



Subpart E (Agricultural Water): New Proposed Compliance Dates, Thinking about Update Training, and Identifying Grower Needs

Produce Safety Educator's

Call #61

August 22, 2022



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 for Today

- Preview draft Subpart E supplemental slides
 - Proposed Agricultural Water requirements
 - Proposed compliance dates
 - Request for input from YOU
- Summarize stakeholder discussions
- Plans for Subpart E Outreach



Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water

- FDA released the proposed revisions to Subpart E – Agricultural Water on December 2, 2021
 - Docket FDA-2021-N-0471
 - <https://www.regulations.gov/document/FDA-2021-N-0471-0001>
- Proposed revisions move from testing as the primary metric for decision making to an Agricultural Water Assessment meant to look at the whole water system
- The expectation is for each grower to set their standards and understand why those standards are safe
 - Should be prepared to explain to inspectors



Agricultural Water Assessment

- *Growers would be required to evaluate these factors to identify conditions reasonably likely to introduce known or reasonably foreseeable hazards onto produce or food contact surfaces*

Ag Water system

- Source and location (surface, ground, municipal)
- Water distribution system (open or closed)
- Degree of protection from possible contamination including other users, animal impacts, and adjacent land uses

Ag Water practices

- Type of application method (overhead, drip, furrow, flood)
- Time interval between last direct application and harvest

Crop characteristics

- Susceptibility to surface adhesion or internalization

Environmental Conditions

- Frequency of rain or extreme weather that might impact the agricultural water system or might damage produce
- Air temperatures
- Sun (UV) exposure

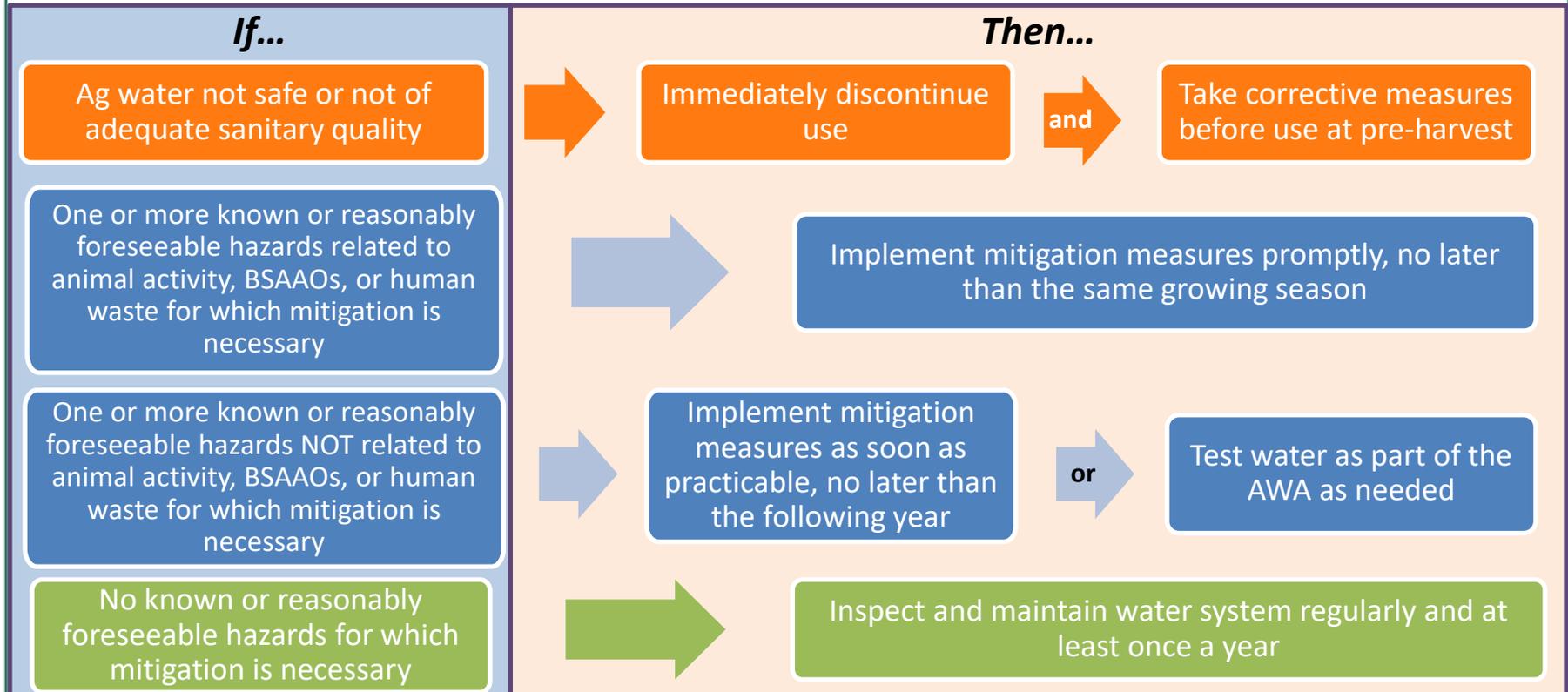
Other factors

- Includes results of testing



Agricultural Water Assessment

- *Outcomes: Farms would use the outcomes of the AWA to determine corrective or mitigation measures*





Agricultural Water Assessment

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: minimum 4 days between last direct application → harvest (microbial die-off)
- Increasing time interval for harvest → storage (microbial die-off)
 - Other activities such as: Commercial washing
- Changing water application method
- Treating water (PSR standards)
- Taking alternative mitigation measures supported by scientific information

SUPPLEMENTAL MATERIAL



New Term, Same Practices

Corrective Measures (in 2015 Final Subpart E)

- Applying a **time interval for microbial die off**
 - Between last application and harvest
 - Between harvest and end of storage and/or removal during activities such as commercial washing
- Re-inspect water system and **make necessary changes**
- **Treat the water**

Mitigation Measures (in 2021 Proposed Subpart E)

- **Making necessary changes** such as repairs
- **Increasing time interval**: minimum 4 days between last direct application → harvest (microbial die-off)
- **Increasing time interval** for harvest → storage (microbial die-off)
 - Other activities such as: Commercial washing
- Changing water application method
- **Treating water** (PSR standards)
- Taking alternative mitigation measures supported by scientific information



Reassessment

- Conduct 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
 - i.e. changing to a surface water source
- Evaluate: Impact of the changes, new hazards
- Record: Written determination of whether corrective or mitigation measures needed



Records

- Written records of the pre-harvest AWA during initial assessment and reassessment, including:
 - Description of factors evaluated
 - Written determination of whether corrective or mitigation measures are needed
- Growers testing pre-harvest ag water as part of their assessment must maintain documentation related to sampling and testing procedures
- Supervisors must written pre-harvest AWA and determinations



Exemptions

Farms exempt from conducting a pre-harvest AWA if the water:

- Meets certain harvest and post-harvest agricultural water criteria* *may require record
- Received from a public water system or supply that meets established requirements (i.e. certificates of compliance, public system results), **OR**
- Is treated in accordance with standards outlined in FSMA PSR

SUPPLEMENTAL MATERIAL



***NEW* FDA Proposes Compliance Date Extension for Pre-Harvest Agricultural Water Requirements**

- Compliance dates for harvest and post-harvest agricultural water requirements
 - January 26, 2023, for all other businesses;
 - January 26, 2024, for small businesses; and
 - January 26, 2025, for very small businesses.
- Compliance dates for pre-harvest agricultural water requirements for covered produce other than sprouts
 - 9 months after the effective date of a final rule for all other businesses;
 - 1 year and 9 months after the effective date of a final rule for small businesses; and
 - 2 years and 9 months after the effective date of a final rule for very small businesses.



FDA Proposes Subpart E Compliance Dates

- FDA proposes compliance dates for proposed pre-harvest agricultural water requirements for covered produce other than sprouts

Business Size	Proposed Water Related Compliance Dates
All other businesses (>\$500K)	9 months after the effective date
Small businesses (>\$250K-500K)	1 year, 9 months after the effective date
Very small businesses (>\$25K-250K)	2 years, 9 months after the effective date



FDA Proposes Subpart E Compliance Dates

- FDA proposes compliance dates for harvest and postharvest agricultural water requirements

Business Size	Proposed Water Related Compliance Dates
All other businesses (>\$500K)	January 26, 2023
Small businesses (>\$250K-500K)	January 26, 2024
Very small businesses (>\$25K-250K)	January 26, 2025



Commenting on the Proposed Subpart E Compliance Dates

- FDA is reopening the comment period for comments on the proposed compliance dates for pre-harvest agricultural provisions
- Deadline for comments is **September 19, 2022**
- Submit comments to docket FDA-2021-N-0471 at [regulations.gov](https://www.regulations.gov)

Note to trainers: Only show this slide before September 19, 2022 to encourage growers to comment.



Discussion: Input on the Supplemental Slides

- Are these supplemental slides useful? **(Poll)**
 - Can be posted on PSA website
- Is there anything missing? **(Poll)**
 - If so, what?
- What other materials would be useful to have *before* Subpart E is finalized?
- Any other comments to share?



Discussion:

Proposed Compliance Dates

- Have you all read the new proposed compliance date document? **(Poll)**
- Thoughts on current proposed compliance dates?
- What is a reasonable amount of time for pre-harvest ag water compliance dates for large farms? (<1 year, 1 year, 2 years, 3 years, 5 years) **(Poll)**



PSA Initial Thoughts on Proposed Compliance Dates

- Having two different compliance dates for water will add complexity and confusion
 - PSA bias: we will need to retrain everyone and many modules are likely to change, so training may not happen until after proposed implementation dates have passed
- Nine months is too short for pre-harvest ag water
 - Significant changes to expectations will require training, probably best done on-farm
 - Not enough trained people to help
 - Unlikely new PSA training will be ramped up by then
- Comment until 9/19/22



Subpart E Outreach and Feedback: Trainer Alignment

- Hosted 6 Subpart E Office Hours (4 English, 2 Spanish)
 - Align understanding of what is currently being proposed
 - Discussed research and its impact to proposed rule
- Key Topics discussed
 - What is an Agricultural Water Assessment
 - Science of microbial die-off and current research
 - Water treatment
 - Adjacent Land Use
- Special thanks to our national colleagues!



Subpart E Outreach and Feedback: Grower Input

- Goal was to address the need for grower comment in the docket
 - FDA expressed need at IAFP in 2021
- Held 4 Regional and Spanish-Language Grower Focus Groups
- Submitted project through IRB to ensure objective approach
- Submitted comments to FDA docket after participants reviewed summaries



Subpart E Focus Groups – Key Messages

- Need for more detail (and education) about many parts of proposed rule
- Some farmers expressed that they are already doing water assessments and testing
- It was stated that the proposed rule would allow for more flexibility than the previous version

“The proposed rule puts a lot of responsibility back on the grower, while growers may not have access to the scientific information needed to understand their responsibility”

“Provides a good basis to determine what our true risks are and how we are going to assess those” and that this proposed rule would “move towards more tailored response to the needs of your organization”.



Plans for Subpart E Outreach: Curriculum Updates

- Update PSA Grower Training Curriculum (version 2.0)
 - Changes include updates to:
 - Module 1 (compliance dates)
 - Module 2 (postharvest water provisions)
 - Module 4 (adjacent land use, worker training)
 - Module 5.1 (entire module)
 - Module 5.2 (compliance dates, equivalent water testing methodology supplemental slides, water treatment, provision numbers)
 - Module 6 (postharvest water provisions)
 - Module 7 (documentation and recordkeeping; possibly traceability)
 - Perhaps more, depending on the final Rule
- Incorporating updates into curriculum translations



Plans for Subpart E Outreach: Materials & Resources Updates

- Updates to extension factsheets and resources
 - Required Records
- Materials to support implementation of an agricultural water assessment
- Research database of water quality research





Plans for Subpart E Outreach: Hands-on, In-person Workshop

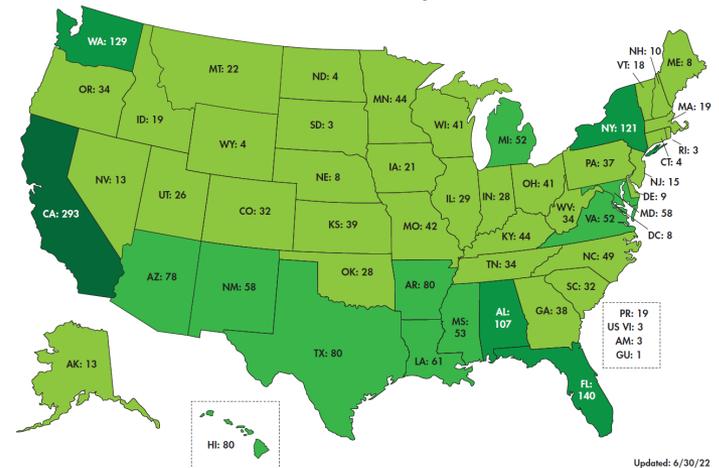
- Expect growers will need substantial help to learn how to do an effective Agricultural Water Assessment
- An on-farm workshop would provide an opportunity to assess risks and develop working knowledge
- Do not anticipate this would be required
- Would require nationwide collaboration and training
- Would be best chance to develop an AWA that focuses on biggest risks
- **Poll question: discussion**



Plans for Subpart E Outreach: Getting Trainers Trained!

- Almost 3,500 PSA Trainers
- Updating PSA Trainers/Lead Trainers
 - Develop set of supplemental update slides for trainers so they may update their growers
 - Host several PSA Train-the-Trainer (Ag Water Edition) courses
 - Remote and In-person
- Anticipate participation in an update training will be required
- **Poll question**

Nationwide Produce Safety Alliance Trainers & Lead Trainers
Locations of All Trainers Through June 2022

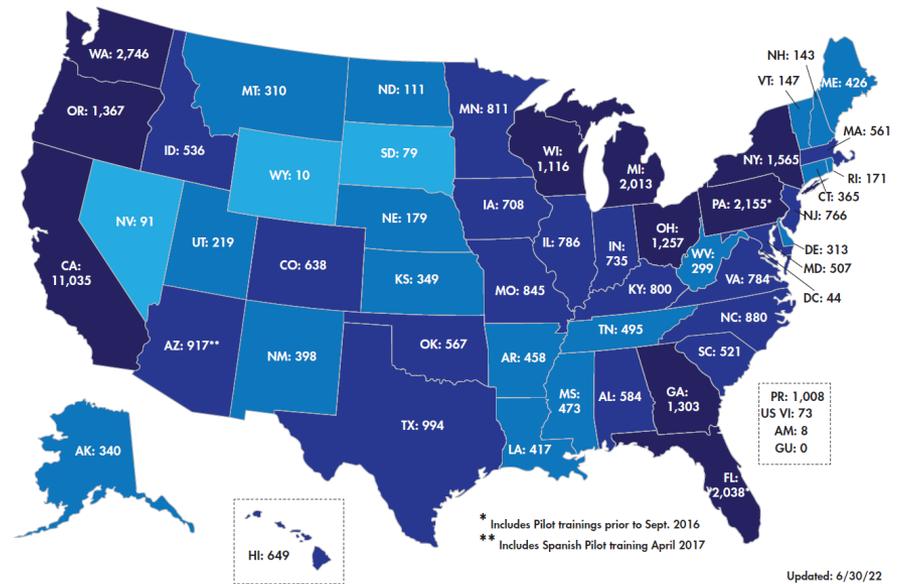




Plans for Subpart E Outreach: Getting Growers Trained!

- Almost 80,000 PSA Grower Training participants
- Host several update trainings for PSA GT participants in English and Spanish)
 - Remote and In-person
 - PSA Trainer delivered
- Attendance may be required. Will be tracked.

Nationwide Produce Safety Alliance Grower Training Course Participants
Locations of Participants Through June 2022 (In-Person, Remote, and Online Deliveries)





Your turn to provide more input...

- Initial thoughts on our plans.
 - Anything that jumps out to you immediately?
- In thinking about your own plans and goals, if the final Subpart E requirements are similar to those in the proposed rule, what additional resources will be helpful?
 - Do you think the growers you work with will need additional help/educational materials?
- Your biggest concern about implementation of new Subpart E?



2022 PSA Update Webinar

- Available in English and Spanish
- English webinar: October 25, 2022, 2-3:30pm Eastern
- Spanish webinar: November 30, 2022, 2-4pm Eastern

- Registration coming soon! Details will be sent out via Educator's Listservs and email to all trainers.



Next Educator's Call

- Incorporating interactive training elements into produce safety trainings
 - Date: October 24, 2022
 - Speakers: Dr. Kristin Woods, Ms. Gretchen Wall, Mr. Billy Mitchell



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 it is a navigation menu with links for "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 overhead irrigation systems. 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, which consists of the words "Produce Safety" in a green sans-serif font above the word "ALLIANCE" in a smaller, all-caps green font. 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 main photo is a smaller thumbnail image of a field with irrigation, 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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