2024
 - The parts described in Module 5, Part I → production water changed
 - The parts described in Module 5, Part II → postharvest water did not change and are separate from production water
 - This is a temporary delivery module for Module 5, Part I
 - Use until version 2.0 of the PSA Grower Training Manual is created
 - These slides are different from your printed manual
 - Production water is now called pre-harvest water
- Slide 4:** Introduction (continued)
 - Module 5, Part I (Production) Pre-harvest Water) provision numbers use the revised Subpart E (2024) version
 - Slides from the printed manual that have not changed are labeled with 4.2 slide numbers
 - New, temporary provision numbers in separate slides were added in to the manual to refer to the 2.0 of the printed manual that is available
 - Module 5, Part E (Postharvest Water) provision numbers use the final Produce Safety Rule (2022) system
 - The version of Module 5, Part II is current
 - PSA needs to update provision numbers in version 2.0 of the PSA Grower Training Manual slides
- Slide 5:** FDA Revised Subpart E Compliance Dates

Business Size	Pre-harvest Agricultural Water Related Compliance Dates
All other businesses (2020K)	April 7, 2025
Small businesses (102.5K-200K)	April 6, 2024
Very small businesses (50K-100K)	April 5, 2023
- Slide 6:** FDA Subpart E Compliance Dates

Business Size	Pre-harvest Agricultural Water Related Enforcement Dates
All other businesses (2020K)	January 26, 2023
Small businesses (102.5K-200K)	January 26, 2024
Very small businesses (50K-100K)	January 26, 2025
- Slide 7:** Agricultural Water Quality
 - All agricultural water must be safe and of adequate sanitary quality for its intended use
 - Applies to water used for purposes outlined in both Parts I and II of this module
- Slide 8:** Helpful Definitions
 - Agricultural water means water used in covered activities on covered produce where water is collected, stored, or applied to covered produce on or near contact surfaces
 - Covered produce means produce that is subject to the requirements of the Produce Safety Rule. The term "covered produce" refers to the harvestable or harvestable part of the produce.
- Slide 9:** Is this Agricultural Water?
 - Lettuces
 - Overhead irrigation
- Slide 10:** Is this Agricultural Water?
 - Apples
 - Pesticide application
- Slide 11:** Is this Agricultural Water?
 - Carrots
 - Drip irrigation
- Slide 12:** Is this Agricultural Water?
 - Potatoes
 - Overhead irrigation
- Slide 13:** Is this Agricultural Water?
 - Head lettuce
 - Roots-on harvest
- Slide 14:** Is this Agricultural Water?
 - Avocados
 - Packing line sanitation
- Slide 15:** Module 5: Part I – Production/Pre-Harvest Water 2024 Revised Slides

SUPPLEMENTAL MATERIAL



Two Sections on Water

- **Part I: Production Water**
 - Water used in contact with produce during growth
 - Irrigation, fertigation, foliar sprays, frost protection
- **Part II: Postharvest Water**
 - Water used during or after harvest





Introduction

- The FSMA PSR, including Subpart E (Agricultural Water), was published in 2015 and is printed in your PSA Grower Training Manual v1.2
- Subpart E was revised in 2024
 - The parts described in Module 5: Part I – Production Water changed
 - The parts described in Module 5: Part II – Postharvest Water did not change in any substantial way; provision numbers only
- This is a temporary delivery module for Module 5: Part I
 - Use until Version 2.0 of the PSA Grower Training Manual is created
 - These slides are different from your printed manual
- **Production water** is now called **pre-harvest water**



Introduction (continued)

- Module 5: Part I (Production/ Pre-Harvest Water) provision numbers use the revised Subpart E (2024) system
 - Slides from the printed manual that have not changed are labeled with v1.2 slide numbers v1.2 Manual-slide 4
 - Note: Some regulatory provision numbers in original slide notes were updated in the Revised Module 5: Part I to match the 2024 revised numbering
 - Slides that are not in the v1.2 manual are not labeled
- Module 5: Part II (Postharvest Water) provision numbers use the final Produce Safety Rule (2015) system
 - The content of Module 5: Part II is correct
 - PSA intends to update provision numbers in Version 2.0 of the PSA Grower Training Course slides



FDA Revised Subpart E Compliance Dates

- For pre-harvest agricultural water requirements for covered produce other than sprouts (Module 5: Part I)

Business Size	<u>Pre-harvest</u> Agricultural Water Related Compliance Dates
All other businesses (>\$500K)	April 7, 2025
Small businesses (>\$250K-500K)	April 6, 2026
Very small businesses (>\$25K-250K)	April 5, 2027



FDA Subpart E Compliance Dates

- FDA began enforcement for harvest and postharvest agricultural water requirements (Module 5: Part II) one year after the applicable compliance dates

Business Size	<u>Postharvest</u> Agricultural Water Related Enforcement Dates
All other businesses (>\$500K)	January 26, 2023
Small businesses (>\$250K-500K)	January 26, 2024
Very small businesses (>\$25K-250K)	January 26, 2025



Agricultural Water Quality

- All **agricultural water** must be safe and of adequate sanitary quality for its intended use
 - Applies to water used for purposes outlined in both Parts I and II of this module





Helpful Definitions

- **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
- **Covered produce** means produce that is subject to the requirements of the Produce Safety Rule. The term “covered produce” refers to the harvestable or harvested part of the crop





Is this Agricultural Water?



Lettuce



Overhead irrigation



Is this Agricultural Water?



Apples



Pesticide application



Is this Agricultural Water?



Carrots



Drip irrigation



Is this Agricultural Water?



Potatoes



Overhead irrigation



Is this Agricultural Water?



Head lettuce



Roots-on harvest



Is this Agricultural Water?



Avocados



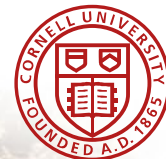
Packing line sanitation



Module 5: Part I – Production/ Pre-Harvest Water



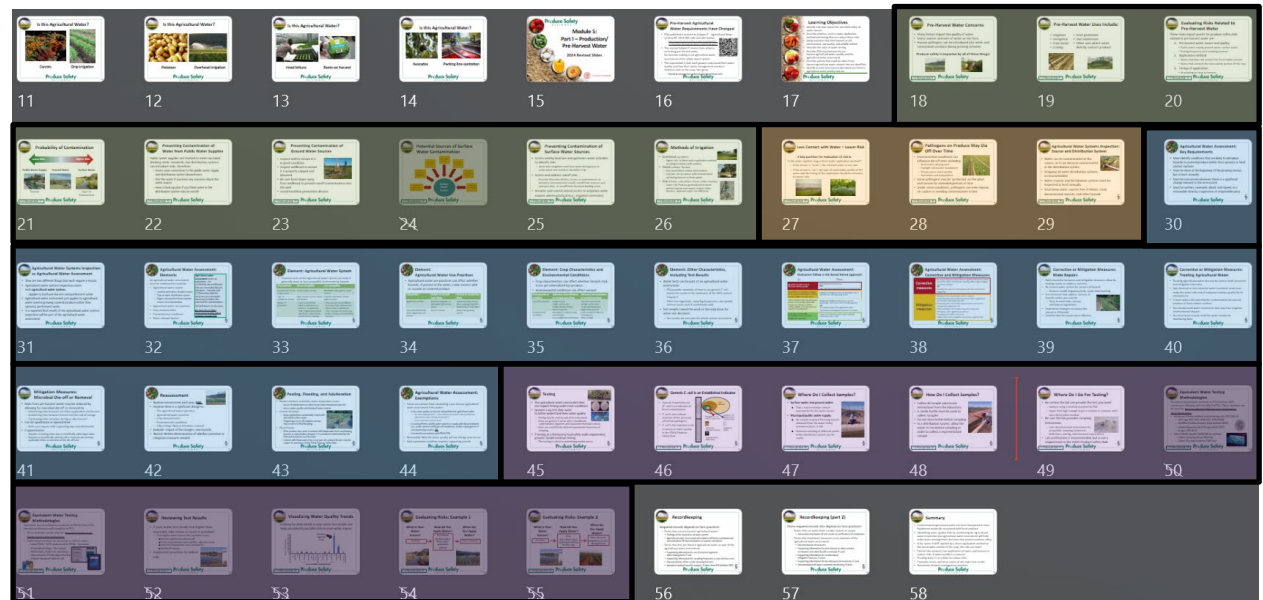
2024 Revised Slides





General Layout – Revised Module 5.1

- Slides 18-26 describe GAPs and scientific principles
- Slides 27-29 introduce agricultural water systems inspection (all ag water) and agricultural water assessment (pre-harvest)
- Slides 30-44 ag water assessment process
- Slides 45-55 value of testing



SUPPLEMENTAL MATERIAL



Pre-Harvest Agricultural Water Requirements Have Changed

- FDA published a revision to Subpart E – Agricultural Water on May 06, 2024 (QR code and URL below)
 - <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-pre-harvest-agricultural-water>
- The revised Subpart E moves from reliance on testing pre-harvest water for decision making to an agricultural water assessment of the whole water system
- The expectation is that each grower understand their water quality and how their water management practices minimize risks to the crops they grow.
 - Should be prepared to explain during inspectional visits



Learning Objectives

- Identify risks that impact the microbial safety of water sources
- Describe practices such as water application method and timing that can reduce those risks
- Adopt practices that limit impacts to the environment, soil quality, and wildlife habitat
- Describe the value of water testing
- Describe FDA requirements for pre-harvest agricultural water quality and the agricultural water assessment
- Describe actions that could be taken if pre-harvest agricultural water related risks are identified
- Identify records necessary to document pre-harvest agricultural water quality and use





Pre-Harvest Water Concerns

- Many factors impact the quality of water
- Many sources and uses of water on the farm
- Human pathogens can be introduced into water and contaminate produce during growing activities

Produce safety is impacted by all of these things!





Pre-Harvest Water Uses Include:

- Irrigation
- Fertigation
- Crop sprays
- Cooling
- Frost protection
- Dust abatement
- Other uses where water directly contacts produce





Evaluating Risks Related to Pre-Harvest Water

Three main impact points for produce safety risks related to pre-harvest water are:

1. Pre-harvest water source and quality
 - Public water supply, ground water, surface water
 - Testing frequency and sampling location
2. Application method
 - Water that does not contact the harvestable portion
 - Water that contacts the harvestable portion of the crop
3. Timing of application
 - At planting or close to harvest



Probability of Contamination



Public Water Supply



Treated

Ground Water



Surface Water



Open to
Environment



Preventing Contamination of Water from Public Water Supplies

Public water supplies are treated to meet microbial drinking water standards, but distribution systems can introduce risks, therefore:

- Assess your connection to the public water supply and distribution system downstream
- Test the water if you have any concerns about the water source
- Have a back-up plan if you think water in the distribution system may be unsafe



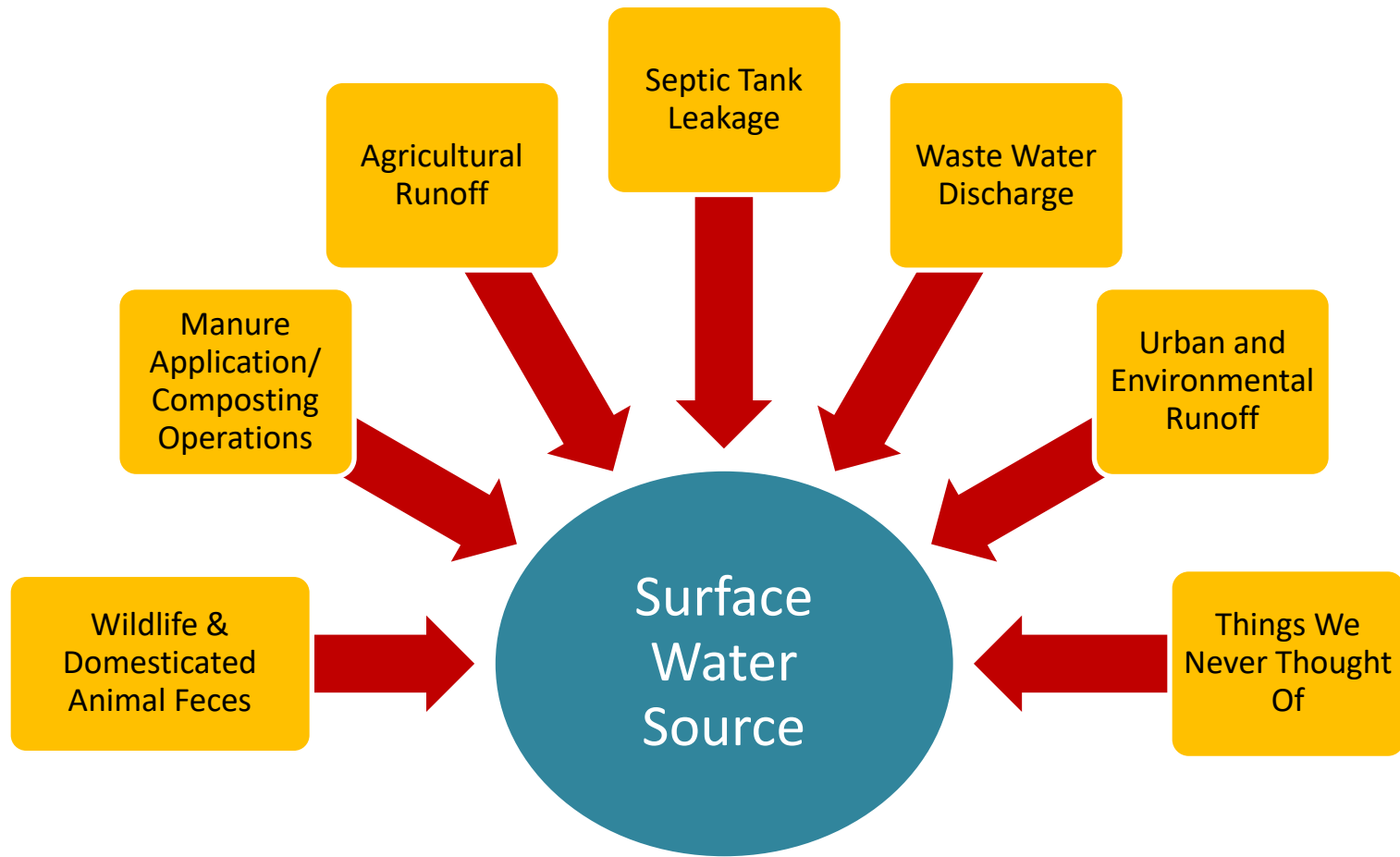
Preventing Contamination of Ground Water Sources

- Inspect well to ensure it is in good condition
- Inspect wellhead to ensure it is properly capped and elevated
- Be sure land slopes away from wellhead to prevent runoff contamination into the well
- Install backflow prevention devices





Potential Sources of Surface Water Contamination





Preventing Contamination of Surface Water Sources

- Assess nearby land use and upstream water activities to identify risks
 - Work with neighbors and local watershed groups to understand and minimize identified risks
- Assess and address runoff risks
 - Develop diversion ditches, berms or containments to minimize environmental runoff, runoff from manure and compost piles, or runoff from livestock feeding areas
- Monitor and control animal access to irrigation water sources where practical (e.g., irrigation reservoirs)

Methods of Irrigation

- Overhead (sprinkler)
 - Higher risk: A direct water application method resulting in contact with produce
- Flood (surface, furrow)
 - May avoid direct contact with produce
 - Consider risk of contact with contaminated soil during harvest or from splash
- Drip (trickle, subsurface, micro, under canopy)
 - Lower risk: Produce generally not in direct contact (except root crops), reduces foliar diseases, improves water use efficiency





Less Contact with Water = Lower Risk

A key question for evaluation of risk is:

“Is the water applied using a direct water application method?”

- If the answer is “never”, the risk from water is very low
- If the answer is “yes”, the type of commodity, quality of the water and the timing of the application should be reviewed to assess risks





Pathogens on Produce May Die Off Over Time

- Environmental conditions can influence die-off rates including
 - Desiccation (drying out)
 - Sunlight (ultraviolet irradiation)
 - Temperature and humidity
 - Starvation and competition
- Some pathogens may be ‘protected’ on the plant and survive for extended periods of time
- Under some conditions, pathogens can even regrow on a plant so avoiding contamination is best





Agricultural Water Systems Inspection: Source and Distribution System

- Water can be contaminated at the source, or it can become contaminated in the distribution system
- Mapping all water distribution systems is recommended
- Water sources and distribution systems must be inspected at least annually
- Must keep water sources free of debris, trash, domesticated animals, and other hazards





Agricultural Water Assessment: Key Requirements

- Must identify conditions that are likely to introduce hazards to covered produce (other than sprouts) or food contact surfaces
- Must be done at the beginning of the growing season, but at least annually
- Must be reassessed whenever there is a significant change relevant to the assessment
- Must be written, reviewed, dated, and signed, in a reasonable time by a supervisor or responsible party



Agricultural Water Systems Inspection vs Agricultural Water Assessment

- They are two different things that each require a record.
- Agricultural water systems inspection covers each **agricultural water system**;
 - Applies to both pre-harvest and postharvest water
- Agricultural water assessment just applies to agricultural water used in growing covered produce (other than sprouts); pre-harvest water
- It is expected that results of the agricultural water systems inspection will be part of the agricultural water assessment



Agricultural Water Assessment: Elements

An agricultural water assessment must be conducted to evaluate:

- Agricultural water system
 - Location and nature of water source
 - Type of water distribution system
 - Degree of protection from possible sources of contamination
- Agricultural water use practices
- Crop characteristics
- Environmental conditions
- Other relevant factors

Agricultural water assessment means an evaluation ... to:

- (1) Identify any condition(s) that are reasonably likely to introduce ... hazards; and
- (2) Determine whether measures are reasonably necessary to reduce the potential for contamination ...

Full definition is in the notes

[An Agricultural Water Assessment Builder tool is available through FDA](#)



Element: Agricultural Water System

- Characteristics of the agricultural water system can make it generally more or less susceptible to intrusion by hazards

Characteristic	More susceptible	Less susceptible
Location and nature of the source	Surface water sources	Municipal water, ground water sources
Type of distribution system	Open systems such as canals and laterals	Properly maintained, closed (piped) system
Degree of protection	<ul style="list-style-type: none"> • Used for recreation • Open to animal access • Close to, not protected from, neighboring animal operations, other animal waste sources, housing 	<ul style="list-style-type: none"> • Recreational uses prohibited • Protected from animal access • Distant from, or protected from, fecal waste sources (e.g., berms, fencing, waste handling systems)



Element: Agricultural Water Use Practices

- Agricultural water use practices can affect whether hazards, if present in the water, make contact with or survive on covered produce

Use practice	Contact or survival more likely	Contact or survival less likely
Application method	Overhead irrigation or foliar (plant protective) sprays	Subsurface drip, furrow, flood, seepage irrigation (depending on crop type)
Time interval between direct application and harvest	Close to harvest	Early in the growing season



Element: Crop Characteristics and Environmental Conditions

- Crop characteristics can affect whether hazards stick to (or get internalized by) produce
- Environmental conditions can affect survival

Characteristic or condition	Adhesion, internalization, or survival more likely	Adhesion, internalization, or survival less likely
Crop characteristic	Rough texture Larger surface area Fragile epidermal layer Closer to ground	Smooth, waxy texture Smaller surface area Tough epidermal layer Higher from ground
Environmental conditions	Damaging to crop (freezing, hail damage) Less sunlight (less ultraviolet)	Promote plant health and development More sunlight



Element: Other Characteristics, Including Test Results

- Water tests can be part of an agricultural water assessment
 - FDA provides examples of how to use generic *E. coli*-based test results in the comments of the 2024 revised Subpart E
 - Other test organisms, sampling frequencies, and quality criteria can be used if scientifically valid
- Test results cannot be used as the only basis for water use decisions
 - Test results are one part of a whole-system 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



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



Corrective or Mitigation Measures: Make Repairs

- Both corrective measures and mitigation measures allow for making repairs to address concerns.
- Re-inspect water system for sources of hazards
 - Manure runoff, migratory birds, septic tank leaching
- Use measures that address sources of hazards under your control
 - Keep in mind state, county, and federal regulations
- Implement strategies to reduce the presence of hazards
- Confirm that the repairs were effective





Corrective or Mitigation Measures: Treating Agricultural Water

- Treating agricultural water also can be used as both corrective and mitigation measures
- Any chemical or non-chemical water treatment used must make the water safe and of adequate sanitary quality for its intended use
- It must reduce the potential for contamination of covered produce or food-contact surfaces
- You should avoid water treatments that may have negative environmental impacts
- You must keep records of all the water treatment monitoring done



Mitigation Measures: Microbial Die-off or Removal

- Risks from pre-harvest water may be reduced by allowing for microbial die-off or removal by
 - Maximizing time between last direct application and harvest
 - Maximizing time between harvest and the end of storage
 - Conducting other activities during or after harvest
- Can be qualitative or quantitative
 - Both uses require valid supporting data and information
- If quantitative:
 - Requires a starting value and a scientifically-valid target value
 - Requires a scientifically-valid die-off or removal rate and any applicable limits on duration of the die-off rate



Reassessment



- Routine reassessment each year, **AND**
- Anytime there is a significant change in:
 - The agricultural water system(s)
 - Agricultural water practices
 - Crop characteristics
 - Environmental conditions
 - Other things likely to introduce a hazard
- Evaluate: Impact of the changes, new hazards
- Record: Written determination of whether corrective or mitigation measures needed



Pooling, Flooding, and Adulteration

- Broken emitters and other water application issues
 - Assess if maintenance or other issues have introduced new risk
 - Assess water quality and timing of water contact
- Human Mistakes
 - Spray applications accidentally mixed with untreated surface water
 - Forgetting to turn off irrigation pumps, may result in in-field flooding
- Flood Events
 - If the produce has come in contact with flood water from overflowing streams or open bodies of water, it is considered adulterated by the FDA and cannot be used for food
 - Contact with flood water that is not part of a natural disaster may be subject to provisions of the FSMA Produce Safety Rule





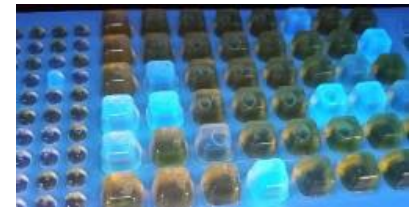
Agricultural Water Assessment: Exemptions

- Farms are exempt from conducting a pre-harvest agricultural water assessment if the water:
 - Is the same quality as harvest and postharvest agricultural water
 - No detectable generic *E. coli* in 100 mL and meets other postharvest agricultural water testing requirements
 - Is not untreated surface water
 - Is received from a public water system or supply with documentation (i.e., public system certificates of compliance, public supply generic *E. coli* monitoring results), **OR**
 - Is treated in accordance with FSMA PSR
- Reasonably likely the water quality will not change prior to use
- Each exemption condition requires supporting records



Testing

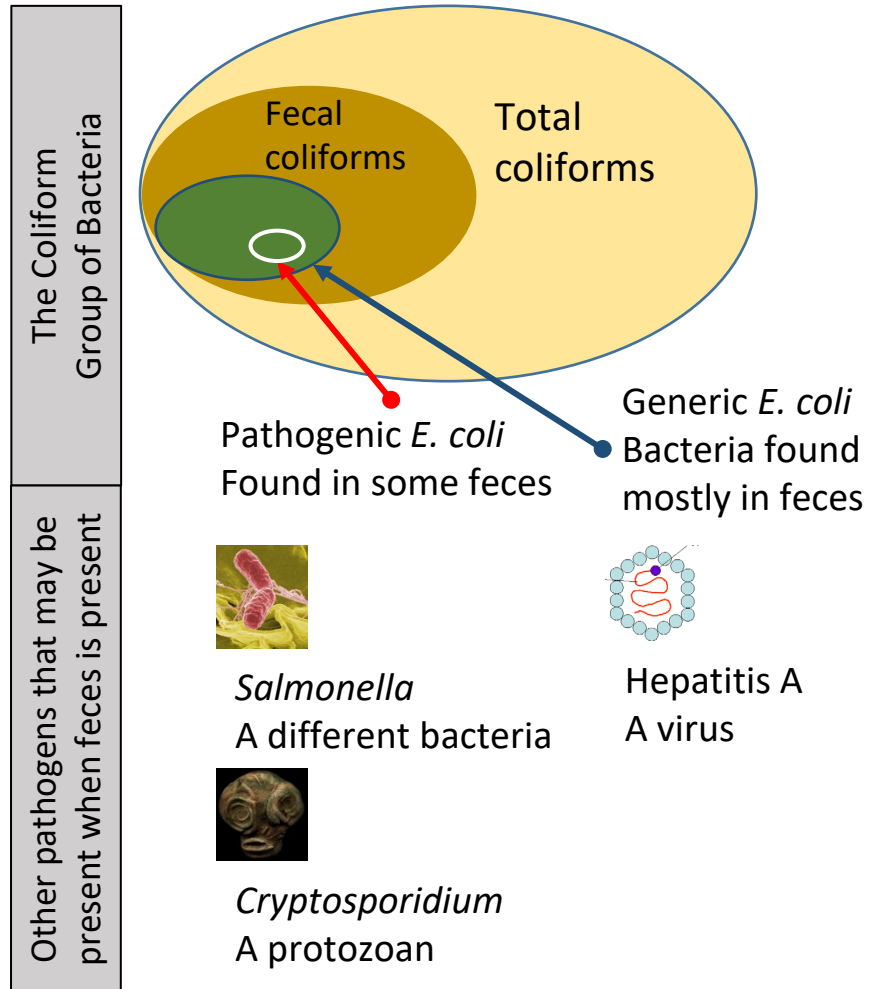
- The agricultural water assessment does not require testing under most conditions
- Growers may test their water to better understand their water quality
 - Testing may be used as part of an assessment
 - Must use generic *E.coli* or other scientifically valid indicator organism and associated microbial criteria
 - Must use scientifically valid and appropriate frequency of sampling
- If testing as a third-party food safety audit requirement, growers should continue testing
 - This testing is critical to maintaining market access



Generic *E. coli* is an Established Indicator



- Generic *Escherichia coli* (*E. coli*) is an indicator of fecal contamination
- *E. coli* is not a direct measure of the presence of human pathogens
- *E. coli* is the indicator used to measure water quality in the FSMA Produce Safety Rule





Where Do I Collect Samples?

- **Surface water and ground water:**
 - Take a representative sample appropriate for the water source
- **Municipal/public water supply:**
 - No sample required if testing reports obtained from the water utility, treatment plant, or lab
 - Optional sampling at different points in the distribution system can be useful





How Do I Collect Samples?

- Follow all sample submission instructions from the laboratory
- A sterile bottle must be used to collect samples
- Do not rinse bottle before sampling
- In a distribution system, allow the water to run before sampling in order to collect a representative sample





Where Do I Go For Testing?

- Be certain the lab can provide the test you need
 - Analysis using a method accepted by FDA
 - Upper limit high enough to get a number to compare with any criteria when needed
- Be sure the lab provides sampling instructions
 - Labs should provide instructions for acceptable sampling containers, hold times, storing, and transport expectations
- Lab certification is recommended, but is not a requirement in the FSMA Produce Safety Rule

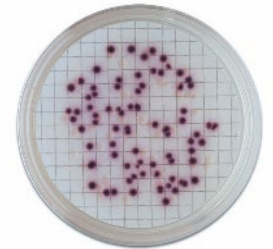




Equivalent Water Testing Methodologies

Equivalent quantitative methods to EPA Method 1603 (membrane filtration with modified mTEC). These methods can be used for both pre-harvest AND harvest/ postharvest agricultural water.

- Membrane filtration methods (colony forming units, CFU/100 mL)
 - mTEC agar (EPA 2010, APHA 2012, ASTM 2000)
 - mColiBlue PourRite Ampules (Hach method 10029)
 - mEndo followed by NA-MUG agar (APHA 1997)
 - MI agar (EPA 2012)
- Most Probable Number (MPN/100 mL) methods
 - Colilert (using Quantitray 2000 tray)
 - Colilert 18 (using Quantitray 2000 tray)

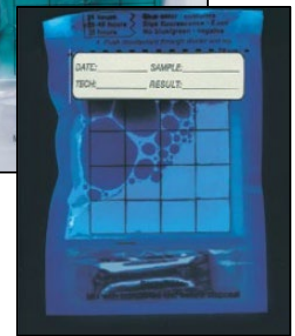




Equivalent Water Testing Methodologies

Equivalent presence/absence methods to EPA Method 1603 (membrane filtration with modified mTEC).

- These methods can be used for agricultural water used during harvest and postharvest:
- Broth-based methods for detection in 100 mL water
 - Veolia TECTA™ EC/TC medium and the TECTA™ Instrument
 - CPI Modified Colitag™ Test method
 - IDEXX Colilert, Colilert 18, and Colisure
 - Charm Sciences E*Colite Bag or Vial Test
 - Millipore ReadyCult Coliforms 100





Reviewing Test Results

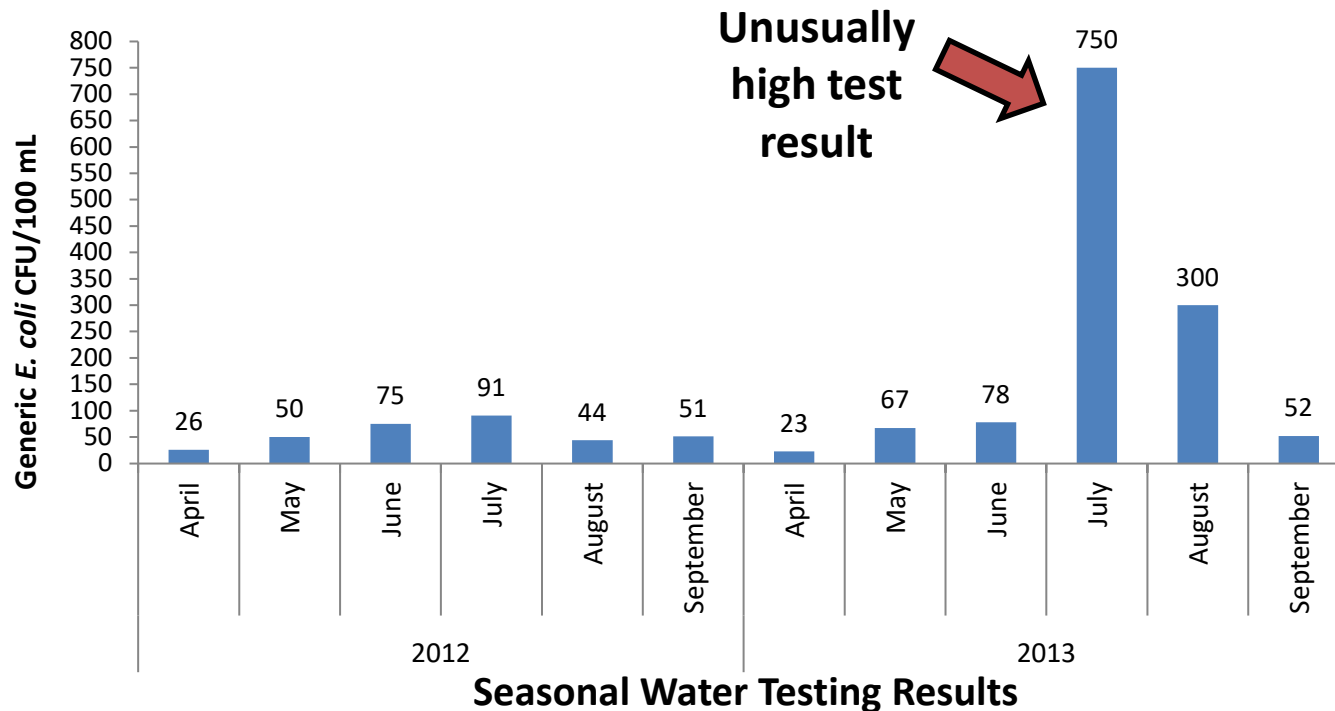
- If your water test results are higher than expected, take action as soon as possible!
 - Investigate water sources for possible causes
 - Manure application and run-off
 - Fecal contamination from wildlife, migratory birds
 - Incorrect/inadvertent cross connections
 - Wellhead impacts
- Implement practices to reduce risks





Visualizing Water Quality Trends

Looking for data trends in your water test results can help you identify possible risks in your water source.



Evaluating Risks: Example 1



What Is Your Water Source?

Surface



How Do You Apply Water?

Overhead
Applied using a direct water application method

When Do You Apply Water?

Near Harvest





Evaluating Risks: Example 2

What Is Your Water Source?

Surface

How Do You Apply Water?

Drip
Not a direct water application method for this crop

When Do You Apply Water?

Near harvest
Irrigated up to and during harvest





Recordkeeping

Required records depend on farm practices.

- Farms that use pre-harvest agricultural water:
 - Findings of the inspection of water system
 - Agricultural water assessment descriptions of factors evaluated and determination OR documentation to support exemption
- Farms that test pre-harvest agricultural water as part of the agricultural water assessment:
 - Supporting information for use of any test organism other than generic *E. coli*
 - Supporting information for sampling frequency or any criterion used
 - Documentation of the results of analytical tests
 - Analytical method used for analysis, if other than EPA Method 1603



Recordkeeping (part 2)

These required records also depend on farm practices:

- Farms that use water from a public system or supply
 - Annual documentation of test results or certificate(s) of compliance
- Farms that implement measures as an outcome of the agricultural water assessment
 - Documentation of measures
 - Supporting information for time interval or other practice to enhance microbial die-off or removal, if used
 - Supporting information for an alternative mitigation measure, if used
 - Supporting information for the adequacy of treatment, if used
 - Documentation of water treatment monitoring, if done



Summary


- Contaminated agricultural water has been implicated in some foodborne outbreaks associated with fresh produce
- Identifying water quality risks by conducting the agricultural water inspection and agricultural water assessment will help make water management decisions that protect produce safety
- If the water IS NOT applied by a direct application method to the harvestable portion of the crop, the risks are lower
- Extend time between last application of water and harvest to reduce risks, if water quality is a concern
- Treating water is an option to reduce risks
- Promptly review and keep copies of any water test results
- Document all water management practices



Visit the FDA Web Page for Updated Resources

 An official website of the United States government [Here's how you know](#) ▾



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FSMA Final Rule on Pre-Harvest Agricultural Water

Direct link



Updated resources include:

- Fact Sheet on the Final Rule
- Factors for Agricultural Water Assessment to Consider
- Agricultural Water Assessment Builder version 2
- Corrective and Mitigation Measures for Pre-harvest Agricultural Water for Non-Sprout Covered Produce
- Annual Agricultural Water Assessments and Risk-Based Outcomes



Comments and Questions

- **Let's take a moment to discuss if anything is unclear about the content of this new slide set**



Policies and Expectations



Expectations for PSA Trainers

- Use Revised Module 5-1 at all PSA GT Courses
 - Use PSA resources to guide your delivery
 - Ensure that participants have printed copies for reference and note taking
- Be clear that all prior versions are different from current regulatory requirements
 - Relevant for participants using V 1.1 or V1.2 Manuals or participants who are re-taking the course



Use of Module 5-1 V1.2

- If using Module 5-1 V1.2, we strongly recommend adding the PSA supplemental slide set that describes the **proposed** Subpart E revisions
 - Important because Module 5-1 V1.2 may mislead growers
 - Short-term option described in the 03 May email
- It is **not acceptable** for a PSA Lead Trainer to allow delivery of Module 5-1 V1.2 without describing the 2024 revisions



Printed Copies of Revised Module 5-1

- Upon release of Revised Module 5-1 presentation slides, PSA also plans to do the following:
 - Post a printable PDF in which Revised Module 5-1 (also called V1.2a) slides and slide notes are laid out
 - Post print-ready files for commercial printing
 - Look for Grower Manual **V1.2 – V1.2a** PDF Files for Commercial Print
 - Post a new interactive PDF that contains Revised Module 5-1
 - Look for Grower Manual **V1.2 – V1.2a** – Interactive PDF
 - **Is there a need for commercially-printed handouts for sale through the NYSAES bookstore for use with PSA Grower Training Manual V1.2?**
 - Once current stock of manuals is exhausted, plan is to print a **V1.2 – V1.2a** of the PSA Grower Training Manual
 - Contain Revised Module 5-1. This is not a V2.



Timeline for Revised Module 5-1

- Revised Module 5-1 will be released as soon as:
 - Both English and Spanish Revised Module 5-1 are complete
 - Revised Module 5-1 slides and notes are formatted properly for printing
 - Printed copies of Revised Module 5-1 are available in both English and Spanish
- Associated materials will be available as soon as possible
 - English/Spanish TTT tutorial video
 - English/Spanish GT tutorial video



How Will Revised Module 5-1 Files Be Made Available?

- Trainers will be sent an email message when complete
- Files will be on the PSA web site under Trainer Resources for Module 5
 - Will need to verify your status as a PSA Trainer
 - Share contact information so we can reach you if anything changes and there is an update
- As is probably already obvious, we are scrambling to get things done as soon as possible but want to stick to our expectations for accuracy and quality
 - Thanks for your patience.



Discussion



Discussion: Input on the Revised Module 5-1 Slides

- Does this approach allow you to confidently continue providing PSA Grower Training Courses? **(poll)**
- Do you need additional educator calls sharing resources and recommendation for delivery of PSA Grower Training Courses? **(poll)**
- What other materials would be useful to have for outreach related to pre-harvest water? **(poll)**



Open Mic: Your Perspectives

- Overall thoughts about presenting the requirements of revised Subpart E as part of your PSA Grower Training Course delivery?



Final Questions?



The PSA Website

<http://producesafetyalliance.cornell.edu/>

En español: es.producesafetyalliance.cornell.edu

The screenshot shows the homepage of the Produce Safety Alliance website. At the top, the title "Produce Safety Alliance" is displayed in a red serif font. Below the title is a horizontal navigation menu with the following items: "Training", "PSA Curriculum", "Resources", "News", "Food Safety Modernization Act", "The Alliance", and "Contact Us". The main content area features a large photograph of a farmer operating a red tractor in a field, with a large irrigation system spraying water over the crops. A small "Produce Safety Alliance" logo is visible in the bottom left corner of the photo. Below the photo is a red banner with the text "WELCOME TO THE PRODUCE SAFETY ALLIANCE WEBSITE!". To the left of this banner is the "Produce Safety ALLIANCE" logo. Below the logo is a short paragraph: "Providing fundamental, science-based, on-farm food safety knowledge to fresh fruit and vegetable farmers, packers, regulatory personnel and others interested in the safety of fresh produce." To the right of the banner is a smaller photo of an irrigation system, with the heading "Water Summit Meeting" and a short paragraph: "The Produce Safety Alliance hosted a Water Summit on February 27-28, 2016 at the".



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