

Water and FSMA

Changes to water requirements in the proposed produce safety rule of the Food Safety Modernization Act

By Michelle Danyluk, Mark Ritenour, Renée Goodrich and Keith Schneider



The proposed produce safety requirements under the Food Safety Modernization Act (FSMA) are built upon the Food and Drug Administration's (FDA) previous guidance for Good Agricultural Practices (GAPs) and Good Handling Practices to establish science-based minimum standards for the safe growing, harvesting, packing and holding of produce on farms. The proposed produce safety rule takes a "risk-based" approach that looks at risks associated with practices, not commodities. Any grower whose citrus may enter the fresh market will need to be aware of and prepared for the produce safety rule. This article will describe changes made to the proposed standards associated with agricultural

water released in supplemental materials in September 2014.

INSPECTING THE WATER SYSTEM

The FDA proposes that water sources and distribution systems be inspected at the beginning of each growing season, and that the system under a grower's control be evaluated regularly.

WATER TESTING STANDARDS

Not all water used during crop production needs to be tested, and not all water that needs to be tested has the same numerical standard for microbiological water quality that must be met. Microbiological water quality is measured in colony forming units (CFU) or most probable number

(MPN). CFUs are used to quantify the number of bacteria present in a sample and MPNs are used to statistically estimate the number of bacteria present in a sample. Both CFUs and MPNs are based on the type of test performed and are used to determine how many bacteria are in a sample.

Water must have no detectable generic *E. coli* in 100 milliliter (ml) if it:

- Is used to make treated agricultural teas
- Comes into contact with citrus

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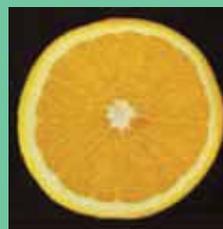
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Water that is intended to contact the harvestable portion of citrus at any point in preharvest must be tested.

during or after harvest

- Is used to wash surfaces that come into contact with citrus during harvest
- Is used to wash hands during or after harvest

Water that is intended to contact the harvestable portion of citrus at any point in preharvest (including citrus peel contact) must be tested to establish a water quality profile (see below) and have ≤ 126 CFU/100 ml generic *E. coli* geometric mean (GM) and ≤ 410 CFU/100 ml generic *E. coli* in an estimate of the statistical threshold value (STV).

A GM is different than an “arithmetic mean,” or the means used in common calculations. Free online programs to help calculate the geometric mean are available, and can be found by searching “free geometric mean calculator.” The STV, calculated from the same samples used to calculate the geometric mean, approximates the 90th percentile of the water quality distribution, and is not to be exceeded by more than 10 percent of the samples taken. At this point, there is no easy way to calculate an STV, but FDA has said that it’s working on a simple online calculator — we’ll keep you posted on that.

Under the proposed rule, if water is out of compliance with the generic *E. coli* metrics, growers have several options:

1. The first is to implement a pre-harvest interval, to apply a time (in days) between the last time water contacted the harvested portion of the product and harvest. To determine how long this time should be, take the value of the water test and figure out how long it would take for this number of *E. coli* to reduce to the proposed metrics (GM ≤ 126 CFU/100 ml; STV ≤ 410 CFU/100 ml). In the absence of any other data on microbial die-off rates, growers can assume a 0.5 log CFU/day reduction.

2. Option two is to implement a postharvest intervention or storage interval. Here, the grower or packer would either apply a time (in days)

between harvest and the end of storage before distribution, or evaluate microbial removal rates during packing activities (like washing citrus).

Again, to determine how long the storage should be, or what log reduction is required in washing, take the value of the water test and figure out



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what is needed to reduce the *E. coli* numbers in the water to the proposed water metrics (GM \leq 126 CFU/100 ml; STV \leq 410 CFU/100 ml). Industry data is needed to establish microbial die-off rates and log reductions during treatment.

3. If options 1 or 2 are not selected, the grower would be required to immediately stop using that source of water, and take follow-up actions. These actions may include re-inspecting the water source and distribution system to determine why *E. coli* populations are high, altering the system as appropriate, and retesting the water, or treating the water.

Currently there are no standards for water that does not contact the citrus fruit preharvest.

WATER TESTING FREQUENCY

Water testing frequencies in the proposed rule vary depending on the water source being used. Water samples should be collected as water is used during growing activities following the direct application method, or should be collected at point of use (from a sprinkler head or when being loaded into a spray tank).

Water that is from a public source or is treated to reduce microbial populations does not require testing. It should be noted that if city water is used, while testing is not required, growers/packers should maintain records of the annual water testing reports provided to them by the municipality.

Untreated ground water must be tested at least four times a year, during harvest, to establish a baseline water quality profile. In subsequent years, if the first year of water testing meets the requirements of its intended use (i.e., the *E. coli* metrics discussed above), it can be tested once annually during harvest. If the water does not meet the requirements of its intended use, a new

baseline (i.e., four water tests per year) must be established.

Any grower using untreated surface water must develop a water quality profile baseline for each of his or her water sources. This involves collecting a minimum of 20 water samples over a minimum of two years during the harvest season and calculating a GM and STV.

Once the baseline is established, in subsequent years a minimum of five samples need to be collected during harvest to verify the water quality profile. Should the results of these five annual tests not support the baseline water quality profile, growers would be required to develop a new water quality profile baseline and modify their use accordingly. This new water quality profile baseline can include the annual survey data collected that year and samples collected most recently, or can include the annual survey data collected that year and new data, to make up a dataset of at least 20 samples.

Should the grower know or have reason to believe the water quality profile no longer represents the water, he or she must develop a new baseline. Factors that may require a new baseline being developed include significant changes in adjacent land use, erosion, or other factors outside the grower's control. Baseline water quality profiles must be repeated a minimum of every 10 years.

ALTERNATIVES AND VARIANCES TO WATER TESTING STANDARDS

Under the proposed produce safety rule, farms would be allowed to establish *Alternative Practices or Standards* for water testing standards without asking for permission or petitioning FDA, as long as they have adequate scientific data and documentation to support those alternatives. Farms may then use the alternative measure and

provide documentation if asked.

States and foreign countries may also request *Variances* from the proposed water testing standards by submitting a formal petition to FDA. These petitions would need to include information demonstrating that the variance does not increase the likelihood of adulteration and provides the same level of public health protection. Variances would be granted or denied following petition to FDA.

RECORD KEEPING ASSOCIATED WITH WATER TESTING

Growers will be required to keep records of water testing under the proposed rule including:

- Water source/distribution inspection findings
- Public (municipal) water source/system documentation (if used)
- Water treatment method SOP (standard operating procedure)/treatment monitoring results (if treating water)
- Water testing results
- Scientific data/information to supporting alternative (if used)

COMPLIANCE DATES

FDA has proposed to extend compliance dates associated with water testing beyond the effective dates for the rest of the proposed produce safety rule. It is important to understand the size of the farm as defined in the proposed rule. Those extended dates for water testing, monitoring and recordkeeping are:

- Six years from the effective date of the final rule for very small farms
- Five years from the effective date of the final rule for small farms
- Four years from the effective date of the final rule for other farms

MORE INFORMATION

It is important for Florida's citrus industry to stay informed about proposed rules and guidance that is developed as a result of FSMA and to be active in providing feedback during the comment period. Visit www.fda.gov/FSMA for the most current information and details about FSMA. This site also provides a way to sign up to receive FSMA updates via e-mail.

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