

# Bridging the GAPS: Approaches for Treating Water On-Farm Agricultural Water Treatment and FSMA

---

**John Buchanan**, Associate Professor and Extension Specialist,  
Department of Biosystems Engineering and Soil Science,  
University of Tennessee

**Travis Chapin**, Former State Specialized Extension Agent, Food Safety,  
University of Florida IFAS

**Faith Critzer**, Associate Professor and Extension Specialist, School of Food Science,  
Washington State University

**Michelle Danyluk**, Professor and Extension Specialist, Food Science and Human  
Nutrition, University of Florida IFAS

**Chris Gunter**, Professor and Extension Specialist, Horticultural Science,  
North Carolina State University

**Laura Strawn**, Associate Professor and Extension Specialist, Food Science and  
Technology, Virginia Tech

**Annette Wszelaki**, Professor and Extension Specialist, Department of Plant Sciences,  
University of Tennessee



# Bridging the GAPs: Approaches for Treating Irrigation Water On-Farm

The goal of this series of modules on water treatment is to equip growers with the knowledge to successfully implement water treatment systems on their farms. Fruit and vegetable growers are continually assessing their operations to determine where they can limit risk and increase productivity. As a result, many have expressed interest in learning more about how on-farm preharvest water treatment systems work and how they may fit within their current setup.



Licensed under [CC BY-SA](https://creativecommons.org/licenses/by-sa/4.0/)

These four modules help growers to: 1) understand the background for water treatment; 2) learn about different approaches to treating water on-farm; 3) how to implement these systems to meet requirements of the Produce Safety Rule; and 4) how to verify that the system is operating as intended.

W 920-A, Agricultural Water Treatment and FSMA

W 920-B, Agricultural Water Treatment Tools

W 920-C, Developing On-farm Agricultural Water Treatment Programs

W 920-D, Implementing Agricultural Water Treatments on the Farm



A photograph of a lush green agricultural field with rows of crops. A center pivot irrigation system is visible, with multiple wheels and arms extending across the field. The sun is shining brightly in the upper right corner, creating a lens flare effect. A semi-transparent green rectangular box is overlaid on the center of the image, containing white text.

# **Agricultural Water Treatment and FSMA**

## **Module 1**



A special thank you to the Produce Safety Alliance who allowed us to use portions of their curriculum for this module.

Bihn, E., Wall, G., Acuña-Maldonado, L., Fisk, C., Humiston, M., Pahl, D., Stoeckel, D., Way, R., and Woods, K. 2019. Produce Safety Alliance National Curriculum. Version 1.2 Produce Safety Alliance, Cornell University.

**Produce Safety**  
ALLIANCE



## Learning Objectives

1. Describe the purpose of water treatment within the context of on-farm irrigation and agricultural water as defined by the Produce Safety Rule (PSR)
2. Communicate scenarios for which a treatment system would help mitigate on-farm food safety risks posed by agriculture water
3. Explain the connectivity between implementing a water treatment system and reducing risk on the farm
4. Describe the regulatory context of water treatment technologies



## FDA Water Compliance Date Extension

In March 2019, FDA published a rule called *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E*.

- Extends ALL provisions of Subpart E (Agricultural water) other than sprouts including the safe and sanitary quality, annual inspection, and postharvest water monitoring requirements.
- FDA has stated that the reason for this extension is to allow time *“to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to protect public health.”*
- Until the process of consideration is finished, the water requirements are those currently stated in the Rule



## Water Compliance Date Extension

Farm Size	Compliance Dates
Large Farms	2022
Small Farms	2023
Very Small Farms	2024


5

Large farms > \$500,000 in 2011 dollars, refer to inflation chart to determine actual value for the year you are training

Small = \$250,000-499,999






Very Small Farms = \$249,999-25,000

\*Must have begun testing during while actively growing by January of the compliance year. For example, if I'm a tomato grower on a large farm and my season starts in May and ends in October. I would need to begin testing during that 2021 growing season in order to meet the January 2022 compliance date.\*



## Production Agricultural Water

- Production Agricultural Water (PSR Definition)
  - Water used in contact with the harvestable portion of covered produce during the growing season

-  Irrigation
-  Fertigation
-  Foliar Sprays
-  Cooling
-  Frost Protection

Define Agricultural Water in the context of the Produce Rule – water that comes into contact with the harvestable portion of the crop before harvest. Then discuss the different types of water this could include listed on the right.

Make relevant for your audience and the types of commodities that they are using.





## Agricultural Water Quality

- All agricultural water must be safe and of adequate sanitary quality for its intended use
- 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**  
ALLIANCE 7

- A general requirement of subpart E of the FSMA Produce Safety Rule is that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). This requirement applies to agricultural water that is intended or likely to contact covered produce or food contact surfaces and includes agricultural water used during growing activities for covered produce using a direct water application method (covered in Part I of this module), and water used for certain activities during and after harvest (covered in Part II of this module) and for sprout irrigation.
- Bihn, E., Wall, G., Acuña-Maldonado, L., Fisk, C., Humiston, M., Pahl, D., Stoeckel, D., Way, R., and Woods, K. 2019. Produce Safety Alliance National Curriculum. Version 1.2 Produce Safety Alliance, Cornell University.



## Evaluating Water Quality: Use of Microbial Water Quality Profiles

- Testing is the only way to quantitatively evaluate the microbial quality of the water
- The microbial water quality profile (MWQP) can help you:
  - Understand the long-term quality of your water source
  - Understand appropriate uses for each source
  - Determine when corrective measures are needed, if the microbial water quality profile exceeds numerical criteria in the FSMA Produce Safety Rule

**Produce Safety**  
ALLIANCE 8

- Requirements related to the microbial water quality profile, corrective measures, and numerical GM and STV criteria are discussed in the upcoming slides. The geometric mean (GM) is a log-scale average, the “typical” value. The statistical threshold value (STV) is a measure of variability, the estimated “high range” value (approximated 90<sup>th</sup> percentile). Both of these are discussed in the slide *Geometric Means and Statistical Threshold Values*.
- The microbial water quality profile (MWQP) is a long-term management strategy, and for production water, it is not meant to be used for day-to-day management and decision making about whether the water is suitable for a use at that particular time.
- § 112.46(b)(1) requires that growers subject to the rule must establish an initial microbial water quality profile for untreated water sources (surface or ground water) that are applied using a direct water application method during growing.
- It is important to understand that surface water quality can change quickly over time and throughout the season. Water testing only provides an indication of the water quality at the time of sampling and may provide information on long-term sources of fecal contamination that impact the water source.
- Bihn, E, Wall, G, Fisk, C, Humiston, M, Pahl, D, Stoeckel, D, Way, R, and Woods, K.

2017. Produce Safety Alliance National Curriculum. Version 1.1 Produce Safety Alliance, Cornell University.



## Criteria for Water Used During Growing Activities

- Each source of production water must be tested to evaluate whether its water quality profile meets the following criteria:
  - **126 or less** colony forming units (CFU) generic *E. coli* per 100 mL water geometric mean (GM)
  - **AND**
  - **410 or less** CFU generic *E. coli* per 100 mL water statistical threshold value (STV)

**Produce Safety**  
ALLIANCE <sup>9</sup>

- § 112.44(b) specifies criteria for untreated agricultural water (both surface water and ground water) that is applied with a direct water application method to covered produce during growing activities.
- The numerical GM and STV criteria are used to evaluate the microbial water quality profile (MWQP).
  - These criteria capture two different pieces of information about the distribution of generic *E. coli* levels in a water source. The geometric mean (GM) is essentially the average amount of generic *E. coli* in a water source. The STV reflects the amount of variation in the *E. coli* levels. Collectively, both pieces of information provide a more complete description of your water quality than either one alone.
- Some terms, as defined in § 112.3(c), are critical to understanding the scope of what is covered under these criteria.
  - **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.
  - **Direct water application method** means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

- **Covered produce** means produce that is subject to the FSMA Produce Safety Rule. The term “covered produce” refers to the harvestable or harvested part of the crop.
- Production water that does not meet the definition of agricultural water (see above) is not covered by the GM and STV criteria in the FSMA Produce Safety Rule. For example, water used for drip or furrow irrigation in apple orchards would not be considered agricultural water as long as the water does not contact the apples. That same water would be considered agricultural water if it were used to mix protective sprays that were then applied directly to the apples.

#### **Additional Resources:**

- FD&C Act Chapter IV: Food, Section 342 Adulterated Food:  
<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIV-sec342.pdf>
- United States Environmental Protection Agency (EPA) 2012 Recreational Water Quality Criteria:  
<http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/upload/RWQC2012.pdf>
- For information about how the numerical GM and STV water quality criteria were developed
  - Food and Drug Administration (FDA) (2015) How did FDA Establish Requirements for Water Quality and Testing of Irrigation Water? Questions and Answers with Samir Assar:  
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM473335.pdf>
- For a historical context of water quality standards:
  - Suslow, T. (2009). Standards for Irrigation and Foliar Water Contact. Pew Charitable Trusts at Georgetown University. Produce Safety Project.  
<http://www.pewtrusts.org/~media/Assets/2009/PSPWaterSuslow1pdf.pdf>
  - Dufour, A., & Schaub, S. (2007). The evolution of water quality criteria in the United States. *Statistical Framework for Recreational Water Quality Criteria and Monitoring*, 65, 1.
- Bihn, E, Wall, G, Fisk, C, Humiston, M, Pahl, D, Stoeckel, D, Way, R, and Woods, K. 2017. Produce Safety Alliance National Curriculum. Version 1.1 Produce Safety Alliance, Cornell University.



## Testing Requirements for Water Sources

Source	Testing Requirement
Public Water Supply	<ul style="list-style-type: none"><li>• Copy of test results or current certificates of compliance</li></ul>
Ground	<ul style="list-style-type: none"><li>• 4 or more times during the growing season or over the period of a year</li><li>• 1 or more samples rolled into profile every year after initial year</li></ul>
Surface	<ul style="list-style-type: none"><li>• 20 or more times over a period of 2 to 4 years</li><li>• 5 or more samples rolled into profile every year after initial survey</li></ul>

- With appropriate documentation, there is no requirement to test water that meets the requirements for public water supplies.
- Profile samples must be representative of use and must be collected as close in time as practicable to, but before, harvest.

**Produce Safety**  
ALLIANCE <sup>10</sup>

- §§ 112.46(a)(1) and (a)(2) state that if water is sourced from a public water supply (such as municipal drinking water), growers subject to the rule do not need to test the water source as long as they have Public Water System results or a current water supply certificate of compliance that the water meets requirements of the Safe Drinking Water Act, or that it is free of detectable generic *E. coli* in 100 mL of water.
  - If municipal drinking water is held in containments open to the environment prior to using it as agricultural water, it is considered equivalent to untreated surface water and then it would need to be surveyed as surface water (see the slide *Microbial Water Quality Profile: Survey of Surface Water Sources*).
- Though not required, it is a good idea to sample and test at the point of use to ensure that there are no impacts from the water distribution system.
- It is important to understand that depending on business size growers will have between January 2022 and January 2024 to begin sampling for a MWQP and otherwise come into compliance with the agricultural water requirements, unless the requirements change in the interim.

Bihn, E., Wall, G., Acuña-Maldonado, L., Fisk, C., Humiston, M., Pahl, D., Stoeckel, D., Way, R., and Woods, K. 2019. Produce Safety Alliance National Curriculum. Version 1.2 Produce Safety Alliance, Cornell University.



## Assessing Water Quality Now

- Growers currently testing their water may continue to do so
- If not testing, growers may consider starting to test to better understand their water quality
- Follow Good Agricultural Practices (GAPs) to protect and maintain water quality
- Develop water management strategies, such as water system surveys, to identify and reduce risks

**Produce Safety**  
ALLIANCE <sup>11</sup>

- It is very important for growers to know that nothing on this slide is required by the FSMA Produce Safety Rule. Review the slide ***FDA Water Compliance Date Extension*** for more information.
- Most importantly, growers should be encouraged to continue water testing if it is already being done to understand their water quality and maintain market access by meeting buyer and audit requirements.
- Growers who are not testing but are interested in better understanding the quality of their water may want to begin testing for quantified generic *E. coli*. For surface water sources, a good recommendation for growers that are just beginning is to test three times per season (once before they start using the water and other tests during periods when they are using the water source). The goal is to begin the process of understanding water quality and how it might change over time.
- Growers should follow Good Agricultural Practices to protect and maintain water quality. Growers may want to inspect their water source and distribution systems to assess risks that could impact water quality, for example, by surveying the land around the water source. This could include assessing activities happening upstream that may impact quality (e.g., operations that allow animal access to the water source such as grazing cattle).



**Additional Resource:**

- FSMA, Produce Safety Rule; Extension of Compliance Dates for Subpart E, 21 CFR 112 (2019), Comment/Response 9, page 9712. Available at <https://www.govinfo.gov/content/pkg/FR-2019-03-18/pdf/2019-04652.pdf#page=7>
  - In response to Comment 9, FDA states, *“In the meantime, farms should focus their attention on good agricultural practices to maintain and protect the quality of their water sources. (See, e.g., FDA’s “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,” ...). Farms currently testing their water may choose to continue with their current water testing programs, and farms that are not currently testing their water may choose to begin doing so.”*



## Corrective Measures

- Three types of corrective measures are allowed if the microbial water quality profile does not meet water quality criteria:
  - Apply a time interval for microbial die off
    - Between last application and harvest
    - Between harvest and the end of storage and/or removal during activities such as commercial washing
  - Re-inspect the water system, identify problems, and make necessary changes and confirm effectiveness
  - **Treat the water**

**Produce Safety**  
ALLIANCE

12

- Corrective measures specify requirements outlined in the FSMA Produce Safety Rule when specific numerical criteria are not met.
- § 112.45(b) requires that if the source microbial water quality profile (MWQP) does not meet numerical GM and STV criteria (see the slide *Water Quality Criteria for Water Used During Growing Activities* for details), growers subject to the rule must discontinue use of the water as soon as practicable and no later than the following year unless a corrective measure is implemented. Options for corrective measures include the following:
  1. § 112.45(b)(1) allows growers to achieve the water quality criteria by applying a time interval for die-off, or a reduction by removal processes.
    - i. Apply a time interval between last application and harvest as described in *Corrective Measure: Water Application and Timing*. Provision 112.45(b)(1)(i)(A) includes a die-off rate of 0.5 log per day, for up to four consecutive days. § 112.45(b)(1)(i)(B) allows use of alternative microbial die-off rates and accompanying maximum time intervals, if scientifically valid.
    - ii. Apply a time interval between harvest and end of storage. Provision 112.45(b)(1)(ii) allows application of a time interval between harvest and end of storage using a scientifically valid die-

off rate. The provision also allows use of appropriate microbial removal rates during activities such as commercial washing.

2. § 112.45(b)(2) allows growers to re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective and adequately ensure that agricultural water meets the applicable microbial quality criteria.
  3. § 112.45(b)(3) allows growers to treat the water in accordance with § 112.43. See *Corrective Measure: Treating Production Water* for more information.
- As a guide, a 1 log removal or die-off is 90% reduction (10% remaining). A 0.5 log removal or die-off can be approximated as 68% reduction (32% remaining).
  - Bihn, E, Wall, G, Fisk, C, Humiston, M, Pahl, D, Stoeckel, D, Way, R, and Woods, K. 2017. Produce Safety Alliance National Curriculum. Version 1.1 Produce Safety Alliance, Cornell University.



## Corrective Measure: Treating Production Water

- Any chemicals used to treat water must be EPA registered and labeled for the intended use
- Non-chemical treatments, called pesticide devices by EPA, may be used if they adequately reduce microbial risks
  - Filter units, UV light units, ozonator units
- You should avoid water treatments that may have negative environmental and soil quality impacts
- You must keep records of all treatment monitoring done

**Produce Safety**  
ALLIANCE

13

- If the treatment option is used (see the slide *Corrective Measures* for details), any chemicals used to treat water must be EPA-registered for that use and targeted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) before they can be lawfully used.
- Non-chemical options such as filtration and/or UV may be used, but growers must be sure they are adequate in terms of the volume of water that needs treatment and the resulting microbial risk reduction is sufficient to meet regulatory requirements (as indicated by the text of § 112.43(a)(1)).
  - Simple sand filters may remove large particles from the water, but are less effective at removing bacteria such as generic *E. coli*.
- Treating any sources of agricultural water requires a careful review of the potential environmental impacts. Chemically treating water sources, especially if they are open to the environment, can be detrimental to wildlife habitat.
- Growers subject to the rule are required to use treatment methods that are effective (§112.43(a)(1)). The FSMA Produce Safety Rule does not require growers to test treated water to determine generic *E. coli* levels after treatment. However, growers are encouraged to verify that the treatment they applied was effective under the conditions on their farm by testing one or more samples of treated water for generic *E. coli* levels.

- Bihn, E, Wall, G, Fisk, C, Humiston, M, Pahl, D, Stoeckel, D, Way, R, and Woods, K. 2017. Produce Safety Alliance National Curriculum. Version 1.1 Produce Safety Alliance, Cornell University.



## Why treat your water?

- Improve microbial quality
- Increase efficiency and effectiveness of infrastructure
  - Clogged emitters from algae buildup, etc.
- Mitigate issues from limited or infrequent use
- Minimize effects of seasonal variability and unexpected events
- Inability to create MWQP due to land leasing or rotation
- No PSR requirement to test water or maintain MWQP
  - Audits may still require testing
  - Most likely component of verification

14

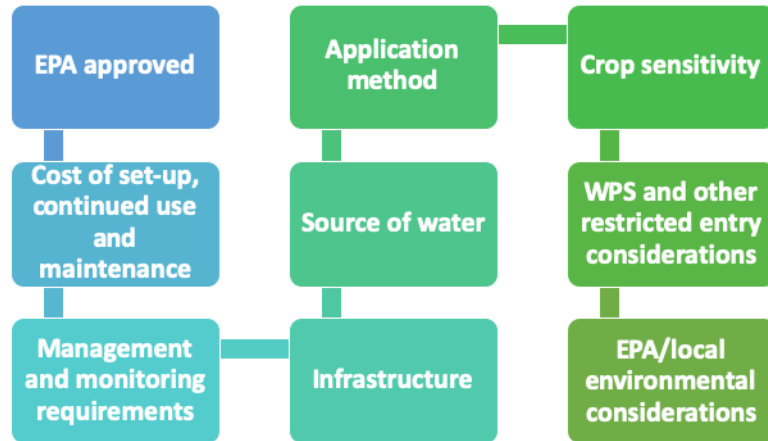
Ask class if any of them do treat their water, and why?

Comment that water treatment is a great risk reduction strategy, because of all the things that are listed on this slide.

You could also have the discussion here of why you wouldn't want to treat your water – cost, management, use, etc. and how the benefits may outweigh these areas.



## How to choose a water treatment method?



15

There are many things to consider when choosing a water treatment system, and it is very unique to each water source/situation.

Selecting the appropriate water system treatment is probably the most difficult part of treating your water.

Highlight the different considerations on this slide as appropriate for your audience or region.



## Chemical vs. Device

- Chemicals (antimicrobial pesticides) must be EPA registered for their use and be targeted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) before they can be lawfully used- “labeled for intended use”
  - Chemicals may have supplemental information based on scientific studies within labeled uses that set limits for control of foodborne pathogens
- Pesticide devices are physical treatments (non-chemical)
- Pesticide devices are regulated by EPA but do not require EPA registration
- Some states may require registration of pesticide devices

16

At this point there are two main approaches to treating water: One is through use of chemicals, and the other is through use of pesticide devices.

Chemical treatments fall under pesticide labeling requirements for EPA (FIFRA). They must be labeled for their intended use.

MORE information will be provided in additional slides for using chemicals in a food safety context

Pesticide devices are also regulated by EPA, but they may or may not require registration.





## Examples of Chemicals and Devices

- **Chemical (antimicrobial pesticide products)**
  - Hypochlorites (calcium or sodium)
  - Chlorine gas
  - Peroxyacetic acid (PAA)
  - Sodium chlorite
  - Chlorine dioxide
  - Hydrogen peroxide
- **Pesticide device**
  - Filter units
  - Ultraviolet light units
  - Ozonator units

17

### Chemical (antimicrobial pesticide products)

Calcium hypochlorite (Accutab), sodium hypochlorite (Ultra Clorox Brand Regular Bleach), chlorine gas (Olin Chlorine), PAA with hydrogen peroxide (Sanidate, Tsunami), sodium chlorite (Selectrocide)



## EPA Regulation of Chemicals

- Required for chemicals (antimicrobial pesticide products)
  - Label should include EPA *registration* number and instructions for treating irrigation water
  - Some states may also have registration and environmental requirements
- There is no EPA-approved chemical treatment of production agricultural water for reducing microbiological indicators (like *E. coli*) or enteric pathogens; **however, scientific studies may exist that set limits for control of foodborne pathogens or indicators**
  - Chemicals should not exceed limits set for uses on the label (e.g., concentration, contact time, etc.)

18

See “PSA labeled sanitizers for produce” excel sheet from PSA.

<https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Sanitizer-Factsheet.pdf>

There are no EPA-approved chemical treatment of production agricultural water for food safety – there are labeled chemicals for water treatment for other agricultural uses.



## Current Status of EPA Antimicrobial Pesticide Products to Treat Microbial Quality of Production Agricultural Water

- Certain registered antimicrobial products are labelled for use in the treatment of irrigation water systems or irrigation ponds to control bacterial and algae growth
- Independent studies may be performed by academia or industry to demonstrate efficacy against foodborne pathogens and indicator organisms within the label

19

At this time, no EPA registrations exist for chemical substances (classified by EPA as “pesticide products”) for antimicrobial treatment of agricultural water used during the growing of crops (Ref. 128). However, as discussed in Chapter 4.2 of the EIS, EPA maintains a list of “Antimicrobial Products Registered with the EPA as Sterilizers.” Each of these products received approval under FIFRA as amended in 1996 ([40 CFR parts 152](#), 156, and 158). Like all registered pesticide products, registrations for antimicrobial products are specific to the use that was considered as part of the registration process, and thus the products may be legally used for the specified registered use only. Among compounds on the list of EPA's registered antimicrobial products as sterilizers are certain registered antimicrobial washes, which are authorized for use during postharvest fruit and vegetable washing. These products can be used to treat agricultural water that is used to wash produce postharvest, such as in packing houses. However, because these antimicrobial products are not authorized by EPA for use on agricultural fields, they cannot be used to treat irrigation water that is applied prior to harvest. Also on this list are certain registered antimicrobial products for use in the treatment of irrigation water systems or irrigation ponds to control bacterial and algae growth. However, because these antimicrobial products **are not authorized by EPA for use to control human pathogens or indicator organisms**, they cannot be used to treat irrigation water to

comply with the microbial quality criteria in § 112.44(b).

Reference 128. Environmental Protection Agency. Availability of Pesticides for Use in Produce Wash or Process Water to Control *E. coli*, January 2014." Washington, DC.



## Current Status of EPA Antimicrobial Pesticide Products to Treat Microbial Quality of Production Agricultural Water

- Other registered antimicrobial products are labeled as antimicrobial washes for use during postharvest fruit and vegetable washing
- Because these antimicrobial products **are not labeled by EPA for use on agricultural fields**, they cannot be used to treat irrigation water that is applied prior to harvest

20

At this time, no EPA registrations exist for chemical substances (classified by EPA as “pesticide products”) for antimicrobial treatment of agricultural water used during the growing of crops (Ref. 128). However, as discussed in Chapter 4.2 of the EIS, EPA maintains a list of “Antimicrobial Products Registered with the EPA as Sterilizers.” Each of these products received approval under FIFRA as amended in 1996 ([40 CFR parts 152, 156, and 158](#)). Like all registered pesticide products, registrations for antimicrobial products are specific to the use that was considered as part of the registration process, and thus the products may be legally used for the specified registered use only. Among compounds on the list of EPA's registered antimicrobial products as sterilizers are certain registered antimicrobial washes, which are authorized for use during postharvest fruit and vegetable washing. These products can be used to treat agricultural water that is used to wash produce postharvest, such as in packing houses. However, because these antimicrobial products are not authorized by EPA for use on agricultural fields, they cannot be used to treat irrigation water that is applied prior to harvest. Also on this list are certain registered antimicrobial products for use in the treatment of irrigation water systems or irrigation ponds to control bacterial and algae growth. However, because these

antimicrobial products **are not authorized by EPA for use to control human pathogens or indicator organisms**, they cannot be used to treat irrigation water to comply with the microbial quality criteria in § 112.44(b).

Reference 128. Environmental Protection Agency. Availability of Pesticides for Use in Produce Wash or Process Water to Control *E. coli*, January 2014." Washington, DC.



## Current Status of EPA Chemicals to Treat Microbial Quality of Production Agricultural Water

- FDA does not have specific information on the pesticides that might be submitted to EPA for registration for production agricultural water to control specific target organisms

21

FDA has analyzed the potential environmental impacts of the agricultural water standard in Chapter 4.2 of the EIS. As part of the analysis, FDA has determined that presently, there is no EPA-approved chemical treatment for contaminated water used to irrigate cropland (Ref. 128). FDA does not have specific information on the pesticides that might be submitted to EPA for registration for uses to control specific target organisms, such as pathogens, specifically in agricultural water applied to produce. However, as described in greater detail in Chapter 3.1 and 4.2 of the EIS, we agree that the most commonly used antimicrobials for microbial population reduction are chlorine chemicals, specifically sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. It is anticipated that chlorine compounds would be among the preferred chemicals for which industry would be likely to seek FIFRA registration. FDA has considered the potential impacts of this rule on the environment and worker health as part of the EIS (Ref. 126). With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use (see Comment 194).

Should a covered farm choose to treat their agricultural water to ensure it meets the applicable requirements for its intended use, we expect any treatment that is used

would be applied in accordance with all applicable federal, State, tribal, and local regulations.

Several comments discuss EPA's registration requirements related to pesticide use. Acknowledging our [FDAs] statement in the 2013 proposed rule that no EPA registrations currently exist under FIFRA for chemicals used in the treatment of irrigation water, comments express concern about the current lack of available EPA-approved antimicrobial treatments for irrigation water and the purported lack of an available EPA process by which such chemicals could be approved. Such comments state diverse concerns, including that: providing treatment of irrigation water as an alternative under the produce safety regulation may not be a viable option; the absence of available treatment methods may jeopardize the use of some agricultural water sources and could force some farms to stop irrigating crops and to suffer economic hardship; treating irrigation water without available registered options is illegal, in that the use of unapproved substances would violate both State and federal pesticide-use regulations; and, due to the lack of approved treatments, farms may treat water with unapproved methods that could lead to environmental and public health concerns. Another commenter recommends eliminating proposed § 112.43(a) because no approved treatment products for this use currently exist.

Similarly, another commenter recommends that the water treatment provisions should not be implemented until a registry of approved water disinfection agents exists.

Several comments also request that FDA work with EPA and other relevant agencies to provide clear direction to industry regarding acceptable and available water treatment options. One commenter believes that reliance on a process that is regulated by another government agency may create uncertainty for farms. This commenter recommends that FDA collaborate with EPA to: 1) Identify and make information available about currently-registered compounds and 2) establish a priority review process to ensure that farms have effective options available for the treatment of irrigation water prior to the compliance dates for the water requirements. One comment requests clarification on the approval that would be required to use an existing microbial pesticide to meet the requirement in § 112.43.

Other comments state that EPA-approved products for treating irrigation water are currently available. For example, one comment reports that the National Pesticide Information Retrieval System (NPIRS) database shows that nearly 90 federally-registered disinfectant products are available for uses in fruit or vegetable wash water or processing water, and that other products are labeled for use in treatment of agricultural and irrigation water systems, including drip irrigation systems. Another comment provides an example of a treatment, asserting that it is registered with EPA



for use in all types of irrigation water systems, including in USDA-inspected fruit and vegetable wash water operations.



## EPA Regulation of Pesticide Devices

- Devices do not require registration but devices are regulated in that “false or misleading claims” cannot be made about their effectiveness
  - Needs scientific data to support claims (manufacturer validation)
  - A manufacturer of a pesticide device that is regulated will have an EPA *establishment* number even though the device itself is not registered
- Pesticide devices must meet the EPA definition:
  - *An instrument or contrivance other than a firearm (or medical device) that is used to destroy, trap, repel, or mitigate (lessen the severity of) any pest such as insects, weeds, rodents, birds, mold/mildew, bacteria, and viruses*

22

Any device that relies more on the performance of the user to be effective than the device is not regulated (e.g., fly swatter, mouse trap)

All devices that could be used for water treatment are regulated - Filter units, ultraviolet light units, ozonation units

Pesticide Device Registration is state regulated, and varies state by state. Check with your state pesticide regulatory agency to determine if a particular pest control device is required to be registered with your state

[http://npic.orst.edu/reg/state\\_agencies.html](http://npic.orst.edu/reg/state_agencies.html)



## Summary

- Water treatment is an effective preventive strategy and risk reduction measure to reduce microbial contamination from water
  - Testing of treated water is not required under the PSR
- Treatment by an EPA regulated chemical or device can be used as a corrective measure for production agriculture water
  - There is no EPA-approved chemical treatment of production agricultural water for reducing microbiological indicators (like *E. coli*) or enteric pathogens
  - **However, scientific studies may exist that set limits for control of foodborne pathogens or indicators**
- Chemicals and devices must be used in accordance with the EPA



# Questions?

**UT EXTENSION**  
INSTITUTE OF AGRICULTURE  
THE UNIVERSITY OF TENNESSEE

WASHINGTON STATE  
UNIVERSITY  
EXTENSION

**NC STATE**  
EXTENSION



**SC**  
Southern Center  
for Training, Education, Extension, Outreach, and  
Technical Assistance to Enhance Produce Safety

**Virginia  
Cooperative  
Extension**  
Virginia Tech • Virginia State University

**UF** | IFAS Extension  
UNIVERSITY OF FLORIDA



This work was supported by Food Safety Outreach Program grant no. 2016-70020-25803 from the USDA National Institute of Food and Agriculture.



[UTIA.TENNESSEE.EDU](http://UTIA.TENNESSEE.EDU)

W 920-A 07/20 20-0126 Programs in agriculture and natural resources, 4-H youth development, family and consumer sciences, and resource development. University of Tennessee Institute of Agriculture, U.S. Department of Agriculture and county governments cooperating. UT Extension provides equal opportunities in programs and employment.