Food & Drug Administration (FDA)
Food Safety Modernization Act (FSMA)
FDA FOOD SAFETY MODERNIZATION ACT

• Suite of rules to enhance the safety in our food system
• Primary focus: Growing, Harvesting and Post-Harvest Handling of Produce AKA Produce Safety Rule
• Prevention, no detection
Produce Safety Rule Timeline

- Draft released January 4, 2013
- First comment period closed November 22, 2013
- Proposed supplemental rule September 29, 2014
- Second comment period closed December 15, 2014
- Final rule expected October 2015
FSMA Produce Safety Rule

• Agricultural Water
• Biological Soil Amendments of Animal Origin
• Worker Health, Hygiene and Training
• Wild and Domestic Animals
• Equipment, Tools, Buildings and Sanitation
Agricultural Water Quality

- Ag water is used during growing activities for covered produce using direct application method
  - Direct application: overhead irrigation, topical sprays, frost protection, cooling, etc.
  - One exception: Sprouts
FDA Proposes

1. Microbial quality requirements consistent with 2012 EPA recreational water quality criteria (RWQC)
2. Provide allowance for microbial die-off between irrigation and harvest, 0.5 log per day
3. Provide allowance for microbial reduction between irrigation and end of storage
4. Apply appropriate microbial removal methods (i.e. washing)
5. Allow use of alternative in lieu of specified microbial die-off rate between irrigation and harvest
RWQC:

A GM of 126 or less generic *E.coli* CFU/100 mL water

&

An STV of 410 or less generic *E.coli* CFU/100 mL water
CFU= Colony Forming Unit

mL= milliliter

GM= Geometric Mean

STV= Statistical Threshold Value
Geometric Mean

What it is?
How do you calculate it?
The reason you use an arithmetic average for test scores is that each test score is an independent event.

If one student does really well or really bad it will not affect other scores.

$$50 + 35 + 35 + 40 + 150 = 310/5 = 62$$

Arithmetic Mean AVERAGE
The test results are not independent

Concentrations may vary anywhere (10-10,000) over a given period, variability expected

To dampen the effect of very high or low values we log transform the numbers and get a meaningful measurement of bacterial counts

Geometric Mean

\[ GM = (50 \times 35 \times 35 \times 40 \times 150)^{\frac{1}{5}} = 51.65 \]
Step 1
• Find log of each number
  • log 50 = 1.69; log 1.54 etc.

Step 2
• Add logs of all numbers
  • 1.69 + 1.54 + 1.54 + 1.60 + 2.17 = 8.54

Step 3
• Divide the sum by number of samples
  • 8.54/5 = 1.71

Step 4
• Find antilog \(10^x\)
  • This value is GM
Statistical Threshold Value

-Approximates the 90\textsuperscript{th} percentile of water quality distribution

- A value that should not be exceeded by 10% of samples taken (410 CFU/100mL)
Establishing a Baseline

• The proposed Produce Safety Rule requires a minimum 20 samples over 2 years to establish a geometric mean (GM) and a statistical threshold value (STV)
• Establishing a baseline of water quality can help identify when you may have a problem with your water source
• Water quality profile

Source: E. Bihn, G. Wall
Establishing a Surface Water Quality Profile

**START:**
Establish water quality profile
Take 20 samples over two years

**ANNUALLY AFTER START:**
Take 5 samples
Compare to established water quality profile

**SAMPLING DOES MATCH PROFILE:**
Continue to test 5 samples annually

**TEN YEAR RE-EVALUATION:**
Take 20 samples to establish a new water quality profile

**SAMPLING DOES NOT MATCH PROFILE:**
Use the 5 annual samples, plus an additional 15 new samples (20 total) to establish a new profile

**APPLY ALTERNATE METHODS:**
1. Time interval to achieve 0.5 log microbial die-off per day between water application and harvest
2. Time interval between harvest and end of storage to achieve microbial die-off
3. Other activities that may achieve microbial die-off, i.e. washing
4. Discontinue use

Source: E. Bihn, G. Wall
Visualizing Water Quality Trends

Comparing water test results to your baseline can help you identify possible risks in your water source.

Source: E. Bihn, G. Wall
Untreated Ground Water

Another tiered approach:

• Test 4 times during growing season or over 1 year
• Minimum of 4 samples collected as close to harvest as possible
• If samples meet applicable microbial standard, test once a year thereafter
• *Must test quality of each water source*
Indirect Water Application

- Water is not intended to, and is not likely to, contact harvestable portion of the crop not considered agricultural water
- Drip, Furrow, etc.
- This water is still subject to Section 402(a)(4) of FD&C Act

Source: E. Bihn, G. Wall
Postharvest Water Quality

Proposed microbial standard:

• No detectable generic *E. coli* per 100mL water
• ‘Potable’ or drinking water quality
• Includes: water used for washing or cooling activities and water used to wash hands
Data Sharing

• Farms using same water source with no identifiable sources of contamination between sampling sites and farms involved

• Third parties (i.e. co-ops) may share data if they adequately represent your agricultural water and all other requirements of proposed rule are met

• Alternatives
Proposed Exemptions

Proposed standard states there is no requirement to test water when:

• You receive water from public water system (obtain test results)
• Your water is treated in a matter proven safe and appropriate for intended use
Agricultural Water – Proposed Microbial Standards

Is the water sourced from a public water system/supply and do you have required documentation? [112.45 (a)(1) or 112.45 (a)(2)]

Yes: No Testing Required [112.45(a)]

OR

Is the water treated following the requirements in section 112.43 of the proposed produce safety rule? [112.45 (a)(3)]

Yes: Microbial standard for such use: The geometric mean is not to exceed 126 colony forming units (CFU) of generic E. coli per 100 mL and the estimate of the statistical threshold value (STV) of samples must not exceed 410 CFU of generic E. coli in 100 mL of water. (The STV approximates the 90th percentile of the water quality distribution and is intended to be a value that should not be exceeded by more than 10 percent of the samples taken.) [112.44(c)]

No

Is the water intended to or likely to contact the harvestable portion of produce (other than sprouts) or food contact surfaces during growing? [112.44(c)]

Yes: The water may still be used for this purpose if you:
- Meet the microbial standard using a calculated die-off or removal rate:
  - Apply an appropriate time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day, and/or;
  - Apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate, provided there is adequate supporting scientific data, and/or;
  - Apply appropriate microbial removal rates, provided there is adequate supporting scientific data, during activities such as commercial washing, or;
- Discontinue use of that source of agricultural water until the water system is re-inspected; potentially hazardous conditions are identified; necessary changes are made; and the water is retested and shown to meet the standard, or;
- Treat the water in accordance with the requirements of 112.43, or;
- Establish and use alternatives to the microbial standard and/or the 0.5 log/day microbial die-off rate, provided there is adequate supporting scientific data as described in 112.12.

No

If the water source does not meet the standard above, can it still be used during growing, in contact with covered produce (other than sprouts)?

Yes

Is the water used to make treated agricultural teas? [112.44(a)(3)]

No

Is the water used as sprout irrigation water? [112.44(a)(1)]

No