

FSMA Produce Safety Rule Water Requirements: Insights to Get You Organized!

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There has been a lot of talk about the water requirements that are part of the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). This article is intended to help you know what is written in the PSR, the changes that have occurred since the original PSR publication, the timing of the requirements, and other key things. There will be more information coming on the topic, that likely will include guidance from FDA. This article is an introduction to some of the main water requirements including key terms and phrases marked in bold; you can expect to see these terms again so now is a good time to start getting used to them. The main points of this article are:

- Understand when water meets the definition of **agricultural water**
- Understand compliance dates and quality requirements for agricultural water used during growing activities or during and after harvest
- Describe the **Microbial Water Quality Profile (MWQP)**: What it is, how many samples you need to build one, and what resources are out there to help you
- Know your options if your agricultural water does not meet microbial water quality criteria

The Definition of Agricultural Water

Here is the exact definition from the PSR.

“Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).”

Notice a couple of things in that definition.

- **Agricultural water** is used during **covered activities** on **covered produce**. Covered activities refer to activities that are described in the rule (i.e., growing, harvesting, packing, and holding covered produce). Covered produce has a specific definition in the PSR; generally, produce that is normally consumed raw and is a raw agricultural commodity (e.g., strawberries, apples, carrots, celery, and leafy greens).

- In order to fit the definition of agricultural water, the water must be used in **direct contact** with the **harvestable portion** of covered produce or **food-contact surfaces** (including hands). Water used in other ways on the farm does not fall under the definition of agricultural water. For example, water that contacts potatoes would not be agricultural water since potatoes are not a covered crop, but water that contacts a conveyor that moves produce in the field during leafy greens harvest would be agricultural water.

The water quality requirements in the FSMA PSR apply to farms that 1) are covered by the rule and 2) that use water in direct contact with the harvestable part of the covered crop or food contact surfaces. The language directly from the PSR requires that *“all agricultural water must be safe and of adequate sanitary quality for its intended use”* (§ 112.41). Remember that water in contact with food-contact surfaces is included in this definition, so agricultural water quality requirements will have to be met when establishing cleaning and sanitation programs as well as when growing and handling crops.



Compliance Dates and Quality Requirements for Agricultural Water Used During Growing Activities, or During and After Harvest

First, it is important to understand when the requirements of the PSR go into effect. For many farms the answer is never. Some farms are not covered, or they qualify for exemptions or modified requirements. Even without a legal requirement to follow the PSR, a buyer might insist that a grower follow the provisions in the PSR.

For farms subject to the PSR, compliance dates for most provisions began January 26, 2018, depending on the farm’s **business size**. A follow-up [FDA rule](#) in 2019 extended the compliance dates for parts of the PSR dealing with agricultural water (except for sprouts) to begin in 2022, 2023, or 2024. Sample collection and analysis begins at the compliance date; the MWQP that is described in the next section does not need to be complete before the compliance date. See the [FSMA Produce Safety Rule Compliance chart](#) for more details about compliance dates.

In addition to meeting microbial water quality criteria, growers subject to the PSR are required to inspect their agricultural water systems at least once a year, and to maintain their water sources and water distribution systems. Compliance dates for these practices are also extended, to begin in 2022. It is important to remember that *“all agricultural water must be safe and of adequate sanitary quality for its intended use”* (§ 112.41) so during the inspection you may have to pay attention to other water quality issues in addition to testing for generic *E. coli*.

To help with the inspection, it is important to talk more about what is covered by the PSR. The PSR only covers microbiological hazards, so the water requirements only include microbiological testing. Controlling fecal contamination is one key to minimizing produce safety issues, and the test for generic *E. coli* indicates fecal contamination without the cost of testing for all microbial human pathogens. Other observations during the inspection can also indicate microbial hazards, such as the presence of animals, trash, and debris in the water source.

The water quality criteria are different for water used during growing activities and for water used during and after harvest. Both criteria are based on a test for **generic *Escherichia coli***, which is an indicator of fecal contamination. Water used during growing activities can have a limited amount of *E. coli* present in the water, whereas water used during or after harvest must have no detectable generic *E. coli* present in a 100 mL water sample. The next section of this article talks about the MWQP and references fact sheets and online calculators to help with the associated calculation; for now, just review the numbers.

- The requirement for agricultural water used during growing activities is a microbial water quality profile (MWQP), based on a rolling 4-year data set of water testing results, that has a **geometric mean** (GM) of 126 or less CFU generic *E. coli*/100 mL water and a **statistical threshold value** (STV) of 410 or less CFU generic *E. coli*/100 mL water.
- The requirement for agricultural water used during and after harvest is no detectable generic *E. coli* in 100 mL of water.

Please read the remainder of this article for explanations of those main points, and flexible management options included in the PSR for water that does not meet the *E. coli*-based water quality requirements.



Microbial Water Quality Profile: What it is, how many samples you need to build one, and what resources are out there to help you

For agricultural water that is used during growing activities, a MWQP needs to be developed. The MWQP is intended to help a grower make water management decisions using a rolling 4-year data set of water testing results. The data set leads to two statistical calculations: a geometric mean and a statistical threshold value. The MWQP is based on at least 4 samples for ground water sources of agricultural water (e.g., protected well), and at least 20 samples for surface water sources of agricultural water (e.g., pond, stream, river) tested for generic *E. coli*.

The initial 4 samples for a ground water MWQP are all collected in the compliance date year; the initial 20 or more samples for a surface water MWQP are collected starting the compliance date year and it takes at least 2 years (but not more than 4 years) to collect the full initial surface water MWQP sample set. Voluntary sampling to understand the quality of water may be done before the compliance dates.

As mentioned earlier, the numeric requirement for agricultural water used during growing activities is a MWQP that has a GM of 126 or less CFU generic *E. coli*/100 mL water, and a STV of 410 or less CFU generic *E. coli*/100 mL water.

The terms GM and STV will be new to many people. There are tools available to help do the calculations. For those who want to do the calculations by hand, a fact sheet entitled [Geometric Means, Statistical Threshold Values, and Microbial Die-Off Rates](#) will help. For those who would rather use a calculator, several options can be found at the [Western Center for Food Safety website](#). Two important take away messages regarding the MWQP are:

- resources are available to help you do the calculations, and
- the PSR requirements do not go into effect until 2022 at the earliest, depending on farm business size.

Please note that FDA is expected to publish guidance to help you implement water testing strategies and the creation of the MWQP. Until guidance is released, you should not invest in changes to your testing to create the MWQP. If you are already doing water tests to meet buyer requirements or as part of a third party audit, then continue to do that water testing. Do not make significant changes or investments in additional water testing until FDA releases its guidance, so you can be assured that the changes and investments you are making will be in compliance with the PSR. If you have never tested the quality of your water, you may want to collect samples to get a feel for your water quality so you are not surprised. Earlier understanding about the quality of your agricultural water can give you time to invest in water quality management, if necessary, before your MWQP is required.



Options if Your Water Does Not Meet Microbial Water Quality Criteria

Once the GM and STV values for the MWQP are calculated, they will be compared against the numeric criteria in the PSR (the numbers 126 and 410 that were described in detail above). In order to be in compliance with the PSR, agricultural water used during growing activities has to meet both the GM criterion and the STV criterion. If a calculated value is above one of those criteria, the PSR includes flexibility in the form of management options called corrective measures. Growers have time to apply one or more of these corrective measures. The language of the PSR says that corrective measures, if needed, must be implemented “as soon as practicable and no later than the following year” after calculating the MWQP.

The corrective measures are:

- Re-inspect the agricultural water system and take corrective action to address contamination sources or other issues.
- Treat the water, being sure that any antimicrobial pesticides (e.g., sanitizers, disinfectants) are used according to the label.
- Manage the water use and produce handling to include a time interval for die-off before harvest, or to allow for log reduction during other steps. These management options result in calculated reductions to the original GM and STV value. The reduction is based on expected rates of microbial die-off in the field (0.5 log/day for up to 4 days), or during storage, or removal during processes such as commercial washing (scientifically validated die-off or removal rate with supporting documentation).

Look forward to more information about water quality and water-related requirements in the PSR. In particular, FDA is working on [re-evaluation of the requirements](#) and we anticipate future guidance from FDA to clarify expectations. Corrective measures will be covered in more detail after FDA finishes re-evaluation of the water requirements in the PSR – for now, hopefully, this is enough information to get you organized and headed in the right direction.

[Contact the PSA](#), a collaborating [produce safety outreach team](#), or the [FDA Produce Safety Network](#) if you have questions about what the water rules mean to you. For authoritative answers about PSR water quality requirements and regulatory compliance, you can submit questions to [FDA’s Technical Assistance Network](#).

