



FSMA Proposed Rule on Agricultural Water Webinar

Drs. Joy Waite-Cusic, Linda Harris, and Channah Rock
March 10, 2022



Image Credit: Flickr, Oregon Department of Agriculture, 2016



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Extension in Microbial Food Safety



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Professor and Water
Quality Specialist





GENERAL OBJECTIVES

Linda will provide:

- Overview on agricultural water

Joy will provide:

- High level comparison between the current and proposed rules related to agricultural water
- Summary of the proposed agricultural water assessment
- Summary of proposed mitigation measures related to agricultural water
- How water testing fits into the proposed rule


Channah will provide

- Overview of water treatment options
- Expected FDA activities related to the proposed rule

Channah, Linda, and Joy will provide:

- General instructions for commenting on the proposed rule
- Address questions submitted from webinar registration
- General comments/concerns related to the proposed rule

Subparts of the Produce Safety Rule

A: General Provisions
B: General Requirements
C: Personnel Qualifications and Training
D: Health and Hygiene
E: Agricultural Water 
F: Biological Soil Amendments of Animal Origin and Human Waste
G-H: Reserved
I: Domesticated and Wild Animals
J: Reserved

K: Growing, Harvesting, Packing, and Holding Activities
L: Equipment, Tools, Buildings, and Sanitation
M: Sprouts
N: Analytical Methods
O: Records
P: Variances
Q: Compliance and Enforcement
R: Withdrawal of Qualified Exemption



Two Sections on Water in PSR

- **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

Proposed Rule
Changes





No Changes to Part II
Harvest/Postharvest Water



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



Produce Safety
ALLIANCE

§

Manual slide 5

Helpful Definitions

- **Agricultural water** must be safe and of adequate sanitary quality for its intended use.
 - **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?

Citrus is “covered produce” ✓



Drip irrigation

“not intended to or likely to contact”



Micro sprinkler



Application of Crop Protection Sprays

If fruit in tree:
“intended to or likely to contact” ✓

FDA Proposed Rule Subpart E Agricultural Water

Published in Federal Register December 6, 2021

Docket FDA-2021-N-0471

<https://www.regulations.gov/document/FDA-2021-N-0471-0001>

Comment period closes April 5, 2022

No change to the underlying regulatory requirement of subpart E:

21 CFR 112.41 – All agricultural water must be safe and of adequate sanitary quality for its intended use.

Current Rule



FDA defines adequate sanitary quality:

Pre-harvest applications:

Microbial water quality profile:
GM <126 CFU/100 ml
STV <410 CFU/100 ml
Generic *E. coli*

Harvest and Post-harvest applications:

Microbial water quality profile:
No detectable
Generic *E. coli*
(<1 CFU/100 ml)

Proposed Rule



Farm makes a determination
of adequate sanitary quality:

Agricultural Water Assessment

112.43

OR

Exemptions:

112.43(b)

- 1) Ground water: No detectable generic *E. coli*
(Testing required)
- 2) Public water supply (Documentation required)
- 3) You treat your ag water (Other requirements)

✓ Supervisor
112.161(b)

Agricultural Water Assessment - 112.43

Must identify conditions that are reasonably likely to introduce hazards to covered produce or food contact surfaces based on:

WRITTEN & FOR EACH WATER SYSTEM

DESCRIPTION:

1. Location and nature of water source
2. Type of distribution system
3. Degree of protection from possible contamination

OTHER WATER USERS
ANIMAL IMPACTS
ADJACENT/NEARBY LAND USE
BSAAO
HUMAN WASTE

PRACTICES:

1. Type of direct application
2. Time interval between last direct application and harvest

CROP CHARACTERISTICS:

Susceptibility of produce to surface adhesion or internalization

ANNUAL INSPECTION OF
AG WATER SYSTEM
(112.42(a))

Reassessment:

Annually and if significant change

ENVIRONMENTAL CONDITIONS:

1. Frequency of heavy rain or extreme weather events that could:
 - a. Impact water system (disrupt sediment)
 - b. Impact covered produce (damage edible portion)
2. Air temperatures
3. Sun exposure

MAINTENANCE OF
SYSTEM
(112.42(b))

Regular monitoring to identify hazards
Correct deficiencies
Properly store equipment
Keep source clean
Avoid pooled water

OTHER RELEVANT FACTORS:

Results of any testing

AWA Outcome
DETERMINATION:

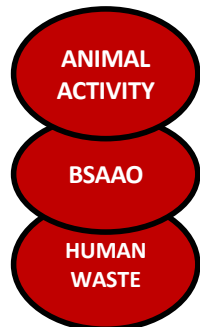
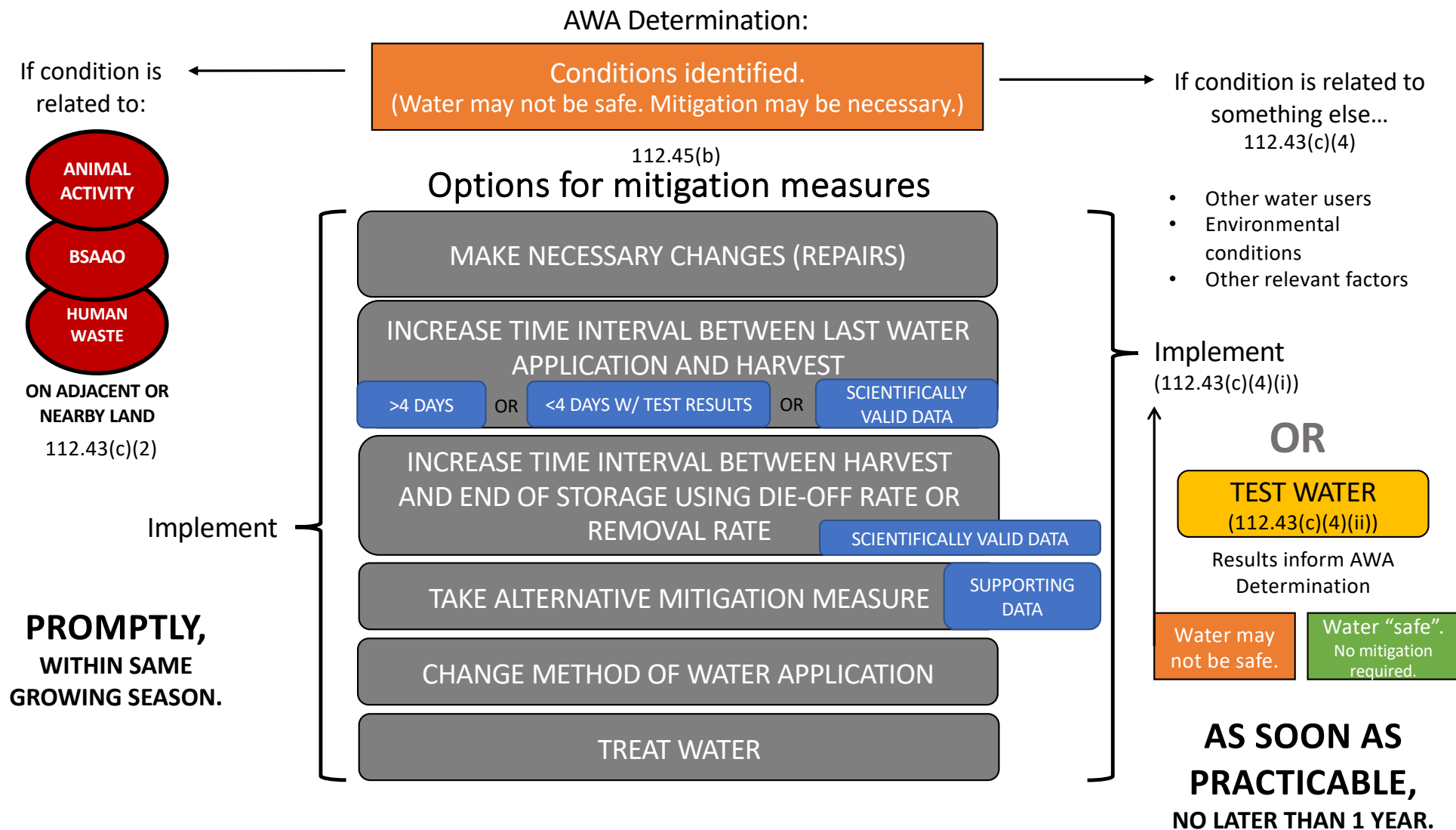
No conditions identified.
(Water is of safe and adequate sanitary quality.)
(112.43(c)(3))

OR

Conditions identified.
(Water may not be safe.
Mitigation may be necessary.)
(112.43(c)(2) or 112.43(c)(4))

OR

Water is NOT safe.
(Discontinue use.)
(112.43(c)(1))



ON ADJACENT OR
NEARBY LAND
112.43(c)(2)

**PROMPTLY,
WITHIN SAME
GROWING SEASON.**

Implement

- Other water users
- Environmental conditions
- Other relevant factors

Implement
(112.43(c)(4)(i))

OR

TEST WATER
(112.43(c)(4)(ii))

Results inform AWA
Determination

Water may
not be safe.

Water "safe".
No mitigation
required.

**AS SOON AS
PRACTICABLE,
NO LATER THAN 1 YEAR.**

If you have reason to believe that your ag water is **not safe** or of adequate sanitary quality for its intended use:

**IMMEDIATELY
DISCONTINUE USE.**

OR if mitigation
measure was
not effective:

112.45(b)(2)

TO REUSE THIS WATER SYSTEM:
Inspect, make changes, confirm OR Treat.

112.45(a)

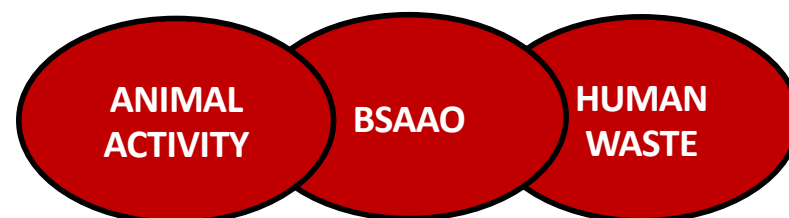
Other situations:

**AS SOON AS PRACTICABLE,
NO LATER THAN 1 YEAR.**

112.45(b)(1)

How soon would a farm have
to implement mitigation
measures?

If the hazard is related to:



ON ADJACENT OR NEARBY LAND

**PROMPTLY,
WITHIN SAME GROWING SEASON.**

112.45(b)(1)

Where does water testing fit in now?

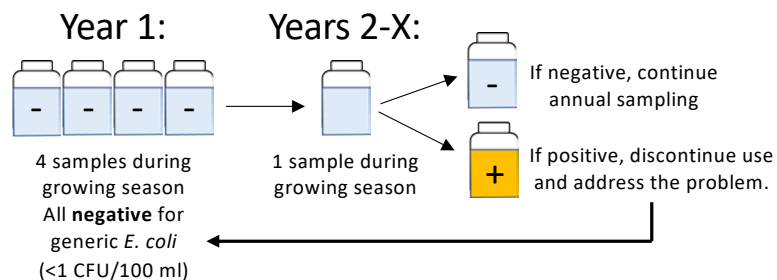
Water testing is **NOT** a mandatory portion of the proposed rule.

OPTIONAL COMPONENT OF AGRICULTURAL WATER ASSESSMENT (112.43(c)(4)(ii))

Certain covered farms **may opt** to conduct water testing to help inform their agricultural water assessment.

EXEMPTION FROM AGRICULTURAL WATER ASSESSMENT UNTREATED GROUND WATER (112.43(b)(1))

Test to prove that you meet post-harvest water quality microbial criterion
(112.44(a) and affiliated)



SUPPORT ALTERNATIVE MITIGATION MEASURE:
<4-DAY TIME INTERVAL BETWEEN
LAST WATER APPLICATION AND HARVEST (112.45(b)(1)(ii))

MWQP and die-off strategy from current final rule? (Preamble)
Records and justification for interval required. (112.50(b)(7))

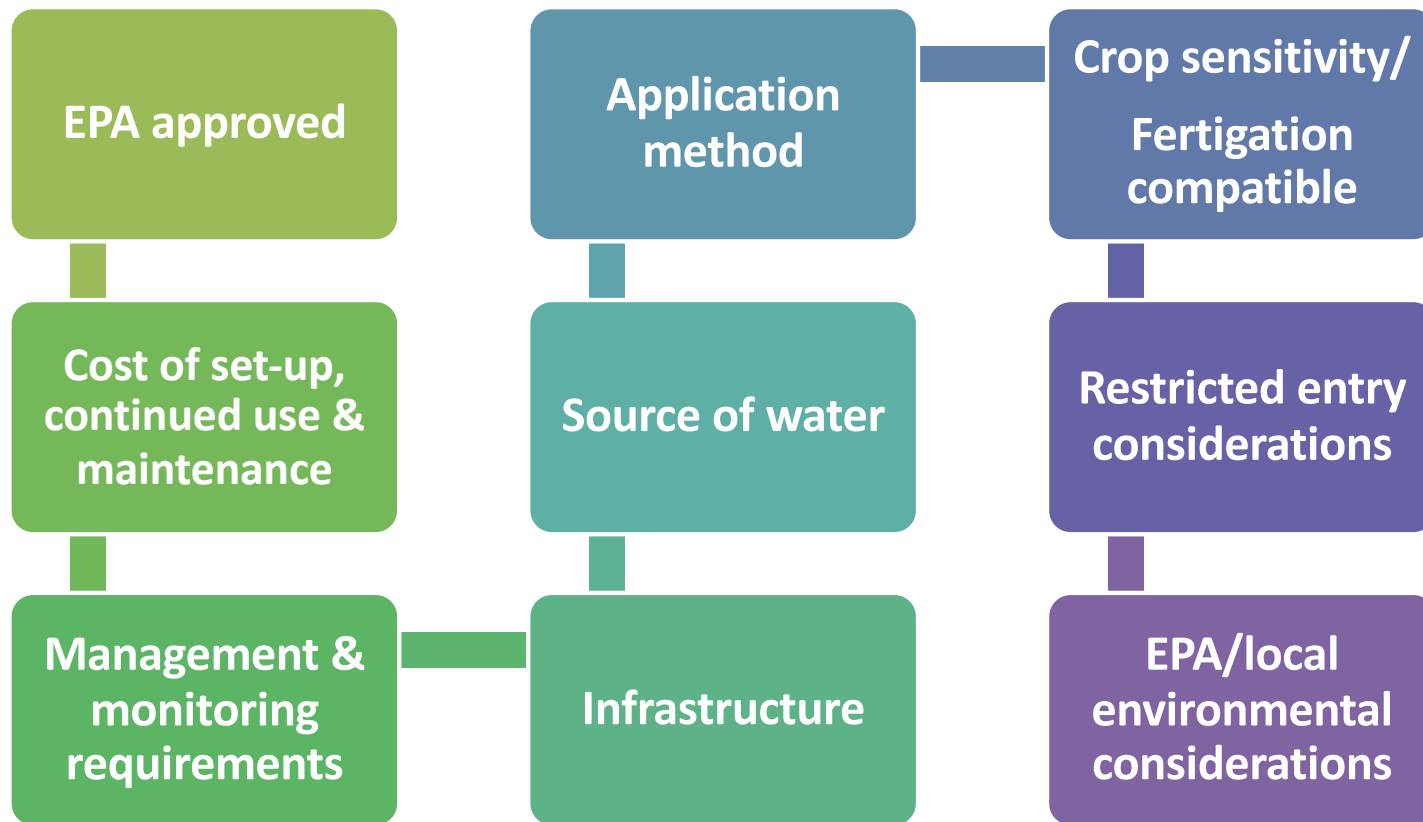
SUPPORT THE ABILITY TO USE A WATER SOURCE THAT
WAS PREVIOUSLY DEEMED UNSAFE/DISCONTINUED USE
(112.45(a)(1))

Inspect, make changes, **determine changes were effective.**

Water Treatment and the PSR

- Has always been an option within the PSR (§ 112.46)
 - Routine operating procedure OR
 - Corrective measure
- Within the proposed rule this is still the case, but growers only have the outcomes of their Ag Water Assessment to drive decisions vs. standards which were originally tied to populations of *E. coli* (GM & STV)

If you must treat, how do you choose a water treatment method?



Commonly Used Water Treatment Chemicals or Devices

- **Physical (Pesticide device)**

- Heat Sterilization
- Ultra Violet Light (UV)
- Filtration (Membrane, or other media)
- Ozone generator

- **Chemical**

- Peroxyacetic Acid (PAA)
- Chlorine Dioxide / Chlorine Gas
- Sodium or Calcium Hypochlorite
- Copper / Silver Ionization
- Bromine

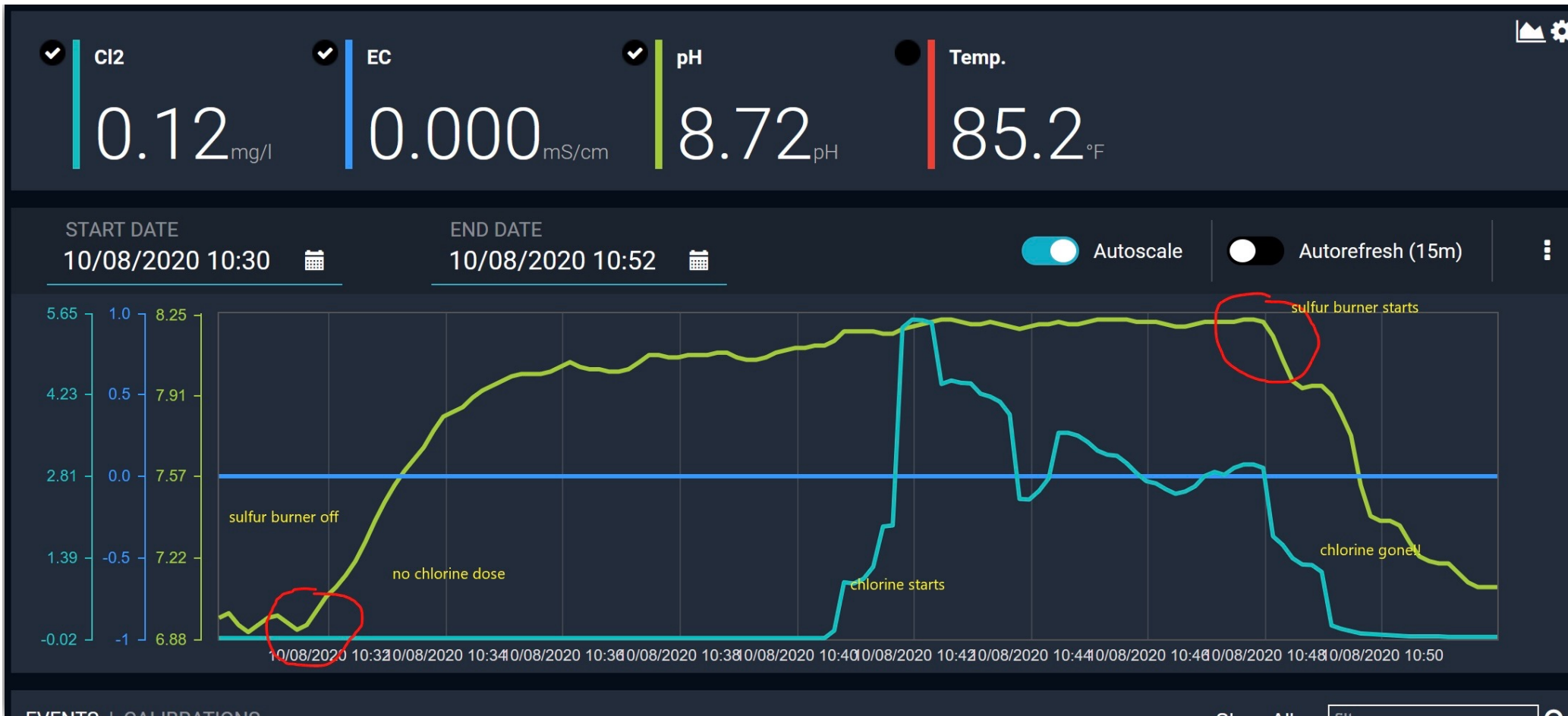


Example: Chemical Disinfection/Sanitation

- Disinfectants/Sanitizers do not kill instantaneously on contact. The rate of inactivation depends on 5 factors:
 1. The Pathogens/Indicators
 2. Chemical Concentration, C (mg/l)
 3. Time, T (minutes)
 4. Temperature of water
 5. pH of water

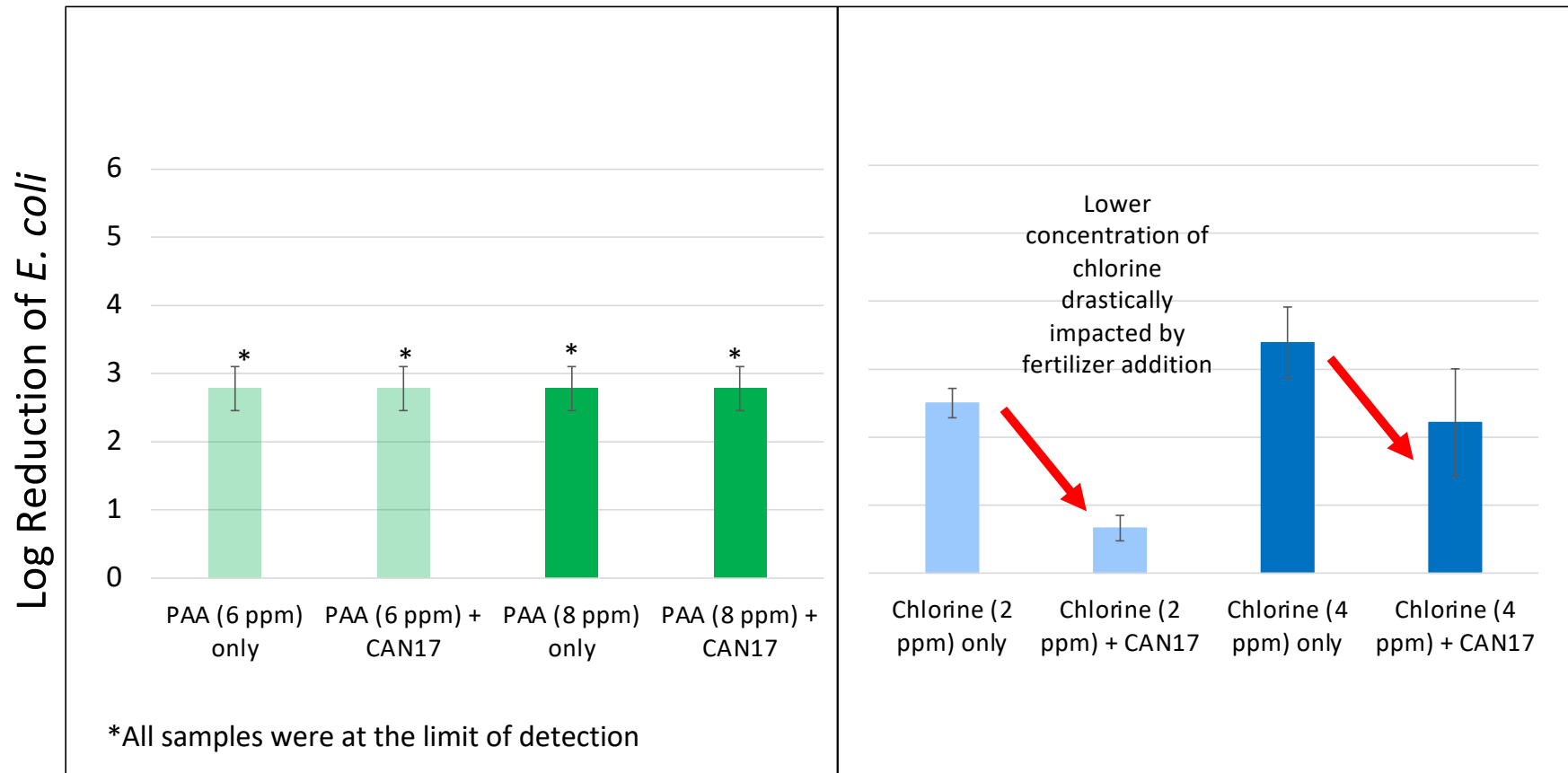
Real Life is Complicated

- Many crop inputs are distributed with water these also can impact efficacy and should be taken into account.
- Fertilizers are a great example, in the next few slides we can see the interaction of fertilizers with different treatments
- Growers can evaluate efficacy of treatments when conducting on-farm validation studies.



- Real life grower scenarios
 - water treatment,
 - pH amending and
 - fertigation

Interaction of PAA and Chlorine with Calcium Ammonium Nitrate (CAN17)



Data from Dr. Channah Rock

Records – Required Documents Proposed Rule

- At least once annually: **prepare a written agricultural water assessment**
- §112.50 Under this subpart, what requirements apply regarding records?
 - (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.
 - (b) You must establish and keep the following records, as applicable:
 - (1) The findings of inspections of your agricultural water systems in accordance with the requirements of §112.42(a);
 - (2) Your written agricultural water assessments, including descriptions of factors evaluated and written determinations, in accordance with §112.43(c)(4)(ii). NEW
 - (4) Scientific data or information that you rely on to support the frequency of testing and any microbial criterion (or criteria) you applied for purposes of §112.43(c)(4)(ii). NEW

What we can expect from FDA

- AN ONLINE TOOL
 - Resource to assist farms in developing the AWA
 - Not available as of March 10, 2022
- ENFORCEMENT DISCRETION
 - Subpart E during rulemaking period
 - Farms should focus their attention good agricultural practices to maintain and protect the quality of their water sources
 - Produce remains subject to FD&C Act



Sharing the proposed rule

Share broadly with links to the proposed rule, appropriate summaries

- See here: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water>

Public Meetings to Discuss Proposed Changes (FDA)

- FDA virtual meetings: February 14 and 25, 2022
- **CDFA/NASDA meeting: March 11, 2022 10 am**
- To register:
<https://www.surveymonkey.com/r/WesternProposedAgWater>

More information: Supplemental Fact Sheets

Agricultural Water Proposed Rule



Agricultural Water Assessment

The FDA is proposing to revise certain pre-harvest agricultural water requirements for covered produce (other than sprouts) in Subpart E of the FDA Food Safety Modernization Act (FSMA) [Produce Safety Rule](#). This proposal, if finalized, would replace the pre-harvest microbial quality criteria and testing requirements for such produce in the Produce Safety Rule with requirements for systems-based pre-harvest agricultural water assessments that covered farms would use for hazard identification and risk management decision-making purposes. As part of the assessment, the farms would be required to evaluate the following factors to identify conditions that would be reasonably likely to introduce known or reasonably foreseeable hazards into or onto produce or food contact surfaces:



- <https://www.fda.gov/media/154334/download>

Agricultural Water Proposed Rule

Factors to consider as part of Agricultural Water Assessment



Agricultural Water Assessment

The FDA is proposing to revise some of the pre-harvest agricultural water requirements for covered produce (other than sprouts) in Subpart E of the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule. This proposal, if finalized, would replace the pre-harvest microbial quality criteria and testing requirements for such produce in the Produce Safety Rule with requirements for systems-based pre-harvest agricultural water assessments. If finalized, covered farms would be required to conduct pre-harvest agricultural water assessments once annually, and whenever a change occurs that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto produce or food contact surfaces.

The following chart summarizes the factors that covered farms would be required to consider as part of the assessment. The proposed requirements can be found in the Federal Register.

- <https://www.fda.gov/media/154447/download>



Commenting on the rule

Docket No. FDA-2021-N-0471

- Comments Due **April 5, 2022**
- Online comments:
 - <https://www.regulations.gov/docket/FDA-2021-N-0471/document>
- Written/Paper Submissions
 - Mail/Hand delivery/Courier:
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

NR NONRULEMAKING DOCKET

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

Created by the **Food and Drug Administration**



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- ☐ Proposed Rule (2)

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PROPOSED RULE

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water; Proposed Rule; Public Meetings; Request for Comments

Agency Food and Drug Administration

Posted Jan 6, 2022

ID FDA-2021-N-0471-0098



Comment

Comments Due Apr 5, 2022

FDA suggestions for comments

- Clearly indicate if you are **for or against** the proposed rule or some part of it and why.
 - FDA regulatory decisions are based largely on law and science, and agency reviewers look for reasoning, logic, and good science in comments they evaluate.
- Refer to the docket number, listed in *Federal Register* notice.
- Include a copy of articles or other references that support your comments. (Electronic attachments will not be forwarded if the "Comment" box is left empty.)

Asking FDA questions

Contact Us

The proposed rule is available for public comment for 120 days. Comments should be submitted to docket FDA-2021-N-0471 on [Regulations.gov](https://www.regulations.gov).

The FDA encourages comments and questions to be submitted to the docket so that the agency can fully consider all feedback.

Additional questions, and requests for meeting and speaker engagements can be submitted via the forms below. For meeting and speaking requests, please include a completed request form when you contact us.

[Submit an Inquiry](#)

[Meeting Request Form](#) (email to AgWater@fda.hhs.gov)

[Speaker Request Form](#) (email to AgWater@fda.hhs.gov)

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water>

When will the final rule be published?

- FDA provides some information on the process:
<https://www.fda.gov/media/81779/download>
 - If no substantive comments received – within 60 days of close of comment period
 - If substantive comments received – less clear
 - Proposed Produce Safety Rule: January 16, 2013
 - Final Produce Safety Rule: November 27, 2015 (about 3 years)
 - Much larger document
- So: >60 days but < 3 years?



Questions?