



## Summary of Revisions to FSMA Proposed Rule for Produce Safety

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FDA has responded to many of the concerns voiced about the first draft of this rule. The official set of revisions was posted today and the comment period ends on 12/15/14. I have tried to summarize the key changes here. The proposed revisions, with lengthy explanations, and the link to submit your comments can be found at: <http://federalregister.gov/a/2014-22447>.

**Exemptions.** The ‘Tester-Hagen’ amendment cannot be changed so criteria for a ‘qualified exemption’ from FSMA remains <\$500,000 annual sales of all food (human and animal) with >50% retail to ‘qualified end users’ within 275 miles. However, farms that do not meet these criteria will now be exempt if they have annual sales of less than \$25,000 of produce, rather than of food. The procedures for FDA withdrawing a farm’s qualified exemption are clarified.

**Compliance.** “Very small business” and “small business” are now defined using annual sales of produce rather than food. Very small businesses have sales of \$25,000-\$250,000 and small businesses have sales of \$250,000-\$500,000. Very small businesses have 4 years after the rule is effective to comply. Small businesses have 3 years. All other farms have 2 years. An additional 2 years is allowed beyond these dates for compliance with water quality standards.

The definition of “farm” is revised. It would allow farms to pack or hold raw agricultural commodities grown on another farm under a different ownership, without being considered a ‘food facility.’ Therefore these activities would be subject to the produce safety rule rather than the preventive controls rule for human food.

**Use of manure.** The proposed 9-month interval between the application of raw manure and crop harvest is withdrawn to allow time for risk assessment and research prior to any future proposal. “At this time, the 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.”

**Use of compost.** The proposed 45-day interval between application of compost and crop harvest is withdrawn.

**Water quality testing.** Generic E. coli will be the indicator of agricultural water quality, despite concerns about how well this represents food safety risks. (Agricultural water is that which contacts the edible portion of crop via irrigation, spraying, etc.)

FDA is withdrawing the previously proposed time intervals for testing of irrigation water (e.g. weekly for streams) and specific levels E. coli that would prohibit water use (a maximum of 235 CFU of generic E. coli per 100 ml in any one water sample, and a rolling average of 5 samples not to exceed 126 CFU.)

Instead, a tiered process of surface water testing is proposed. Growers would take at least 20 samples over 2 years, every 10 years, to develop a 'water quality profile.' Then, they would take at least 5 samples annually to confirm that profile. The samples are to be taken 'as close as practical to harvest.' Ground water testing would involve taking 4 samples for the baseline, with one sample for annual confirmation.

If the water profile, or the annual testing, has an STV (statistical threshold value) over 410 CFU, or if the GM (geometric mean) of all samples exceeds 126 CFU, then a new profile must be developed and steps must be taken to allow die off of potentially dangerous microbes before the water can be used for direct application during growing of covered produce. Those steps include: 1) allowing a sufficient interval of days between last irrigation and harvest, 2) allowing a sufficient interval of days between harvest and the end of crop storage, or, 3) appropriate pathogen removal rates result from activities like washing.

FDA proposes using a 0.5 log per day die-off rate (~68% reduction per day, from the previous day) between irrigation and harvest. This should allow harvest to take place after a reasonably short wait in most cases. No specific die-off rate is proposed for storage or washing; farmers would be able to set these for their own crops and conditions based on scientific data. They do not need FDA approval but must provide the data upon request.

FDA will provide guidance to assist farmers to implement the water testing requirements, if finalized, including tools to calculate the GM and STV. (Note: the STV is the 90th percentile of the samples, the point at which 10 percent of samples have a higher value. The GM is like an average; it is then nth root of the n samples multiplied together.)

**Stay tuned** for more explanation and interpretation of these revisions. Feel free to contact me with questions or concerns [vernon.grubingter@uvm.edu](mailto:vernon.grubingter@uvm.edu)