

Summary of Many Federal (FSMA) Produce Safety Rule Updates

Compliance Dates

Very small businesses, those with more than \$25,000 but less than \$250,000 in annual produce sales, will have four years after the rule's effective date to comply with most provisions. **(Jan, 26, 2020)**

Small businesses, those with more than \$250,000 but less than \$500,000 in produce sales, will have three years after the rule's effective date to comply with most provisions. **(Jan, 26, 2019)**

All other farms will have two years after the effective date to comply with most provisions. (Jan. 26, 2018)

The compliance dates for water quality standards, and related testing and recordkeeping provisions will be an additional two years beyond the compliance dates for the rest of the final rule.

Covered farms better defined

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 being any fruit or vegetable, including mushrooms, sprouts, peanuts, tree nuts, and herbs, but **NOT grains**. Covered produce is usually consumed raw and is unprocessed.

The original proposed rule defined that monetary threshold in terms of all food sales. The FDA is also applying that change to the definitions of "very small business" (\$25,000-\$250,000.) and "small business" (\$250,000.-\$500,000.) to base those monetary thresholds on produce sales rather than food sales. The definition of "farm" has been revised; a farm is no longer required to register as a food facility merely because it packs or holds raw agricultural commodities grown on another farm under a different ownership.

For a **Qualified Exemption** to be considered, a grower must have less than \$500,000.00 in sales of **ALL FOOD (not just produce)**, based on the average of the previous three years sales, adjusted for inflation **AND** your 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 Standard

The water standard is that all water used for irrigation that touches the edible portion of the produce must be ≤ 126 CFU/MPN generic *E. coli* per 100 ml GM and/or \leq CFU/MPN generic *E. coli* per 100 ml STV.

Untreated surface water will need to be tested 20 times over the course of two years, as close in time as practicable to, but prior to harvest. You cannot sample more than once a day or after harvest. This data will create a geometric mean (GM) and a statistical threshold value (STV). Annually thereafter grower must take 5 samples per source and compare 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 one of the following alternatives. Retain all water tests for 4 years minimally.

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

- **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. (An online tool where you input your *E. coli* counts and it computes the die-off period will soon be available. It will also derive STVs and GM values) This method also avoids incurring additional costs for treatments.
- **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.
- **Discontinue use of water supply** if none of these methods works.

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 irrigation. 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 and records should be retained for 4 years minimally.

Manure strategy to be further studied. The FDA has removed the nine-month proposed minimum-time interval between the application of untreated biological soil amendments of animal origin (including raw manure) and crop harvesting. The agency is deferring its decision on an appropriate time interval until it pursues certain actions. These include conducting a risk assessment and extensive research to strengthen scientific support for any future proposal, working with the U.S. Department of Agriculture and other stakeholders.

FDA does not intend to 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.

The FDA has eliminated the proposed 45-day minimum application interval for compost (also known as humus), including composted manures. Properly treated and handled compost is safer than raw manure from a public health standpoint and this change to the proposal would help facilitate its use while still providing an appropriate level of public health protection.

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)

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 QE 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 further clarified--The proposed revisions establish procedures to guide the FDA in withdrawing an exemption for a farm for food safety reasons as specified in the proposed regulation:

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.

The revisions also provide procedures for reinstating a withdrawn exemption.

Clarifying provisions on wild animals

The FDA states that the produce regulation does not authorize or require farms to take actions that would constitute the "taking" of a threatened or endangered species in violation of the Endangered Species Act. This puts the burden of increased vigilance and monitoring and/or cleansing fields of affected produce and residue on growers.

Information compiled to the best of my ability by Linda Titus, AgMatters LLC from sources including the FDA website and the National Sustainable Agricultural Coalition website. More details available for free! linda@agmattersllc.com

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