Produce Safety ALLIANCE

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**: When it comes to water sampling compliance dates, the published Rule says that no farm is required to begin its agricultural water testing using the MWQP schedule and required methods until, at the earliest, January 26, 2018. Small and very-small businesses (as defined by FDA) would have until 2019 and 2020, respectively. In September 2017, FDA published a new proposed rule called *Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E* that would extend the compliance dates for all provisions dealing with agricultural water to 2022-2024 for farms of different sizes. 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**: The US Environmental Protection Agency (EPA) has required water quality monitoring under the Clean Water Act and other laws for many years. Although only EPA Method 1603 (i.e., modified mTEC) is directly named in the FSMA PSR, in September 2017, FDA released a fact sheet called *Equivalent Testing Methodologies for Agricultural Water*. These include membrane filtration methods and most probable number methods. It is important for growers to know that EPA allows many different water analysis methods. Only some of the EPA-approved water testing methods have been included on the FDA list of methods that are equivalent to EPA Method 1603. When selecting a laboratory, growers should try to select one that offers analysis by a method from the FDA-approved list. Growers should also be aware that there is a maximum hold time from collection of a sample to delivery to the lab outlined in the method. In most cases, the maximum hold time is six hours for a chilled sample. The exception is Colilert and Colilert-18, where a maximum hold time is not written into the IDEXX test kit instructions. The six-hour maximum hold time is generally accepted as a standard.

Membrane filtration methods (colony forming units; CFU/100 mL)	
Published method name	**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 9222B and 9222G	m-Endo then NA-MUG agar
Hach Method 10029	m-ColiBlue 24 ampules
Most probable number methods (MPN/100 mL)	
Published method name	**Shorthand method name**
IDEXX Colilert test kits, only if using Quantitray 2000	There are several Colilert method options, be sure that the lab provides one of the approved methods
IDEXX Colilert-18 test kits, only if using Quantitray 2000	

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.

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