

## FSMA Produce Safety Rule: Documentation Requirements for Water Laboratory Analysis Results

*Don Stoeckel, Laura Acuña-Maldonado, Davis Blasini, Collins Buggingo, Donna Clements, Laurie George, Thais Ramos, Thomas Saunders, Rob Way, Elizabeth A. Bihn*  
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The Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR)<sup>1</sup> includes requirements for water quality intended to reduce the number of foodborne illness outbreaks associated with fruits and vegetables. The requirements are qualitative (i.e., § 112.41 requires that all agricultural water must be “safe and of adequate sanitary quality for its intended use”) and quantitative, requiring laboratory analysis (e.g., § 112.44(a)(2-4) require that agricultural water that directly contacts covered produce during or after harvest or food-contact surfaces, or is used for hand washing, must have “no detectable generic *Escherichia coli* (*E. coli*)” in 100 mL). The results of all analytical tests done on agricultural water for compliance with the FSMA PSR must be documented and kept in the farm record (§ 112.50(b)(2)).

Information provided in this fact sheet is focused on documentation and testing requirements in the FSMA PSR for agricultural water used in covered activities during and after harvest. Although these requirements are not expected to change with the upcoming [revised Produce Safety Rule requirements in subpart E](#)<sup>2</sup>, provision numbers or specific language may change.

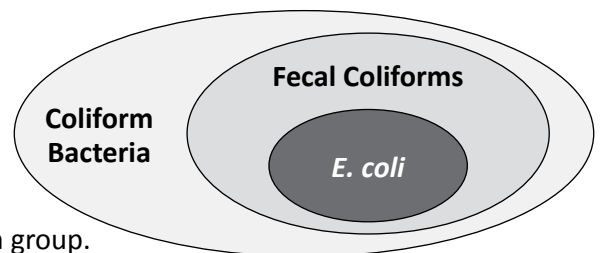
Specific testing requirements for production/pre-harvest water are not addressed in this fact sheet because they are not yet finalized in the FSMA PSR. Currently, FDA advises<sup>2</sup> that farms continue to follow [Good Agricultural Practices](#)<sup>3</sup>, including testing for generic *E. coli*, so we have included information about testing non-potable water such as surface water sources.

### What is required of growers and packers submitting water samples to laboratories for analysis?

The covered farm operator is responsible for knowing that the sample is collected, delivered, and analyzed according to PSR requirements and laboratory specifications. A typical [Standard Operating Procedure](#) for sample collection and delivery is available from the National Good Agricultural Practices Program<sup>4</sup>. Many water microbiology analysis methods, including US Environmental Protection Agency (EPA) Method 1603, incorporate requirements in *Standard Methods for the Examination of Water and Wastewater* sections 9060 A (Sampling) and 9060 B (Preservation and Storage)<sup>5</sup>. Several important general requirements are listed on the next page.

#### Expert Tip: How are the fecal indicator bacteria related?

- Coliform bacteria are found in the environment, soil, and intestines of warm-blooded animals.
- Fecal coliforms are a type of coliform and are more likely to be associated with human or animal feces.
- *E. coli* is one species of bacteria that is part of the fecal coliform group.
- Generic *E. coli* is considered to be the most useful test to indicate when water carries fecal contamination from humans or warm-blooded animals. Fecal coliform testing is sometimes used in other settings (such as recreational water, used for swimming). Coliform testing is used for drinking water wells because there should be no coliform bacteria in a drinking water source.



## General requirements for submitting water samples for laboratory analysis

- Documentation begins with sample collection.
- Always collect with a sterile bottle (often provided by the laboratory).
- The sample for analysis must be at least 100 mL volume. Leave air space (fill to shoulder).
- The sample must be held on wet ice, or otherwise maintained at a temperature less than 10 °C (50 °F) but not frozen.
- The sample must be delivered to the laboratory within a specified hold time:
  - When testing drinking water for compliance purposes (e.g., agricultural water that requires a “present/absent” test), sample hold time of no more than 30 hours from sample collection to analysis. Please note, the FSMA PSR does not require water used during harvest and postharvest activities to be potable, but it must have no detectable generic *E. coli* in 100 mL sample.
  - When testing non-potable water (e.g., agricultural water that requires a quantified test result) for compliance purposes, no more than 6 hours from sample collection to the laboratory and no more than 8 hours from sample collection to analysis. Please note, for compliance with the FSMA PSR untreated surface water cannot be used as agricultural water for harvest or postharvest activities.

Sample collection information is generally requested on the sample submission sheet provided with a sampling kit by the laboratory, which should be filled out by the customer and delivered to the laboratory with the sample. As shown in the [Model Documentation of Results](#) on the next page of this fact sheet, some of the information provided as part of sample submission enables the laboratory to create a laboratory results document that meets PSR requirements.

- Farm name and location. These are required for all PSR required records.
- The sample date and time. This information is critical to verify the hold time requirement was met. The laboratory personnel will add the date and time when analysis was started as well as the date and time the results were read.

- Information about the water source (e.g., ground water, surface water), the organism to be analyzed (e.g., generic *E. coli*), and the type of analysis (i.e., present/absent, quantified).
- The analysis method requested (e.g., Colilert using Quantitray 2000). Some laboratories offer multiple options for analysis method, and not all have been accepted by FDA for FSMA PSR. The FDA Fact Sheet about [equivalent methods](#)<sup>6</sup> outlines acceptable analysis methods.
- Water source ID. The farm has to be able to identify the source for the water that the laboratory is analyzing.

## What documentation should laboratories supply to satisfy FSMA PSR recordkeeping requirements?

Some laboratory reports may not include all of the specific information that a farm operation needs. However the laboratory results document provided to the farm will often contain many of the elements needed for farm records to comply with FSMA PSR requirements.

The *Model Documentation of Results* included in this fact sheet includes information that is typically provided as part of the laboratory results document. Elements in red on the *Model Documentation of Results* are required by the FSMA PSR for agricultural water. Farm personnel may want to check their water test results and records to make sure all elements required for compliance are included.

If any of the required elements is not part of the laboratory results document, the farm’s record reviewer could ask the lab to re-issue the record and include the element, or the farm’s reviewer could write in the necessary information with initial and signature to indicate that the original record was altered. As part of the review, the farm’s record reviewer must sign and date the record and keep it along with other required records for the farm. Provision § 112.161(b) requires that a supervisor or responsible party must review the laboratory results document within a reasonable time.

Required records about water quality analysis, along with other elements that are necessary for all records required by the PSR in Subpart O, are color-coded red in the model record below. These requirements are labeled with associated PSR provision numbers in boxes for reference.

Other elements that often appear in a laboratory report are written in black font.

<h2>Model Laboratory Name</h2>	
<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">Laboratory Address Telephone contact information Internet contact information Laboratory certification or accreditation<sup>A</sup></div> <div style="border: 1px solid black; padding: 5px;">Client: Farm name Farm location Customer name Customer ID</div>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"><b>Sample Information:</b><ul style="list-style-type: none"><li>■ Date received (<i>by lab</i>)</li><li>■ ID assigned at intake (<i>by lab</i>)</li><li>■ Sample date and time (<i>by customer</i>)</li><li>■ Analysis start date and time (<i>by lab</i>)</li><li>■ Results read date and time (<i>by lab</i>)</li><li>■ Report date (<i>by lab</i>)</li></ul></div>
<div style="border: 1px solid black; padding: 2px 10px;">§ 112.161(a)(1)(i)</div>	<div style="border: 1px solid black; padding: 2px 10px;">§ 112.161(a)(1)(v)</div>
<hr/> <h2>Analysis Information</h2> <hr/>	
<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"><b>Sampled by:</b> Name from submission sheet</div> <div style="border: 1px solid black; padding: 5px;"><b>Sample:</b> Lab ID: (<i>From laboratory</i>) Water source ID: (<i>From customer</i>) Parameter: Generic <i>Escherichia coli</i> (<i>E. coli</i>)<sup>B</sup> Analysis Method: Method used by lab<sup>C</sup></div>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"><b>Matrix:</b> Water type (<i>ground, surface</i>)</div> <div style="border: 1px solid black; padding: 5px;"><b>Results:</b> Dilution: (<i>if any</i>) Result: Analytical result Calculated result: (<i>if any dilution</i>) Units: CFU/100 mL or MPN/100 mL</div>
<div style="border: 1px solid black; padding: 2px 10px;">§ 112.44<sup>B</sup>, § 112.50(b)(9)<sup>C</sup>, § 112.151<sup>C</sup></div>	<div style="border: 1px solid black; padding: 2px 10px;">§ 112.50(b)(2), § 112.161(a)(1)(ii)</div>
<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"><b>Reviewed for farm record:</b> Supervisor signature<sup>D</sup></div> <div style="border: 1px solid black; padding: 5px;"><b>Date:</b> Date</div>	
<div style="border: 1px solid black; padding: 2px 10px;">§ 112.161(b)</div>	

Lettered notes appear on next page

<sup>A</sup> The FSMA PSR does not require that analysis be done by a certified or accredited laboratory, though many farms may decide they want to use a certified or accredited laboratory.

<sup>B</sup> The laboratory report might include multiple test results, such as total coliforms and generic *E. coli*. At a minimum, the report must include generic *E. coli* where required by the FSMA PSR. A negative (e.g., no detect, absent, <1 in 100 mL) result for total coliform analysis indicates no detectable generic *E. coli* since *E. coli* is one type of coliform. Note that analysis for *E. coli* O157:H7 or other pathogenic types of *E. coli* is not the same as analysis for generic *E. coli*.

<sup>C</sup> The PSA sheet [The Water Analysis Method Requirement in the FSMA Produce Safety Rule](#)<sup>7</sup> includes common ways methods on the FDA list of equivalent testing methodologies<sup>6</sup> are referenced by laboratories (tables reproduced below).

## 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

<sup>D</sup> Supervisor (or responsible party) signature is required, and should be added by the farm after receipt and review of the record from the laboratory.

## References

1. U.S. Food and Drug Administration 2015. [\*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption\*](#). (Final Rule). Federal Register November 27, 2015. 80(228):747354-74568. Accessed March 2023.
2. U.S. Food and Drug Administration 2021. [\*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water\*](#). (Proposed Revisions to Subpart E). Federal Register December 06, 2021 86(231): 69120-69155. Accessed March 2023.
3. E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, S.K. Amundson, and M.C. Humiston. 2021. [\*Decision Trees: Farm Food Safety\*](#). National Good Agricultural Practices Program, Cornell University. Accessed March 2023.
4. L.E. Acuña-Maldonado, E.A. Bihn, D.P. Clements, C.L. Fisk, T.P. Saunders, D.M. Stoeckel, G.L. Wall, and K. Woods 2020. [\*Water Sampling Protocol for Well Water\*](#). National Good Agricultural Practices Program, Cornell University. Accessed March 2023.
5. American Public Health Association, American Water Works Association, Water Environment Federation. 2023. Standard Methods for the Examination of Water and Wastewater. Lipps WC, Braun-Howland EB, Baxter TE, eds. 24th ed. APHA Press, Washington DC
6. U.S. Food and Drug Administration 2018. [\*Equivalent Testing Methodology for Agricultural Water\*](#). Fact Sheet. Accessed March 2023.
7. D.M. Stoeckel, C. Fisk, D. Clements, G. Wall, K. Woods, E.A. Bihn. 2019. [\*The Water Analysis Method Requirement in the FSMA Produce Safety Rule\*](#). Produce Safety Alliance, Cornell University. Accessed March 2023.