

The Water Analysis Method Requirement in the FSMA Produce Safety Rule

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The topic of water testing, including the sampling schedule and method used to enumerate *E. coli*, comes up at nearly every Produce Safety Alliance (PSA) Grower Training Course and Train-the-Trainer Course. The Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) requires some produce growers to monitor the quality of their agricultural water by analysis of generic *E. coli* using EPA Method 1603 or another “scientifically valid method that is at least equivalent ... in accuracy, precision, and sensitivity” (quoted from 21 CFR §112.151).

The PSR also requires that agricultural water used during growing activities be sampled according to a particular schedule so that a microbial water quality profile (MWQP) can be created. The MWQP is a collection of up to 4 years of water quality results, with frequency of testing determined based on the water source. The ground water requirement is 4 or more samples and the surface water requirement is 20 or more samples.

This article includes information to support agricultural water quality monitoring as outlined in the PSR. It is important to know that this information is based on the preamble and codified text of the PSR as well as FDA announcements and other observations from the scientific literature. Future guidance from FDA on the topic may lead to different or better understanding, but at this time the following bullets summarize the information that the PSA team thinks may be valuable to produce growers.

Compliance Dates for Monitoring Under the FSMA Produce Safety Rule

On March 18, 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*. The new rule extends the compliance dates for all provisions in Subpart E (Agricultural Water, other than sprouts) to allow FDA and stakeholders time to address questions about implementation, including how to reduce the regulatory burden and increase flexibility while protecting public health. FDA plans to consider additional changes to agricultural water requirements.

The new rule extends the compliance dates for all provisions dealing with agricultural water, other than sprouts, to 2022 to 2024 for farms of different sizes.

- Farms with over \$500,000 in annual produce sales will need to begin sampling in 2022.
- Farms with \$250-500K need to begin sampling in 2023.
- Farms with <\$250K need to start sampling in 2024.

The PSA collaborated with the FSMA Southern Regional Center to create an easy-to-use [compliance dates table](#) for different parts of the PSR.

The Microbial Water Quality Profile

Two important announcements came from FDA in March 2017 ([FDA Considering Simplifying Agricultural Water Standards](#)) and September 2017 ([Dr. Gottlieb's Speech to the 2017 NASDA Annual Meeting](#)). Based on the September speech, a FDA [Constituent Update](#) stated the FDA has “plans to engage with stakeholders to learn more from farmers, state regulatory partners and other stakeholders about the diverse ways water is used and ensure that the standards will be as practical and effective as possible for all farming operations.” Growers should not make significant changes to their current water testing practices, as far as compliance with the PSR goes, until more is known about potential changes to regulatory requirements.

Understanding Water Quality Now

Knowing the quality of water used to grow fresh produce is important even before PSR water quality compliance dates come into effect. The only action recommended right now is for growers to test their water quality and to know what method the laboratory uses to measure generic *E. coli*. Growers should focus on understanding the quality of water they use during production of fresh produce. If growers are testing their water to satisfy buyer requirements or to support on-farm water management decision making they should continue. Growers who have never tested their well water or surface water should begin testing their water for quantified generic *E. coli*, especially if the water directly contacts the fresh produce they grow. Again, sampling is not required by the PSR until after the compliance dates but growers should know something about the quality of the water they are using during fresh fruit and vegetable production.

The only way to know *E. coli* levels in water is to test the water. Ideally, growers will be able to have their analysis done using a method that FDA considers equivalent to EPA Method 1603, discussed next.

Methods Information

Although only EPA Method 1603 (i.e., modified mTEC) is directly named in the FSMA PSR, in September 2017 the FDA released a fact sheet called *Equivalent Testing Methodologies for Agricultural Water*. This list of methods included several quantitative options that can be used for any agricultural water. [Updates released in July 2018](#) included presence-absence methods that can be used to test agricultural water that is used during harvest and postharvest.

It is important for growers to know that different water analysis methods are appropriate for different uses of agricultural water. If testing agricultural water used during production, prior to harvest, a quantitative method must be used so calculations like the Microbial Water Quality Profile (MWQP) can be completed. If testing water used at harvest or during postharvest handling, either a presence/absence test or a quantitative test can be used. Presence/absence tests are usually more cost effective. Growers need to be very specific about the tests they request because the lab may not be aware of the FDA’s equivalent methods list. The table in this factsheet can be shared to help ensure an acceptable method is being used.

Growers should also be aware that there is a maximum hold time, from collection of a sample to delivery to the lab. These hold time recommendations are based on Standard Method 9060B since specific guidance on hold times was not provided in the fact sheet by FDA. The specific hold times depend on the type of water that is being analyzed. In most cases, the maximum hold time for a chilled sample, when using a quantitative method on a non-potable water source (e.g., getting a CFU or MPN number per 100 mL of water taken from an irrigation pond), is six hours. Now FDA is allowing presence/absence methods for agricultural water that is used at or after harvest (e.g., getting a positive or negative result for 100 mL of water from a protected well). Samples for presence/absence tests have a maximum hold time of 30 hours (chilled) after sample collection since they are being tested with the same types of methods used for drinking water.

In summary, the issue of testing agricultural water for generic *E. coli* has been a frequent topic of conversation among produce growers, PSA Trainers, extension personnel, produce industry members and others involved in trying to understand the requirements of the FSMA Produce Safety Rule. This article is intended to clarify what is known about acceptable water sampling schedules and analysis methods currently outlined in the PSR. It also includes Good Agricultural Practices (GAPs) recommendations for growers to help them decide how best to manage their water testing prior to the PSR compliance dates.

Production or Postharvest Water

Membrane filtration methods (quantitative, CFU/100 mL)	
Cited method in FDA Fact Sheet	Shorthand method name
EPA Method 1603	Modified mTEC agar
EPA Method 1103.1, Standard Methods 9213 D, ASTM method D5392-93	mTEC agar
EPA Method 1604	MI agar
Standard Methods 9222 B followed by 9222 G	m-Endo followed by NA-MUG agar
Hach method 10029	m-ColiBlue 24 ampules
Most probable number methods (quantitative, MPN/100 mL)	
Product/medium named in FDA Fact Sheet	Method notes
IDEXX Colilert test kit, only if using Quanti-Tray/2000	There are several formats for Colilert, be sure the lab uses the FDA-named quantitative format. One reference protocol for this product is Standard Methods 9223B.
IDEXX Colilert-18 test kit, only if using Quanti-Tray/2000	

Postharvest Water Only

Presence/absence methods (in 100 mL)	
Product/medium named in FDA Fact Sheet	Manufacturer/source
TECTA™ EC/TC medium and instrument	Veolia Water Technologies
Modified Colitag, ATP D05-0035	CPI International
IDEXX Colilert test kit	IDEXX Laboratories, Inc.
IDEXX Colilert-18 test kit	IDEXX Laboratories, Inc.
IDEXX Colisure test kit	IDEXX Laboratories, Inc.
E*Colite Bag or Vial test	Charm Sciences
ReadyCult Coliforms 100	EMD Millipore, catalog 101298

If there are questions or additional facts that could impact the content of this fact sheet, please [contact any member of the PSA team](#).