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

In September 2017, FDA published a Proposed Rule called *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E.*

- If implemented, this Rule would modify the implementation of certain aspects of the agricultural water requirements
- The new compliance dates would include ALL provisions of Subpart E (Agricultural water) including the safe and sanitary quality requirement, the annual inspection requirement, and the postharvest water monitoring requirements
- The reason given for this extension is to “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 achieve our regulatory objectives, in keeping with the Administration's policies.**”

Trainers and participants should be aware of this proposed rule and the intent to reduce the regulatory burden and increase flexibility within the agricultural water requirements of the FSMA Produce Safety Rule. Until this and other processes are
complete, the materials in Modules 5.1 and 5.2 are current and applicable.

**Table reference:**

**Additional Resources:**
FDA Water Compliance Date Extension

In September 2017, FDA published a Proposed Rule called Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E.

- If implemented, extends ALL provisions of Subpart E (Agricultural water) including the safe and sanitary quality requirement, the annual inspection requirement, and the postharvest water monitoring requirements.
- The reason given for this extension is “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 achieve our regulatory objectives, in keeping with the Administration’s policies.”
- Until more is known, the following water requirements outlined in this module are the Rule.

Note: For use in the beginning of Module 5.1, after the slide titled Agricultural Water Quality.
Note: For use in the beginning of Module 5.1, after the supplemental slide titled FDA Water Compliance Date Extension.

- It is very important for trainers to tell growers that nothing on this slide is required by the FSMA Produce Safety Rule.
- It is very likely that growers will ask what they should do in the meantime.
- Most importantly, growers should be encouraged to maintain market access by meeting buyer and audit requirements, many of which require water testing.
- Growers may also want to inspect their water source and assess risks that could impact its quality by surveying the land around the water source. This could include assessing activities that may be happening upstream that could impact quality (e.g., animal operations that allow animals access to the water source such as grazing cattle).
- To better understand the quality of the water source, growers may want to begin testing just a few times per year if they have never tested their water in the past.
FDA Fact Sheet: Equivalent Water Testing Methodologies

Equivalent methods to EPA Method 1603 (membrane filtration with modified mTEC), include:

- Membrane filtration methods (colony forming units, or CFU)
  - mTEC agar (EPA 2010, APHA 2012, ASTM 2000)
  - mColiBlue ampules (Hach method 10029)
  - mEndo followed by NA-MUG agar (APHA 1997)
  - M1 agar (EPA 2012)
- Most Probable Number (MPN) methods
  - Colilert (using Quantitray 2000 tray)
  - Colilert 18 (using Quantitray 2000 tray)

**Note:** For use in Module 5.1, after slide titled *Where Do I Go For Testing.*

In September 2017, FDA released a fact sheet that recognized several equivalent methods for enumeration of generic *E. coli*.

- The fact sheet states: *FDA has determined that the following methods are “scientifically valid” and “at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity”.*
- The methods are described in the slide, and references are provided below
- 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
- The image on the top is a membrane filtration test on modified mTEC; the image on the bottom is a Colilert or Colilert-18 most-probable number test on Quantitray 2000

**Additional Resources:**

- FDA Fact Sheet 2017. *Equivalent Testing Methodologies for Agricultural Water.* Available at www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm575251.htm
- EPA 2006. *Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration*
Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC).
U.S. Environmental Protection Agency. EPA-821-R-06-011

- Hach Company. Coliforms, Total and *E. coli*: m-ColiBlue24 Broth PourRite Ampules. Doc316.53.01213, Method 10029, Hach Company