

The Water Analysis Method Requirement in the FSMA Produce Safety Rule

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The topic of water testing, including the 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). EPA Method 1603, which involves membrane filtration and incubation on modified mTEC agar, includes a requirement that the sample be delivered to the laboratory (chilled) within 6 hours of collection so that it can be analyzed within 8 hours of collection. Many PSA trainers and produce growers have looked for laboratories that offer analysis using EPA Method 1603 and have found that access to a laboratory offering water analysis by this method is limited or non-existent in their state or region.

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 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, no farm is required to start sampling agricultural water using the PSR framework and methods until January 26, 2018. Small and very-small businesses (as defined by FDA) are required to begin sampling in 2019 and 2020, respectively. FDA published a document to clarify compliance timeframes for certain water-related provisions of the PSR in August 2016, which is linked [here](#). In part, the FDA clarification says that growers must begin sampling agricultural water to create a microbial water quality profile (if applicable) at their initial PSR compliance date and that they may take two to four years to complete the initial microbial water quality profile, containing at least 20 water samples, for untreated surface water. The PSA collaborated with the FSMA Southern Regional Center to create an easy-to-use compliance dates table for different parts of the PSR, which is linked [here](#).
- **Methods Information:** The US Environmental Protection Agency has required water quality monitoring under the Clean Water Act and other laws for many years. EPA-approved methods give useful information about generic *E. coli* concentration. These¹ include membrane filtration methods (mTEC, modified mTEC (which is EPA Method 1603), mColiBlue, mFC followed by EC-MUG, MI agar) and most probable number (MPN) methods (Colilert, LB followed by EC-MUG). Many labs offer

¹The full list of EPA-approved methods is published in 40 CFR §136.3, linked [here](#). Go to Table IH -- List of Approved Microbiological Methods for Ambient Water and see entry 5. *E. coli*, number per 100 mL, to learn more about these methods.

analysis for generic *E. coli* by at least one of these methods. It is important to remember that, although these methods are approved by EPA for use in monitoring water for EPA-administered rules, they are not explicitly accepted for use in monitoring agricultural water for the FDA-administered PSR.

- **Equivalence in sensitivity, accuracy, and precision:** To date, FDA responses to questions about method equivalence, through the FDA's Technical Assistance Network, say that information about other equivalent methods will be included in upcoming guidance. The preamble to the PSR says that farms are not required to notify or submit information about methods used for water analysis for FDA's review or approval (page 74508 of the PSR, response to Comment 386). However, some produce growers express concerns about using water analysis methods other than EPA Method 1603 without knowing if the results will be accepted during a (future) FSMA-related regulatory inspection. Some manufacturers and laboratories have stated that the methods they use are acceptable for water testing requirements as outlined in the PSR. As of February 2017, PSA personnel are not aware of any peer-reviewed publications that include the data that compare these methods, to evaluate if they are equivalent in accuracy, precision, and sensitivity. It is also important to know that on February 1, 2017 in regard to current water requirements outlined in the PSR, FDA Commissioner Stephen Ostroff said "We've decided to look at how we can, going forward, work to simplify these standards." With no additional information, it is not possible to know what changes to the PSR may be made by the FDA or what methods will be acceptable, but it is an indication that growers should not be making significant changes to their current water testing practices until more is known.

- **Understanding Water Quality Now:** Knowing the quality of water used to grow fresh produce is important even before PSR compliance dates come into effect. Growers should not stop testing their water because of questions about what method is outlined in the PSR, especially if testing is required as part of a third party audit the growers may need to satisfy buyer requirements. The only action recommended right now is for growers to know what method the laboratory uses to measure generic *E. coli*. Since water quality samples collected in 2017 do not need to be in compliance with the PSR requirements, analysis by any scientifically valid method is still useful. Growers who have never tested the well water or surface water that directly contacts the fresh produce they grow should begin testing their water for quantified generic *E. coli*. 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. Again, as long as the method tells the growers how much *E. coli* is in the water, the method gives useful information.

In summary, the issue of acceptable *E. coli* analysis methods for agricultural water 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 testing 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 Don Stoeckel of the PSA team. His contact information as well as other PSA team members can be found [here](#).