



The following two supplemental slides were developed to address recent FDA announcements on the FSMA Produce Safety Rule. These announcements include:

- *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E*
- *Equivalent Testing Methodologies for Agricultural Water*
- *FDA Considering Simplifying Agricultural Water Standards*

The first announcement is the final rule extending the water quality compliance dates, and the second is a FDA factsheet listing equivalent water testing methodologies. The third announcement states that FDA intends to simplify the microbial quality and testing requirements for agricultural water established by the FSMA Produce Safety Rule.

Many collaborators have asked PSA how to integrate the above announcements into the PSA Grower Training Curriculum. The PSA strongly recommends incorporating the following slides into the PSA Grower Training Curriculum. Additional details on the announcements and suggestions for delivering the supplemental information can be found in the slide notes.

**Release Notes:**

- Originally released 12/2017 with proposed compliance date extension and equivalent methods
- Updated 07/2018 to include FDA updates to equivalent methods (presence/absence)
- Updated 04/02/19 to include FDA final rule for compliance date extension
- Updated 06/21/2019 to match edits to Module 5.1, V1.2

## FDA Rule: Extension of Water Compliance Dates

Business Size	Compliance Dates For Most Requirements	Water Related Compliance Dates
All other businesses (>\$500K)	1/26/18	1/26/22
Small businesses (>\$250K-500K)	1/28/19	1/26/23
Very small businesses (>\$25K-250K)	1/27/20	1/26/24

- In the Final Rule issued March 2019, compliance dates for all agricultural water requirements (other than sprouts) allow for an additional 4 years
- For example, 'all other businesses' could wait until 2022 to begin sampling

**SUPPLEMENTAL MATERIAL**

**Note:** For use in Module 1, after the slide titled *Produce Safety Rule Compliance*.

Could also be duplicated as a reminder, in the beginning of Module 5.1, after the slide titled *Agricultural Water Quality*.

- On March 18, 2019, FDA published a Final Rule called *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E*.
  - 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.”
  - The compliance date extension includes ALL provisions of Subpart E (agricultural water other than sprouts) including the safe and sanitary quality requirement, the annual inspection requirement, and the postharvest water monitoring requirements.
  - Farms should continue to focus their attention on good agricultural practices to maintain and protect the quality of their water sources. See, for example, FDA’s GAPs Guide (the full name of which is “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”), which can be accessed on the FDA’s website. <https://www.fda.gov/regulatory-information/search-fda-guidance->

documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables

- FDA does not expect growers of covered produce (other than sprouts) to implement Subpart E, including sampling, until the new compliance dates come into effect.
- Many farms currently have water testing programs in place, and FDA encourages farms to continue testing their agricultural water in the manner the farm feels is appropriate. Any records related to voluntary water testing are not subject to the records requirements of the FSMA Produce Safety Rule.
- Farms continue to be covered by the general provisions of the Federal Food, Drug and Cosmetic Act, including the adulteration provision of Section 402(a)(4): A food is adulterated “if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” [21 U.S. Code § 342. Adulterated food.]
- Trainers and participants should be aware of this compliance date extension, and should present the compliance date extension as part of the training. Until FDA has completed the process of considering requirements of Subpart E, the materials in Modules 5.1 and 5.2 will reflect the requirements for agricultural water in the final FSMA Produce Safety Rule, published in 2015.

**Table reference:**

- Table adapted from the Southern Center for Training, Education, Extension, Outreach, and Technical Assistance to Enhance Food Safety. *Produce Safety Rule Compliance Dates and Timeline*. Available at <https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule-compliance-dates-timeline>

**Additional Resources:**

- FDA 2019. *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E*. Available at <https://www.govinfo.gov/content/pkg/FR-2019-03-18/pdf/2019-04652.pdf>

## 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*.

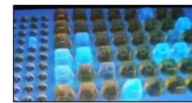
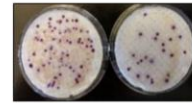
- Extends ALL provisions of Subpart E (Agricultural water) other than sprouts including the safe and sanitary quality, annual inspection, and postharvest water monitoring requirements.
- FDA has stated that the reason for this extension is to allow time “to address questions about the practical implementation 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 completed, the water requirements outlined in **Module 5: Agricultural Water** reflect the requirements for agricultural water in the final FSMA Produce Safety Rule.

**SUPPLEMENTAL MATERIAL**

**Note:** For use in the beginning of Module 5.1, after the slide titled *Module 5: Agricultural Water*.

## 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



SUPPLEMENTAL MATERIAL

**Note:** For use in the beginning of Module 5.1, after the slide titled *Microbial Water Quality Profile: Survey of Surface Water Sources*.

- 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>
  - 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.”*

## Sample Schedule for Compliance

*FDA is re-evaluating the requirements of Subpart E, including MWQP requirements, so required activities may change.*

For Farms Over \$500,000 Annual Produce Sales	Water Source Type	
Compliance Date January 26, 2022 All water requirements (other than sprouts)		
Production Water Sampling Schedule	Surface	Ground
Begin Sampling	2022 season	2022 season
Complete Initial MWQP	By end of 2025	By end of 2022
Use MWQP to Make Decisions	2026 season	2023 season

- **Small businesses (>\$250K – 500K)**
- Compliance and Sampling year = Table +1 year
- **Very small businesses (up to \$250K)**
- Compliance and Sampling year = Table +2 years

**SUPPLEMENTAL MATERIAL**

*This slide is optional.*

**Note:** For use as needed in Module 5.1, after the slide titled *Microbial Water Quality Profile: Survey of Surface Water Sources*.

- Activity schedule consistent with compliance dates, as described in Comment 6 of the final rule *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E*.
  - Published in the Federal Register 3/18/2019
  - MWQP requirements may change prior to the compliance date, which could change the requirements depicted in this table.
  - Remember that farms selling less than \$25K in produce (inflation adjusted) are exempt from the Produce Safety Rule and therefore they do not have to sample for compliance.
- The compliance date is January 26, 2022. The response to Comment 6 begins "Farms are not required to have completed a MWQP by their compliance date. A farm's compliance date means the date on which the farm must begin sampling a water source for its initial survey, which will eventually result in a MWQP" and goes on to say "compliance must begin by the first relevant time period that occurs after the



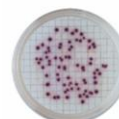
compliance date." The response to comment 6 also provides scenarios consistent with the above table of activities.

- FDA is re-evaluating the requirements of Subpart E, and requirements may change prior to the compliance dates.

## Equivalent Water Testing Methodologies

Equivalent quantitative methods to EPA Method 1603 (membrane filtration with modified mTEC). These methods can be used for both production 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)



**SUPPLEMENTAL MATERIAL**

**Note:** For use in Module 5.1, after slide titled *Where Do I Go For Testing*. This slide covers the methods listed in the original (2017) publication; the following slide covers the additional methods added in a 2018 revision to the fact sheet.

- The methods are described in the slide, and references are provided below.
- § 112.151 requires that the laboratory must test using (a) U.S. EPA Method 1603 (membrane filtration using modified mTEC) or (b)(1), a method that is at least equivalent to Method 1603 in accuracy, precision, and sensitivity or (b)(2) a scientifically valid method for an alternative indicator.
  - In September 2017, FDA released a fact sheet that recognized several equivalent methods for enumeration of generic *E. coli*.
  - In July 2018, FDA released an updated fact sheet that recognized several equivalent methods for detection (presence/absence) of generic *E. coli* in 100 mL sample that may be used when testing agricultural water used for certain purposes (e.g., during harvest or postharvest activities, handwashing, etc.). These methods are discussed in further detail on the next slide.
  - The current version (2018) of the FDA fact sheet states the following in reference to the methods on this slide: “FDA has determined that the following quantification methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), “Method 1603: *Escherichia coli* (*E. coli*) in

*Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC)” (December 2009), in accuracy, precision, and sensitivity in quantifying generic Escherichia coli in agricultural water when used in connection with the criteria described in § 112.44(a) or § 112.44(b).”*

- The list includes some, but not all, of the EPA-accepted methods for monitoring under the Clean Water Act (often, recreational water monitoring) that are listed in 40 CFR 136.3.
- Trainers should remind growers that storage conditions (including time and temperature) between sample collection and analysis can impact test results. Some methods specify a maximum time frame for getting these samples to the lab (e.g. 6 hours). It is also important to let growers know these samples should be cooled immediately after they are collected and kept cool until delivered to the lab.

**Image Note:** The image on the top is a membrane filtration test on modified mTEC with magenta colonies of *E. coli*; the image on the bottom is a Colilert or Colilert-18 most probable number test in Quantitray 2000 under ultraviolet light showing fluorescing wells that contain *E. coli*.

#### **Additional Resources:**

- FDA Fact Sheet. (2018). *Equivalent Testing Methodologies for Agricultural Water*. [www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm575251.htm](http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm575251.htm)
- Francy, DS and Darner, RA. (2000). Comparison of methods for determining *Escherichia coli* concentrations in recreational waters. *Water Research*, 34(10): 2770–2778.
- Stoeckel, D., Clements, D., Fisk, C., Wall, G., Woods, K., and Bihn, E. (2019). The Water Analysis Method Requirement in the FSMA Produce Safety Rule. Factsheet. <https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Water-Analysis.pdf>
- Pope, M. L., Bussen, M., Feige, M. A., Shadix, L., Gonder, S., Rodgers, C., Chambers, Y., Pulz, J., Miller, K., Connell, K., & Standridge, J. (2003). Assessment of the effects of holding time and temperature on *Escherichia coli* densities in surface water samples. *Appl Environ Micro*, 69(10), 6201–6207.

#### **References:**

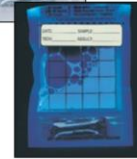
- EPA (2014). Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC). EPA-821-R-14-010. *U.S. Environmental Protection Agency, Washington, DC*.
- EPA (2010). Escherichia coli (E. coli) in Water by Membrane Filtration Using membrane-Thermotolerant Escherichia coli Agar (mTEC). EPA-821-R-10-002. *U.S. Environmental Protection Agency, Washington, DC*.
- APHA (2012). Natural Bathing Beaches (2007). In: Standard Methods for the Examination of Water and Wastewater, 22nd Edition (Rice E.W., et al., Ed.), 9-46 – 9-48. *American Public Health Association, Washington, DC*.
- ASTM (2000). Standard Test Method for Isolation and Enumeration of *Escherichia coli* in Water by the Two-Step Membrane Filter Procedure. In: *Annual Book of ASTM Standards*, Volume 11.02. ASTM International. (1996, 1999, 2000).

- Hach Company. Method 10029: Coliforms, Total and *E. coli*: m-ColiBlue24 Broth PourRite Ampules. Doc316.53.01213. *Hach Company*.
- APHA (1997). Standard Total Coliform Membrane Filter Procedure (1997), followed by 9222 G – MF Partition Procedures (1997) using NA-MUG media. In: Standard Methods for the Examination of Water and Wastewater, 21st Edition (Eaton A.D., et al., Ed.), 9-60 – 9-65, and 9-70 – 9-71, respectively. *American Public Health Association, Washington, DC*. (2005).
- EPA (2002). Method 1604: Total Coliforms and Escherichia coli in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium). EPA-821-R-02-024. *U.S. Environmental Protection Agency, Washington, DC*.
- IDEXX, Inc. *Colilert* .[www.idexx.com/water/products/colilert.html](http://www.idexx.com/water/products/colilert.html)
- IDEXX, Inc. *Colilert-18*. [www.idexx.com/water/products/colilert-18.html](http://www.idexx.com/water/products/colilert-18.html)

## 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



SUPPLEMENTAL MATERIAL

**Note:** For use in Module 5.1, after slide titled *Where Do I Go For Testing*. This slide includes additional (presence/absence) methods that were added by FDA in a 2018 revision to the equivalent methods fact sheet. This slide can also be presented in Module 5.2 as a review, after the slide titled 'Water Quality Criterion for Harvest and Postharvest Activities.'

- In July 2018, FDA released an updated fact sheet that recognized several equivalent methods for detection (presence/absence) of generic *E. coli* in 100 ml sample.
- The fact sheet states the following in reference to the methods on this slide: “*With regard to criteria described only in § 112.44(a), FDA has determined that the following presence/absence methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), “Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC)” (December 2009), in accuracy, precision, and sensitivity in detecting generic Escherichia coli in agricultural water.*”
- The presence/absence testing methods listed here can be used to determine whether the water quality is appropriate for the uses specified in § 112.44(a)(1) to (4) including water used during harvest or postharvest activities.
  - For farms that are testing their wells with results of no detectable generic *E. coli*, this water would meet the quality requirements for production water.
  - Using this approach growers would be unable to calculate a GM and STV as

outlined in the current FSMA Produce Safety Rule.

- Trainers should remind growers that storage conditions (including time and temperature) between sample collection and analysis can impact test results. Some methods specify a maximum time frame for getting these samples to the lab (e.g. 30 hours). It is also important to let them know these samples should be cooled immediately after they are collected and kept cool until delivered to the lab. If growers are curious why they have more time to deliver these samples it is because standards that were developed for drinking water tests, using presence/absence methods, allow 30 hours.
- Specific references for the methodologies listed in the slide are not provided in the FDA Fact Sheet. References below refer to methods that are EPA-approved or otherwise appear to be the same as the FDA-listed equivalent methods.

**Image Note:** Left, Colilert or Colilert-18 test (IDEXX); Right, E\*Colite Bag test (Charm Sciences). Note that *E. coli* positive is indicated by fluorescence under ultraviolet in both cases, not visible blue color. Total coliform is indicated by yellow color (Colilert) or visible blue-green color (E\*Colite).

#### **Additional Resources:**

- FDA Fact Sheet. (2018). *Equivalent Testing Methodologies for Agricultural Water*. [www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm575251.htm](http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm575251.htm)
- Stoeckel, D., Clements, D., Fisk, C., Wall, G., Woods, K., and Bihn, E. (2019). The Water Analysis Method Requirement in the FSMA Produce Safety Rule. Factsheet. <https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Water-Analysis.pdf>

#### **References:**

- EPA (2014). Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC). EPA-821-R-14-010. U.S. Environmental Protection Agency, Washington, DC.
- EPA (2019). Analytical Methods Approved for Compliance Monitoring under the Ground Water Rule. EPA-815-B-19-006. U.S. Environmental Protection Agency, Washington, DC. [www.epa.gov/sites/production/files/2017-02/documents/gwr\\_approved\\_methods.pdf](http://www.epa.gov/sites/production/files/2017-02/documents/gwr_approved_methods.pdf)
- Code of Federal Regulations 2018 Alternative Testing Methods for Contaminants Listed at 40 CFR 141.21(f)(6) (*E. coli*).
  - Modified Colitag Reference 13: Modified Colitag™ Method, “Modified Colitag™ Test Method for the Simultaneous Detection of *E. coli* and other Total Coliforms in Water (ATP D05-0035),” August 28, 2009. Available at <http://www.nemi.gov> or from CPI, International, 580 Skylane Boulevard, Santa Rosa, CA 95403
- Code of Federal Regulations 2018 Alternative Testing Methods for Contaminants Listed at 40 CFR 141.402(c)(2) (*E. coli*)
  - Readycult reference 20: Readycult® Method, “Readycult® Coliforms 100 Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichia coli* in Finished Waters,” January, 2007. Version 1.1. Available from

EMD Millipore (division of Merck KGaA, Darmstadt, Germany), 290 Concord Road, Billerica, MA 01821

- Colilert, Colisure, Colilert-18 referenced as Standard Methods 9223 B
- Tecta EC/TC Reference 33: Tecta EC/TC. “Tecta™EC/TC Medium and Tecta™Instrument: A Presence/Absence Method for the Simultaneous Detection of Total Coliforms and *Escherichia coli* (*E. coli*) in Drinking Water,” version 1.0, May 2014. Available from Pathogen Detection Systems, Inc., 382 King Street East, Kingston, Ontario, Canada, K7K 2Y2
- Tecta EC/TC Reference 43: Tecta EC/TC. “Tecta™ EC/TC Medium and the Tecta™ Instrument: A Presence/Absence Method for the Simultaneous Detection of Total Coliforms and *Escherichia coli* (*E. coli*) in Drinking Water,” version 2.0, February 2017. Available from Pathogen Detection Systems, Inc., 382 King Street East, Kingston, Ontario, Canada, K7K 2Y2
- Charm Sciences documentation
  - *E\*Colite Vial Test for Total Coliforms and E. coli in Potable Water*: [resources.charm.com/file/120](http://resources.charm.com/file/120)
  - *E\*Colite: Test for Total Coliforms and E. coli in Potable Water*: [resources.charm.com/file/89](http://resources.charm.com/file/89)

#### **Product Manufacturer Sites:**

1. TECTA™ EC/TC medium and the TECTA™ Instrument: A Presence/Absence Method for the Simultaneous Detection of Total Coliforms and *Escherichia coli* (*E. coli*) in Drinking Water. (2014). Veolia Water Technologies <http://technomaps.veoliawatertechnologies.com/tecta/en/>
2. Modified Colitag™ Test Method for the Simultaneous Detection of *E. coli* and other Total Coliforms in Water. ATP D05-0035. (2009). <http://www.colitag.com/>
3. IDEXX Colilert Test Kit <https://www.idexx.com/en/water/water-products-services/colilert/>
4. IDEXX Colilert-18 Test Kit <https://www.idexx.com/en/water/water-products-services/colilert-18/>
5. IDEXX Colisure Test Kit <https://www.idexx.com/en/water/water-products-services/colisure/>
6. E\*Colite Bag or Vial Test for Total Coliforms and *E. coli* in Potable Water. Charm Sciences, Inc. <https://www.charm.com/products/test-and-kits/microbial-detection-tests/ecolite-test/>
7. 101298 ReadyCult Coliforms 100. EMD Millipore (division of Merck KGaA, Darmstadt, Germany). [https://www.emdmillipore.com/US/en/product/Coliforms-100,MDA\\_CHEM-101298?CatalogCategoryID=](https://www.emdmillipore.com/US/en/product/Coliforms-100,MDA_CHEM-101298?CatalogCategoryID=)