

Produce Safety Rule Updates for (FSMA)Covered Farms

Please note this update does not include Sprout Grower's information

Compliance Dates

Very small businesses-- If, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than \$25,000 but less than \$250,000 in annual produce sales, the farm falls under the Rule on January 26, 2020. Their Ag Water compliance deadline is now 2024; and their customer written assurances requirement is delayed until 2022.

Small businesses, If, on a rolling basis, the average annual monetary value of produce the farm sold during the previous three-year period is more than \$250,000 but no more than \$500,000 that farm falls under the Rule on January 26, 2019. Their Ag Water compliance deadline is now 2023; and their customer written assurances requirement is delayed until 2021.

All other farms—If, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than \$500,000, that farm comes under compliance on January 26, 2018. Their Ag Water compliance deadline is now 2022 and their customer written assurances requirement is delayed until 2020.

Covered farms

You are a covered farm if you annually gross more than \$25,000.00 per year in sales of produce, averaged across a rolling 3 year period and adjusted for inflation (2011 baseline year), that you either grow, harvest, pack, or hold on a farm. Produce includes any fruit or vegetable, including mushrooms, sprouts, peanuts, tree nuts, and herbs, but NOT grains. Produce that is rarely consumed raw or is not a raw agricultural commodity is not covered by this Rule.(Lists available)

For a **Qualified Exemption (QE)** to be considered, a grower must have less than \$500,000 in sales of **ALL FOOD** (not just produce), based on the average of the previous three years sales, adjusted for inflation **AND** sales to qualified end users must exceed your sales to all other purchasers (51% or more). Qualified end users include farmer's markets, restaurants, and retail food establishments within the same state or within 275 miles.

A Qualified Exempt Farm is exempt from some of the Produce Safety Rule, but is subject to General Provisions; Labeling Requirements; Records; Compliance & Enforcement; Withdrawal of Qualified Exemptions; and must take appropriate measures to minimize the risks of serious adverse health consequences or death from the use of, or exposure to, covered produce. This includes those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce and provide reasonable assurances that the produce is not adulterated.

Water Quality Standards

The water standard for untreated ground water and surface water used for irrigation that touches the edible portion of the produce is a **generic mean of ≤ 126 CFU/MPN generic *E. coli* per 100 mL water (GM) and/or a statistical threshold value of < 400 CFU/MPN generic *E. coli* per 100 mL (STV).**

The water standard for all water used on food contact surfaces, washing hands, and on any harvested product must have **no detectable generic *E. coli* per 100 mL water.**

To determine if the standard is met, one must create a water profile. For **untreated surface water** this requires that water samples are taken and tested 20 times over the course of two-four years, as close in time as practicable to, but prior to harvest. One cannot sample more than once a day per source or after harvest is over. The water sample *E. coli* level data will create a Water Profile which includes a geometric mean (GM) and a statistical threshold value (STV) when it is entered into the tools at <http://wcf.s.ucdavis.edu/> (there is one for surface water and one for ground water) It will also predict appropriate die off periods, if needed.

Annually thereafter, a grower must take 5 samples per surface water source and include them to their established water profile. If they do not match the profile, use the 5 and take 15 more samples to establish a new profile. If the sampling still does not match the new profile, continue to do 5 samples per source annually and consider alternatives listed below. Each year, after the 20 sample profile is complete, the grower adds the current years 5 new samples and eliminates the 5 oldest samples and the profile data is updated and adjusts.

Untreated ground water used for irrigation that touches the edible portion of the produce, must meet the same *E. coli* standard. Testing must be done 4 times a year initially, taken when the water is used for growing. Thereafter one test per year will suffice, if the results match the water profile created by the first four samples. If this is not the case, one must go back to 4 samples per year to create another profile. Again alternative methods may be employed if needed. **All water test records should be retained for 4 years minimally.**

Alternative methods to rid crop of *E coli* residues include:

- **Die-Off** is a time interval that achieves 0.5 log microbial die-off per day (no more than 4 days is allowed.) between water application and harvest.
- **Time interval between harvest and end of storage** to achieve microbial die-off
- **Other activities** that may achieve microbial die-off include washing the produce.
- **Re-inspect water system** for signs of possible contamination and fix them.
- **Discontinue use of water supply** if none of these methods works.

Manure

The FDA currently has no microbial test requirements for raw manure applications. It must be applied in a way that it does not contact covered produce during application and minimizes potential for contact with produce after application. FDA does not take exception to farmers complying with the USDA’s National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.

Properly treated (time/temp records) and handled compost is safer than raw manure from a public health standpoint, but it too must be applied in a way that minimizes potential for contact with produce during and after application.

Labeling

If the produce requires a food packaging label, then the label must prominently and conspicuously include the name and complete business address of the farm where the produce was grown. (by 1/1/2020)

For Qualified Exempt (QE) farms, if the produce does not require a food packaging label, then the name and complete business address of the farm where the produce was grown must be prominently and conspicuously displayed on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business. 1/26/2020 for very small businesses (under \$250,000 in produce sales) or by 1/26/2019 for small businesses (under \$500,000 in produce sales)

Records

A Qualified Exempt farm must keep adequate records necessary to show that the farm satisfies the criteria for the qualified exemption. These records must include the date on each receipt **beginning Jan. 26, 2016** proving that 51% of sales of the year were to qualified end users either in the same state or within 275 miles. (Remember this is a three year rolling average).

Sales receipts to document the \$500,000 threshold do not need to be initialed, but they should be retained long enough to document the qualified exempt status for the applicable year, based on the rolling 3 year average.

These farms must also keep a written record that reflects an annual review and verification of the farm’s continued eligibility for the qualified exemption, beginning a year from the farm’s general compliance date.

Records are not submitted to FDA, but must be retained and made available upon request. They must be detailed, accurate, legible, and dated and signed or initialed by the person performing the documented activity.

Records must be able to be retrieved within 24 hours of a request for official review. They can be written or electronic, they must be original or true copies and can be based on existing records.

Withdrawal of qualified exemptions process

The FDA may consider one or more other actions to protect public health prior to withdrawal, such as a warning letter, recall, administrative detention, or seizure and injunction. The FDA must notify the farm of the circumstances that jeopardize the exemption, provide an opportunity for the farm to respond, and consider actions taken by the farm to address the issues raised by the agency. There are also procedures for reinstating a withdrawn exemption.

FDA has indicated that actual farm inspections will not begin until 2019.

Maine growers have a unique opportunity to be better prepared for these inspections.

The Maine Department of Agriculture, Conservation & Forestry has written a grant which allows their “experts” to visit farms to which they are invited, to take a look at operations and give non-threatening verbal feedback and suggestions to assist growers with FSMA Produce Safety compliance, for free! This would occur by appointment, at the convenience of the grower. This visit needs to occur when the produce is growing.

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