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Food Safety Modernization Act (FSMA): Produce Safety Rule Agricultural Water, Introduction

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The FSMA Produce Safety Rule

The U.S. Food and Drug Administration (FDA)'s Food Safety Modernization Act (FSMA) was signed into law in 2011 with the goal of preventing food safety problems. The FSMA Produce Safety Rule (PSR) is the first mandatory federal standard for fruit and vegetable production in the United States. Prior to FSMA, growers, packers, and the produce industry were encouraged to follow voluntary guidance such as the FDA's 1998 "Guide to Minimize Food Safety Hazard for Fresh Fruits and Vegetables."

The final FSMA Produce Safety Rule was published in the Federal Register on November 27, 2015. The rule took effect 60 days later. This rule might affect different farms and businesses based on operation size, type of produce crops grown, gross sales, and other factors. Fruit and vegetables considered "covered produce" (covered by the law) must follow the rules and regulations of FSMA in order to be legally grown for consumption. The compliance dates for all covered products can be found in **Table 1**.

Water Requirements

The FDA has very detailed guidelines for handling produce when it might touch water or a surface that is wet. Water in this situation would be called agricultural water. There are two kinds of agricultural water: water used to grow and care for the plants (production water) and water used to wash the produce during harvest and after it is picked (post-harvest water). The water requirements apply to any raw produce for sale (which includes 98 specific fruits and vegetables) grown within the US that will be shipped or sold in any state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Table 1: Produce Safety Rule Compliance Dates

Business size (gross sales)	Compliance date for **sprouts**	Compliance date for **most produce**	**Water**-related compliance date
All other businesses (>$500K)	1/26/2017	1/26/2018	1/26/2022
Small business (>$250K-500K)	1/26/2018	1/28/2019	1/26/2023
Very small business (>$25K-250K)	1/28/2019	1/27/2020	1/26/2024

Source: producesafetyalliance.cornell.edu

Production Water

Production water includes any water that has direct contact with the produce before it is harvested; this includes watering (irrigation), fertilizing, pest and chemical sprays, and water used for cooling or protecting plants from freezing. In order to follow the guidelines of the law, the grower must know where the water came from, so he or she can use the right test to monitor it. Production water comes from four main sources: public/municipal drinking water, groundwater, surface water, and reclaimed water. One key regulation within FSMA is monitoring the amount of generic Escherichia coli (E. coli) and the "sanitary quality" of the water, and keeping a record of these findings, called a water quality profile (WQP). Each water source must be tested for bacteria. Growers have to watch two measurements of bacterial growth in the water: numerical geometric mean (GM), which is a special type of average, and

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statistical threshold value (STV), which is used for determining the range. These two numbers are used to create a microbial water quality profile (MWQP). The GM and STV numbers will be translated into another statistic called colony forming units (CFU), or the number of groups of bacteria that can form living colonies in a given sample. CFU is also defined as the units used for expressing the number of viable microbial colonies present in a given sample.

Unless the production water is a public or municipal water source (such as a city water supply), which has already been tested, the FSMA says that the water must be tested to determine its water quality profile. Here are the FDA limits for the presence and distribution of generic E.coli in a water source.

1. The GM of generic E. coli in the sample must be less than or equal to 126 colony forming units (CFU) / 100 mL water, and
2. The STV of generic E. coli in the sample must be less than or equal to 410 CFU / 100 mL water.

It is possible to use the water appropriately, test regularly, and take action to keep levels in range. **Figure 1** below is an example of MWQP chart.

Calculating Bacteria Levels

Geometric Mean

As you might recall from school, arithmetic mean is a simple average found by adding up a group of numbers and dividing by how many numbers were in the group. Geometric mean (GM) is a special average similar to arithmetic mean except that the numbers (**Table 2**) are first converted to logarithmic scale (**Table 3**) before you find the average of the numbers. The below mentioned example will describe how a geometric mean is calculated.

Table 2: Results of Year 1 Water Sample

Sample #	Results (CFU/100ml)
1	73
2	260
3	900
4	5500

We need to convert the data in the table above to a logarithmic scale to calculate the geometric mean. You will need a scientific calculator to make these calculations.

We performed a log transformation by entering the each value from table 2, and then pressing the "LOG" button on our scientific calculator. (i.e. enter 73, press "log", result is 1.863) Once the transformations are done, to get the average:

Table 3: Log transformation of year 1 water sample

Sample #	Results (CFU/100ml) After Log Transformation
1	1.863
2	2.415
3	2.954
4	3.74

1. Add the results (1.863+2.415+2.954+3.740 = 10.972) which should be 10.972.
2. Divide this number by the total number of samples which in this example is 4 (10.972/4 = 2.743).
3. The average of these 4 log-transformed results is 2.743. Next, the log transformed answer has to be converted back to the regular scale. This can be done by using an anti-log function on a calculator (10x) or using the POWER function in Excel.

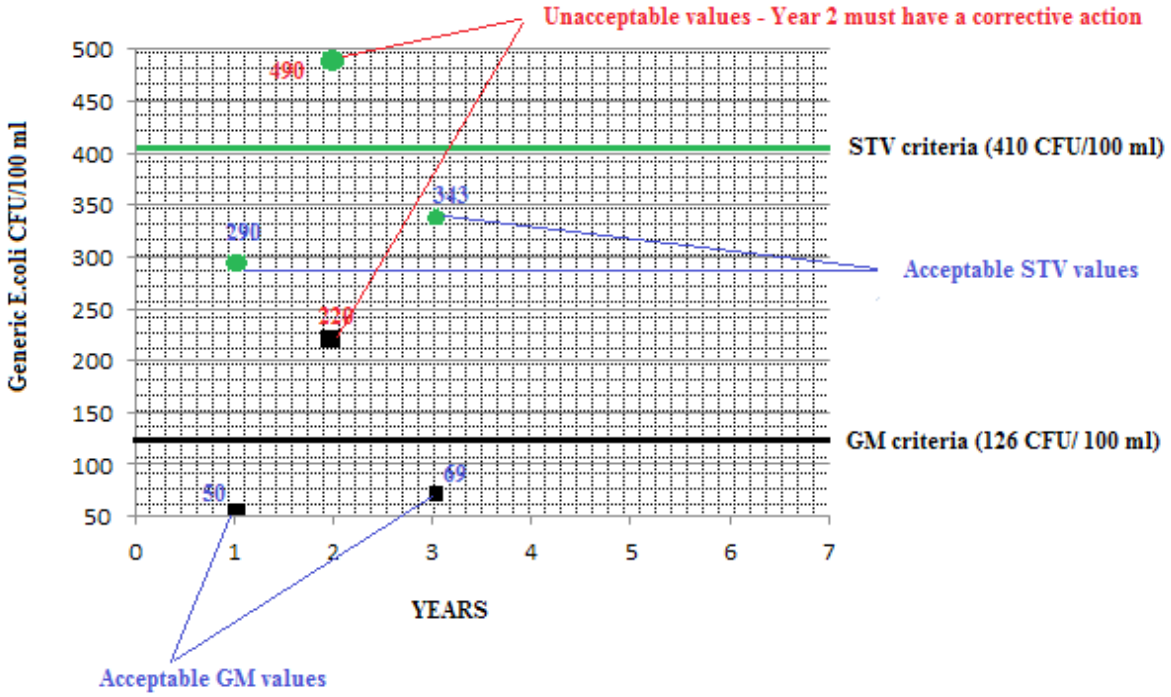
Since the log-transformed value of the GM is 2.743, the regular value of the GM is the antilog of 2.743, which is 553.35, or rounded, 553 CFU/100 ml.

Statistical Threshold Value - STV is a measure of variability which is used for estimating range based on the obtained results. It is complicated to understand the STV value; and we would recommend using a good STV calculator such as the one available from the University of California-Davis (http://ucfoodsafety.ucdavis.edu/files/268306.xlsx)

Public/municipal water

Water sourced from a public water supply (typically called "city" or "municipal" water) is usually tested to see if the water is acceptable according to the Safe Drinking Water Act requirement (free of detectable generic E.coli / 100 ml). Thus, public water has a very low risk of carrying pathogens. According to PSR, farms using public/municipal water do not have to be tested as long as the growers can show a certificate of compliance from their county that the water meets the requirement during an audit. These certificates of compliance are usually available on the municipal water companies' website.

Figure 1 - MWQP chart with GM and STV



Groundwater

Groundwater is a source of production water that usually comes from wells. According to FSMA, groundwater needs testing because many things in the environment and in the handling can contaminate it. PSR requires growers to test groundwater several times the first year and annually after that for calculating the MWQP. During the first year, growers must take at least 4 samples throughout the growing season or over the period of a year. After that, they must take at least 1 sample every year or growing season to develop the MWQP report. The MWQP report must be updated every year with the most recent data added to the previous 4 years to make a rolling data set for untreated groundwater sources.

Table 4: Microbial water quality profile for groundwater

Year	Testing frequency and timing
Year 1	4 times throughout growing season
Year 2, 3, etc.	1 time during season or over course of 1 year

Surface Water

Generating a MWQP for surface water requires more samples, since the quality of the water can change more often than groundwater. Surface water includes rivers, streams, lakes, ponds, manmade reservoirs, and any other water source that is open to the environment. PSR requires growers to do an early round testing on surface water to make a MWQP to see if the water is okay for the intended use. PSR requires growers to collect a minimum of 20 samples over at least two years (but not more than 4 years), with samples being taken as close in time as possible before harvest. After gathering this data, PSR requires a minimum 5 new samples taken every year and added to the existing MWQP to create a rolling data set.

Table 5: Microbial water quality profile for surface water

Year	Testing frequency and timing
First 2-4 years	**Minimum 20 samples** taken over at least 2 years, but not more than 4 years
Following years	**5 or more *new*** samples analyzed each year

Post-harvest water

Post-harvest water is water used during harvest and for post-harvest activities such as washing, cooling, and packaging. Post-harvest water must meet the potable (drinkable) water standard, which is no detectable generic E.coli per 100 mL of sample. Agricultural Water Sampling.

The sample must be typical of the water used for this purpose. Here are some best practices for sampling water, according to the Produce Safety Alliance:

1. The person collecting water samples should follow all sampling instructions from the laboratory, if provided.

2. Samples must be collected in a clean way, using a clean (sterile) bottle; the person collecting the water should even be careful about dirtying the inside of the bottle while taking off the lid.

3. The person collecting samples must not rinse or wash the sterile bottle before collecting samples.

4. When sampling a river or pond, take one sample that is as close to where the water is pulled from the source as possible.

5. When sampling well water, the sample should be collected at the tap used to draw production water. Run the water for a few minutes before collecting the sample. How long you run it before sampling depends on how the water is distributed or used; generally, water in a piped system should run 3-6 minutes or until the water temperature stabilizes throughout.

Testing methods

The FDA says that the following methods are scientifically valid and compare to more formal kinds of water testing in accuracy, precision, and sensitivity. The most prescribed and preferred method for testing a water sample is method 1603, which is listed first below. However, you can also use the other methods listed below to determine the generic E. coli count. If you are sending your samples for analysis, ensure that the lab you choose is using one of the methods below.

1. Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC) (September 2014). U.S. Environmental Protection Agency. EPA-821-R-14-010.

2. Method 1103.1: Escherichia coli (E. coli) in Water by Membrane Filtration Using membrane-Thermotolerant Escherichia coli Agar (mTEC) (March 2010). U.S. Environmental Protection Agency. EPA-821-R-10-002.

3. Method 1604: Total Coliforms and Escherichia coli in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002). U.S. Environmental Protection Agency. EPA-821-R-02-024.

4. 9213 D: Natural Bathing Beaches (2007). In: Standard Methods for the Examination of Water and Wastewater, 22nd Edition (Rice E.W., U.S. Food and Drug Administration 5001 Campus Drive College Park, MD, 20740 www.fda.gov et al., Ed.), 9-46 – 9-48. Washington, DC: American Public Health Association. (2012).

5. 9222 B: Standard Total Coliform Membrane Filter Procedure (1997), followed by 9222 G – MF Partition Procedures (1997) using NA-MUG media. In: Standard Methods for the Examination of Water and Wastewater, 21st Edition (Eaton A.D., et al., Ed.), 9-60 – 9-65, and 9-70 – 9-71, respectively. Washington, DC: American Public Health Association. (2005).

6. D 5392-93: Standard Test Method for Isolation and Enumeration of Escherichia coli in Water by the Two-Step Membrane Filter Procedure. In: Annual Book of ASTM Standards, Volume 11.02. ASTM International. (1996, 1999, 2000).

7. Hach Method 10029 for Coliforms: Total and E. coli, using mColiBlue24 Broth PourRite Ampules.

8. IDEXX Colilert Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.

9. IDEXX Colilert-18 Test Kit, but only if using IDEXX QuantiTray/2000 for quantification.

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For additional information, contact your local County Extension agent