**The Produce Rule and Agricultural Water**

**WHAT WATER IS REGULATED BY THE PRODUCE RULE?**

[FDA defines “agricultural water](https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-2032)” as “water used in covered activities (growing, harvesting, packing, or holding covered produce on a farm) on covered produce (see exclusions) where water is intended to or likely to contact covered produce or food contact surfaces, including water used for:

1. **Harvesting, Packing, And Holding Activities, And Growing Sprouts**

* Hand-washing during harvest/post-harvest handling
* Food-contact surfaces (include ice)
* Purposes that directly contact produce during harvest or post-harvest activities
* For sprout irrigation
* For agricultural tea

1. **Growing Activities (Other Than Sprouts)**

- When used in a manner that directly contacts the harvestable portion, prior to harvest. Water used in irrigation methods that do not directly contact the harvestable portion of covered produce are not regulated. Note - drip irrigation on carrots does directly contact the harvestable portion and is regulated.

*In general, “all agricultural water must be safe and of adequate sanitary quality for its intended use.”*

**WHAT DOES THE WATER QUALITY OF MY AGRICULTUAL WATER NEED TO BE?**   
The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic E. coli, which can indicate the presence of fecal contamination.

1. **Harvesting, Packing, And Holding Activities, And Growing Sprouts**

**WATER QUALITY**: Must be potable, no detectable generic E. coli per 100mL. The rule prohibits use of untreated surface water for uses that require potable water.

1. **Growing Activities (Other Than Sprouts)**

**WATER QUALITY**: The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV).

Confused? The FDA is exploring the development of an online tool that farms can use to input their water sample data to calculate the GM, STV, and die-off values.

1. A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water; and
2. A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water.

[As FDA explains it:](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm472501.htm) “the GM measures what is called the central tendency, which is essentially the average amount of generic E. coli in a water source. The STV reflects the amount of variation in the E. coli levels, which can be caused by events such as a heavy rainfall. It measures expected deviations from the average for a water source. Collectively, both pieces of information provide a more complete description of your water quality than either one alone.”

**HOW OFTEN MUST I TEST MY WATER?** Frequency is based on the type of water source and it’s use.

**- PUBLIC WATER SYSTEMS**

There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule’s treatment requirements.

**- UNTREATED GROUND WATER**

**1. Harvesting, Packing, And Holding Activities, And Growing Sprouts**

For water that is used for the purposes for which no detectable generic E. coli is allowed, the FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for that purpose based on these results.

If the four initial sample results meet the no detectable generic E. coli criterion, testing can be done once annually thereafter, using a minimum of one sample. Farms must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion.

**2.** **Growing Activities (Other Than Sprouts):** The FDA requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of one year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria.

After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV. The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.

**- UNTREATED SURFACE WATER**

**1. Harvesting, Packing, And Holding Activities, And Growing Sprouts**: The rule prohibits use of untreated surface water for uses that require potable water.

**2. Growing Activities (Other Than Sprouts):** Untreated ground water is considered the most vulnerable to external influences—that is directly applied to growing produce (other than sprouts). The FDA requires farms to do an initial survey, using a minimum of 20 samples, collected as close as is practicable to harvest over the course of two to four years. The initial survey findings are used to calculate the GM and STV (these two figures are referred to as the “microbial water quality profile”) and determine if the water meets the required microbial quality criteria.

 After the initial survey has been conducted, an annual survey of a minimum of five samples per year is required to update the calculations of GM and STV.

The five new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.

NOTE: if you apply water from multiple surface water sources they each need the full testing regime. If you draw from several points on the same water source, you do not need to test at each point, as long as there is nothing between the points that would alter the water quality.

**- TREATED WATER:** Seek further guidance (<http://sustainableagriculture.net/> )

**IF THE WATER DOES NOT MEET THE CRITERIA:** **WHAT SHOULD I DO?**

**1. Harvesting, Packing, And Holding Activities, And Growing Sprouts**

1. Stop using the water source until you re-inspect your water distribution system to see if you can determine what’s wrong, rectify it, and then verify that your action was effective to bring the water back under the threshold; or

2. Treat the water

If you are treating your water, there are [requirements](https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-2159) that relate to the effectiveness of treatment, the delivery of treatment, and monitoring the effectiveness of the treatment.

**2. Growing Activities (Other Than Sprouts)** If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops. These options include, for example:

Confused? The FDA is exploring the development of an online tool that farms can use to calculate the appropriate number of days that they need to wait between the end of irrigation and harvest.

- Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days.

- Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.

However, if it would take more than 4 days for the microbial die-off to bring you below the microbial water quality standard, then you cannot use that water source to irrigate covered produce, unless you switch to an irrigation method where the water is unlikely to contact the harvestable portion of the produce, or you treat the water.

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**WHEN DO FARMERS HAVE TO COMPLY WITH TESTING WATER?**

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| --- | --- | --- |
| Farm Size | For all water use, except growing sprouts | For Growing Sprouts |
| Very small farms, > $250,000 | 6 years | 3 years |
| Small farms, $250,000 < $500,00 | 5 years | 2 years |
| Large $500,00 and more | 4 years | 1 year |

**INSPECTION AND REGULAR MAINTENANCE**

At the beginning of the growing season, or at least once annually, [you must inspect](https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-2150) your entire agricultural water system, which includes your water sources, distribution systems, facilities, and equipment, to identify any conditions that are reasonably likely to introduce know or reasonably foreseeable hazards into or onto covered produce or food contact surfaces.

This should include consideration of:

1. The nature of each agricultural water source;
2. The extent of your control over it;
3. The degree of protection each source has;
4. Adjacent and nearby land use that may impact your water quality; and
5. The likelihood of introduction of known or reasonably foreseeable hazards by another upstream water user.

You must adequately maintain: all water sources, to the extent they are under your control (e.g. by regularly inspecting, removing debris, trash etc); your water distribution system to the extent it is under your control; and your water system to reduce the potential for covered produce to contact pooled water.

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**PRODUCE RULE WATER RECORDKEEPING REQUIREMENTS**

**For all agricultural water**

• Inspection of agricultural water sources and systems, and pooling of water

• Generic *E. coli* test results

• Water treatment monitoring

• Public water (annual) documentation

* Scientific data or information you rely on to support the adequacy of a method used to treat water

**For irrigation water that directly contacts harvestable portion:**

* Microbial die-off or removal rates, and scientific documentation of method
* Scientific data or information you rely on to support a microbial die-off or removal rate
* Documentation of actions that support a microbial die-off or removal rate

Additional Resources:

http://sustainableagriculture.net/blog/produce-rule-analysis-part-1/

<http://sustainableagriculture.net/blog/produce-rule-analysis-part-2/>

http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf