DIVISION OF AGRICULTURE
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# Food Safety Modernization Act Produce Safety Rule: Microbial Water Quality Compliance

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## I. Who is this Fact Sheet For?

This fact sheet is designed for producers who must comply with the federal **Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR)** and those interested in learning how to meet the agricultural water requirements in Subpart E of the FSMA PSR. The agricultural water requirements set standards for water quality and require periodic testing to ensure the water is safe and of adequate sanitary quality for its intended use. This means that your water may need to be tested periodically to ensure it is safe for how you plan to use the water.

Farms that grow produce should determine if they must comply with the FSMA PSR. Growers can learn more about compliance regulations, dates, exclusion and exemption criteria by visiting the Food and Drug Administration's FSMA PSR webpage (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety). If you are unsure if this rule applies to your farm, contact the Arkansas Department of Agriculture Produce Safety Team at 501-225-1598 or visit the webpage at https://www.agriculture.arkansas.gov/plant-industries/regulatory-section/produce-safety-program/.

## II. Why Should You Test Your Agricultural Water for Fecal Indicator Bacteria?

Do you get your water from a stream, spring, pond or well? Do you use your water on the farm for your produce operation, drinking water, handwashing or other farm uses? If the answer is yes, it is important that you test your water. Just like municipal water suppliers test water quality, so should you. You are responsible for ensuring the water is safe for its intended agricultural use.

The PSR section Subpart E, which focuses on agricultural water quality, establishes science-based standards for the safe growing, harvesting, packing and holding of fruits and vegetables that are grown for human consumption. These mandatory standards are designed to reduce the chances of contamination in the food supply and ultimately reduce the number of human illnesses from contaminated produce.

## III. Compliance Dates

Compliance dates related to the agricultural water provisions have been extended for covered produce (not including sprouts). Covered produce is defined as produce that is subject to the FSMA PSR regulations,

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produce that is in its unprocessed state and that is usually consumed raw. Sprouts are covered by Subpart M and are required to be in compliance with the agricultural water subpart of the FSMA PSR as the relevant compliance dates have all passed.

The compliance dates related to agricultural water for covered produce (not including sprouts) are in the table below. See 84 FR 9706 (March 18, 2019) for more information.

| Size of farm | Compliance date |
|---|---|
| Very small | January 26, 2024 |
| Small | January 26, 2023 |
| All others | January 26, 2022 |

You can contact the Arkansas Department of Agriculture Produce Safety Team at 501-225-1598, or online at https://www.agriculture.arkansas.gov/plant-industries/regulatory-section/produce-safety-program/, to learn more about farm size and compliance dates.

The U.S. Food and Drug Administration (FDA) does not expect growers of covered produce (other than sprouts) to implement Subpart E until the new compliance dates. The FDA encourages farms to use good agricultural practices to maintain and protect the quality of their water sources (see their "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables"). Farms that currently test their water may choose to continue with their testing programs, and farms that do not currently test their water may begin doing so.

## IV. Requirements for Microbial Testing according to the FSMA PSR

Agricultural water is defined, in part, as water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces (§ 112.3). A covered activity means growing, harvesting, packing or holding covered produce on a farm.

When determining whether or not you have to test your agricultural water, it is important to identify which category of agricultural water you are evaluating – is it production water or post-harvest water?

Also, what is the source of your water – is it surface water (like streams, springs, ponds, etc.), groundwater or municipal water that you store open to the environment? There are different testing frequency and evaluation requirements for these different categories and water sources.

You will also need to know how to properly collect your water sample for water testing. For information about this, see our related fact sheet "Bacterial Water Sample Collection and Submission to the Water Quality Lab."

### *A. Production Water versus Post-Harvest Water*

There are two categories that your agricultural water might fall under: production water or post-harvest water.

1. **Production water** is water used during growing activities (e.g. irrigation water, frost protection, pesticide application; water that directly touches the harvestable portion of the produce).
2. **Post-harvest water** is water used during and after harvest that presents high risk for contamination to occur (e.g. water used in the field during harvest; water used during packing, holding, cooling activities; water used to clean surfaces that food will contact; water used for making ice; water used for washing hands; etc.).

Depending on the water source being used, both of these types of water must be evaluated for bacterial water quality.

### *B. Microbial Water Quality Profile*

As a fruit and vegetable producer, you must establish an initial microbial profile for each untreated water source that you use as agricultural water during growing activities. In future years, you must maintain your microbial profile by testing your water periodically.

Surface water quality can change quickly throughout the year and with changing seasons. Groundwater does not tend to change very dramatically or quickly, but there is potential for your groundwater supply to become contaminated.

Water testing only gives you a snapshot in time, but it can provide important information regarding fecal contamination of your water supply. There are

countless types of fecal pathogens that can be found in water, including different bacteria, viruses and parasites. Generic *E. coli* is a type of fecal bacteria and is the accepted indicator of fecal contamination because it is logistically not possible to test for all potential types of pathogens.

The water quality profile is designed to provide you with long-term information about the quality of your water for agricultural use.

## V. How You Can Interpret Your Results

### *A. Definitions*

In order to understand what your results mean, here are a few important definitions:

1. Geometric mean (GM) is a type of average, or measurement of central tendency, that is calculated from multiple observations or testing results.
2. Statistical threshold value (STV) is a measure using each of your observations or results to assess how different or variable your water quality is over time.
3. CFU/100 mL is the unit of measure for *E. coli* results specified in the PSR; this stands for "Colony Forming Units per 100 mL of sample water." But, other laboratory methods are acceptable under this rule, and MPN/100 mL may be used; this stands for "Most Probable Number per 100 mL of sample water."

It is also important to identify which category of agricultural water you are evaluating – is it *production water* or *post-harvest water*? Also, what is the source of your water – is it *surface water* or *groundwater*? There are different testing frequency and evaluation requirements for these different categories and water sources.

### *B. How to Calculate GM and STV*

There are resources available to help you calculate the GM and STV and understand whether your water meets the requirements of the FSMA PSR:

1. Online tool – developed by the University of Arizona
    a. Producers can create an online account for FREE - https://agwater.arizona.edu/, or download the phone app "Ag Water".
    b. Enter sample information and bacteria results
    c. The tool automatically calculates the GM and STV values and determines if your water meets the criteria for the rule.
2. Microsoft Excel tool – developed by the Western Center for Food Safety at the University of California-Davis.
    a. Producers can download the Excel tool for FREE - https://www.wcfs.ucdavis.edu/resources/.
    b. Enter sample information and bacteria results.
    c. The tool automatically calculates the GM and STV and tells you if your water meets the criteria for the rule.
3. Explanation of the calculations for GM and STV – Cornell University.
    a. You can access a pdf document that details how the GM and STV are calculated: https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/2017%20GM%20STV%20Worksheet%20v1.0.pdf

### *C. Untreated Groundwater for Production Activities*

You must test your groundwater supply as close to harvest as practicable, with the following frequency:

- Year 1: Four times during the growing season
- Year 2, 3, etc: Once a year during the growing season

The samples collected and tested in the first year develop your initial microbial profile, and testing for subsequent years keeps your profile updated. Each year you update, you must recalculate the GM and STV using the most recent four years of data.

The following is the evaluation criteria for water used for production activities. As noted above, results in "MPN/100 mL" is acceptable given the laboratory method being used.

- GM must be 126 CFU (or MPN)/100mL or less; AND
- STV must be 410 CFU (or MPN)/100mL or less

The following outlines the corrective actions you must take if your water sample exceeds the criteria given above:

- Apply a time interval to allow microbial die-off; in other words, wait a specific amount of time to use this water to harvest your produce.
- Inspect your water source and entire system for possible causes of contamination. Implement practices to reduce the risk of contamination.

### *D. Untreated Groundwater for Harvest and Post-Harvest Activities*

**Harvest and Post-Harvest activities** include water used in the field during harvest; water used during packing, holding, cooling activities; water used to clean surfaces that food will contact; water used for making ice; water used for washing hands; etc.

You must test your groundwater supply with the following frequency:

- Year 1: Four times during the growing season (or over a period of one year)
- Year 2, 3, etc: Once each year during the growing season

However, if *E. coli* are detected in any sample (see evaluation criteria below), you must start over as if beginning with year 1. This means if, for example, in year 3, your result shows that *E. coli* is present, you must test your water four more times that year. If results yield no detectable generic *E. coli* in 4 samples, then move to once per year thereafter.

The following is the evaluation criteria for water used for harvest and post-harvest activities:

- NO amount of *E. coli* is acceptable; your result must indicate that no detectable generic *E. coli* are present per 100 mL of water.
    - Some labs report "<1" for the lowest reportable value; this is accepted by the federal FSMA PSR to indicate that no detectable *E. coli* are present.

The following outlines corrective action you must take if your water sample has detectable levels of generic *E. coli*:

- First, immediately stop using that water source for all uses listed under post-harvest water activities.
- If you want to resume using that water source, you must first do at least one of the following:
    - Re-inspect the entire agricultural water system to the extent that it is under your control; identify anything that might lead to contamination of your produce or water source; make any necessary changes and test your water to determine if those changes are effective. This event resets your microbial water quality profile and will require retest to demonstrate the corrective action was successful.
    - Put your water through a treatment process before use; if you treat your water with sanitizers or other treatment actions, you must monitor your water treatment often enough to ensure that the treatment is continually and consistently effective; you will be responsible for keeping documentation on the results of your water treatment monitoring.

### *E. Untreated Surface Water for Production Activities*

You must test your surface water supply as close to harvest as practicable, with the following frequency:

- Years 1-4: at least 20 times total
    - You must collect and analyze 20 samples in the first, second, third or fourth year.
    - For example, you could collect 10 samples per year for years 1 and 2, or you could collect 5 samples per year for years 1, 2, 3, and 4.
    - You cannot collect all 20 samples in the first year; you must collect samples over a period of at least two and less than four years.
- Subsequent years: Five times per year
    - Five times per year could begin with year 3 if you collected all 20 initial samples in the first two years.

Each year you update, you must recalculate the GM and STV using the most recent four years of data. You must also confirm that your water continues to be in compliance with the numerical requirements.

The following is the evaluation criteria. As noted previously, results in "MPN/100 mL" are also acceptable, given the laboratory method used.

- GM must be 126 CFU (MPN)/100mL or less; AND
- STV must be 410 CFU (MPN)/100mL or less

The following outlines the corrective actions you must take if your water sample exceeds the criteria given above:

- Apply a time interval to allow microbial die-off; in other words, wait a specific amount of time to use this water to harvest your produce.
- Inspect your water source and entire system for possible causes of contamination. Implement practices to reduce the risk of contamination.

### *F. Untreated Surface Water for Post-Harvest Activities*

You CANNOT use untreated surface water for post-harvest activities under any circumstances. You may use untreated ground water with no detectable generic *E.coli*. Municipal water is preferred.

## VI. Avenues for Bacteria Analysis

Laboratories provide results as numerical values (CFU or MPN/100 mL), or as Presence/Absence, depending on the method used.

**Production Water:** generic *E. coli* must be quantified as numeric values.

**Harvest and Post-Harvest Water:** generic *E. coli* can be reported in terms of presence or absence.

*A. The AWRC Water Quality Lab in Fayetteville:*

The lab analyzes water samples for *E. coli* using the FDA-approved method IDEXX Colilert Test Kit with Quanti-Tray/2000 for quantification. This method gives numeric results and is approved for use relating to the FSMA PSR. The lab is also certified by the Arkansas Department of Environmental Quality for the analysis of bacteria, as well as many other parameters important for food production. Visit the AWRC website for more information at https://arkansas-water-center.uark.edu/water-quality-lab.php.

*B. The Arkansas Department of Health (ADH) in Little Rock:*

ADH can also test for generic *E. coli* in your water sample using a method that is accepted under the PSR.

The sample collection and submission process for ADH is different from AWRC; please refer to their website for thorough instructions if you are submitting a sample to them: (https://www.healthy.arkansas.gov/programs-services/topics/milk-and-water-testing).

ADH can analyze for the presence or absence of *E. coli*, as well as numeric values. For analysis of Harvest and Post-Harvest Water, you should be sure to request the method that provides quantitative results (in MPN/100 mL), which is required by the FSMA PSR. To request quantitative results, be sure to check "raw with count"on the submission form; if this is not checked, the ADH lab will only analyze for presence/absence, and you will have to submit a new sample to comply with the federal rule.

To submit a sample to ADH, you must use an official ADH sample container and fill out their submission form, which must be included with the sample when shipped or delivered to their lab. You can visit your local ADH health unit for collection containers and submission forms; see https://www.healthy.arkansas.gov/local-health-units for a list of units.

## VII. About the University of Arkansas System Division of Agriculture

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## VIII. Supporting Information

Farmers interested in learning more about the FSMA PSR should attend grower training and can learn about upcoming workshops in Arkansas at www.uaex.uada.edu/producesafety or in other states at https://producesafetyalliance.cornell.edu/training/grower-training-courses/. The Local, Regional, and Safe Foods Program through the University of Arkansas System Division of Agriculture Cooperative Extension Service offers training, outreach and technical assistance to producers.

The Produce Safety Alliance (PSA) is a national program offering training, outreach and technical assistance to produce safety educators and producers. The PSA Grower Training on Agricultural Water and FDA resources on the water regulations can be found below.

Produce Safety Alliance, Module 5: Agricultural Water, Production Water, from Cornell University, https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Tab-6-Ag-Water-1-V1.2.pdf

Produce Safety Alliance, Module 5 Part 2: Post-Harvest Water, from Cornell University, https://producesafetyalliance.cornell.edu/sites/produce-safetyalliance.cornell.edu/files/shared/documents/Tab-7-Ag-Water-2-V1.2.pdf

U.S. Food and Drug Administration, Equivalent Testing Methodology for Agricultural Water, https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water

U.S. Food and Drug Administration, Federal Register, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E, https://www.federalregister.gov/documents/2019/03/18/2019-04652/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-extension

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