



**Produce Safety ALLIANCE**

## Recent FDA Announcements – Agricultural Water

**SUPPLEMENTAL MATERIAL**

Version: 06/21/2019

### 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

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### 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.

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### 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

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### 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

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### 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)

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## 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



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