



Are you Ready for Implementation of the FSMA Produce Safety Rule?

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Proposed Produce Safety Rule

What does the proposed produce safety rule establish?

- The proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms.
- To that end, the rule proposes new standards in the following major areas:
 - Worker Training and Health and Hygiene
 - Agricultural Water
 - Biological Soil Amendments of Animal Origin
 - Domesticated and Wild Animals
 - Equipment, Tools, and Buildings





Proposed Produce Safety Rule

What is covered?

- Applies to raw agricultural commodities, including fruits, vegetables, mushrooms, tree nuts, sprouts and mixes of intact fruits and vegetables:
 - Applies to domestic and imported produce
 - Covers the harvestable portion (including peels) but not the rest of the plant
 - Exhaustive list of “rarely consumed raw” not covered
 - Does not apply to produce that is commercially processed (That’s Preventive Controls)
 - Must have records of who processed it



Proposed Produce Safety Rule

- Biggest change in the 09/2014 supplement:
- Water that...
 - Directly contacts the harvested produce preharvest:
 - Geometric Mean (GM)
<126 *E. coli* in 100 ml
 - Statistical Threshold Value (STV)
<410 *E. coli* in 100 ml





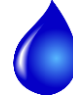
New Sampling Under FSMA Proposed Produce Safety Rule

- Agricultural Water Testing Frequency
 - Untreated ground water
 - Test at least four times each year or growing season as close to harvest as practical to establish water quality profile
 - If water meets requirements of use
 - Test at least once annually
 - If water fails, increase testing back to four times annually to reestablish quality



Proposed Produce Safety Rule

- Agricultural Water Testing Frequency
 - If you use untreated surface water
 - Establish a baseline survey to develop a water quality profile
 - Minimum of 2 years
 - Minimum of 20 samples
 - Collected as close as practical to harvest
 - Include Geometric Mean and STV

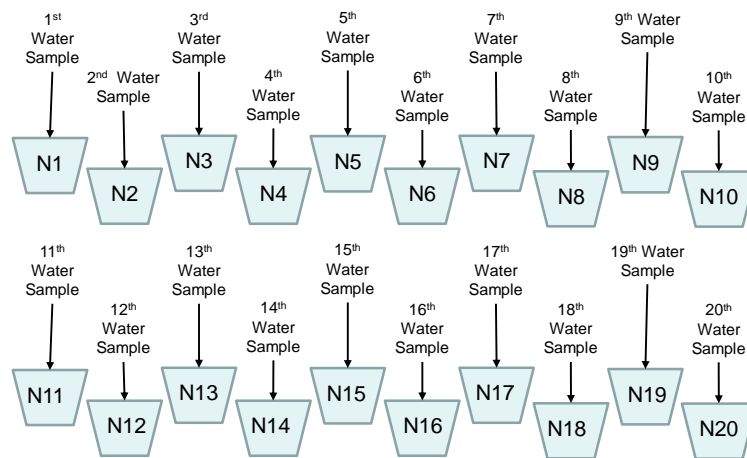


Proposed Produce Safety Rule

- Agricultural Water Testing Frequency
 - After the baseline survey, you must test annually to verify water quality profile
 - Minimum of 5 samples per year
 - Collected at time periods as close to harvest as practical



Establishing a Water Quality Profile



20 water samples collected over 2 years





Establishing a Water Quality Profile

Use these 20 samples to calculate a Geometric mean (GM) and Statistical Threshold Value (STV)

$$\text{Geometric mean (GM)} = \frac{((N1)(N2)(N3)(N4)(N5)(N6)(N7)(N8)(N9)(N10)(N11)(N12)(N13)(N14)(N15)(N16)(N17)(N18)(N19)(N20))^{1/20}}$$

OR

$$\text{Antilog}((\log N1 + \log N2 + \log N3 + \log N4 + \log N5 + \log N6 + \log N7 + \log N8 + \log N9 + \log N10 + \log N11 + \log N12 + \log N13 + \log N14 + \log N15 + \log N16 + \log N17 + \log N18 + \log N19 + \log N20) / 20)$$

Statistical Threshold Value (STV) =

$$\text{Antilog}(\log \text{GM} + (1.28 \times \log \text{Standard Deviation}))$$

N12

N14

N16

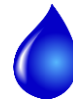
N18

N20

GM <126 *E. coli*/100 ml
STV <410 *E. coli*/100 ml



Geometric Mean Calculator



<http://ncalculators.com/statistics/geometric-mean-calculator.htm>

<http://easycalculation.com/statistics/geometric-mean.php>

(just google “free geometric mean calculator”)

Or you can use Excel “=geomean(x,y,z...)”

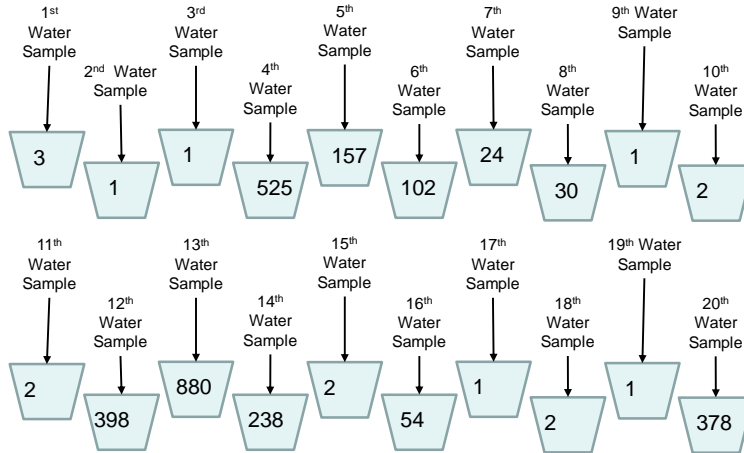
Still looking for an easy STV calculator – its tricky in excel

FDA should be generating one for public use





Establishing a Water Quality Profile - Example



20 water samples collected over 2 years

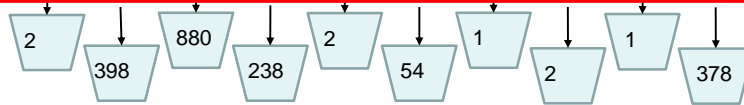


Establishing a Water Quality Profile - Example

Use these 20 samples to calculate a Geometric mean (GM) and Statistical Threshold Value (STV)

Geometric mean (GM) = $((3)(1)(1)(525)(157)(102)(24)(31)(1)(2)(2)(398)(880)(235)(2)(54)(1)(2)(1)(378))^{1/20}$

Statistical Threshold Value (STV) = Antilog $(1.18 + (1.28 \times 1.11))$



20 water samples collected over 2 years





Establishing a Water Quality Profile - Example

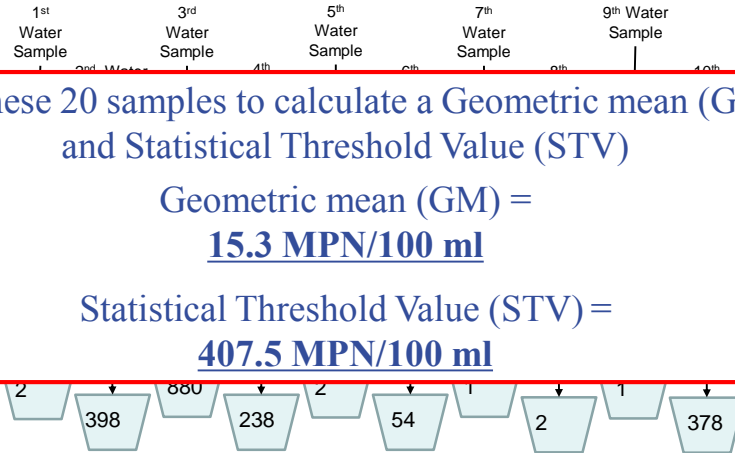
Use these 20 samples to calculate a Geometric mean (GM) and Statistical Threshold Value (STV)

Geometric mean (GM) =

15.3 MPN/100 ml

Statistical Threshold Value (STV) =

407.5 MPN/100 ml



20 water samples collected over 2 years



Proposed Produce Safety Rule

What to do if your water exceeds the rule?

- Option 1: Preharvest interval
 - Apply a time interval (in days) between last irrigation and harvest
 - Assume a die off rate of 0.5 log per day
 - Die off rate can be higher if industry data to support
 - Target is to reduce count in water to:
 - <126 *E. coli* in 100 ml geometric mean
 - <410 *E. coli* in 100 ml STV



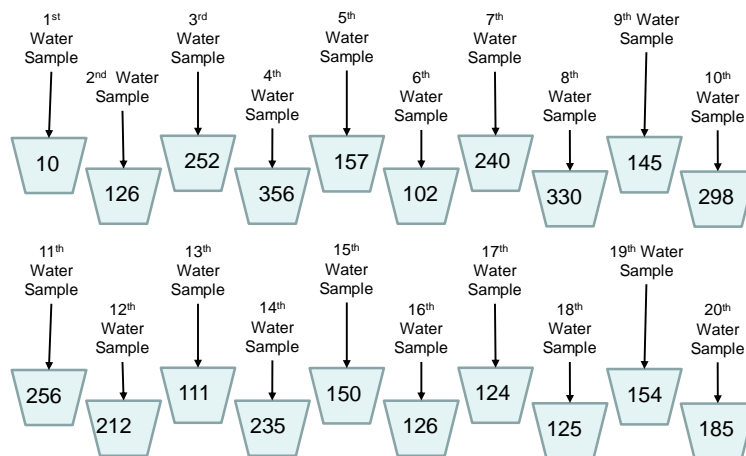


Proposed Produce Safety Rule

- Option 2: Harvest and storage interval
 - Apply a time interval (in days) between harvest and end of storage OR microbial removal rates during activities such as commercial washing
 - Rates must be calculated by industry and supported by data
 - Peer reviewed published is probably best, or done in house during verification activities
 - Target is to apply reduction to reduce count in water to:
 - <126 E. coli in 100 ml geometric mean
 - <410 E. coli in 100 ml STV



Water Quality Profile Does Not Meet Standard – Example 1

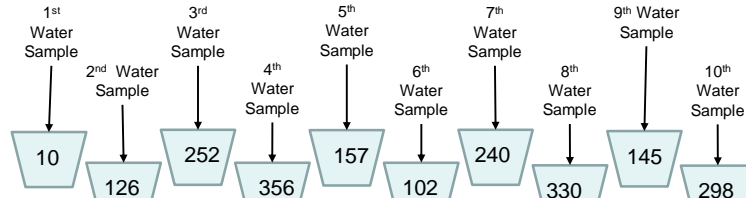


GM – 156
STV – 407

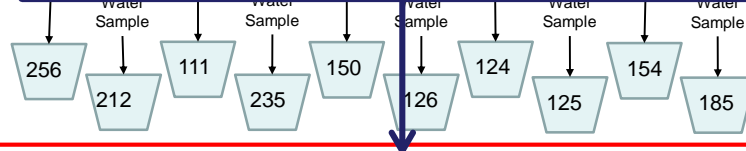




Water Quality Profile Does Not Meet Standard – Example 1



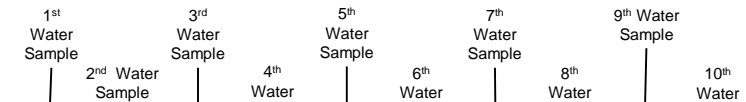
Need to decrease this number to 126



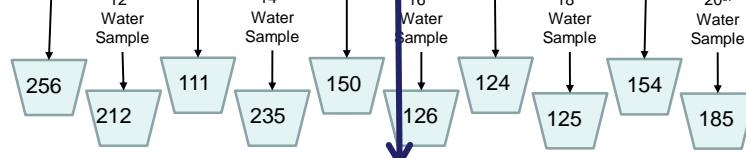
GM – 156
STV – 407



Water Quality Profile Does Not Meet Standard – Example 1



GM = 156 MPN/100 ml (2.2 log MPN/100 ml)
Rule = 126 MPN/100 ml (2.1 log MPN/100 ml)
2.2 – 2.1 = 0.1 log MPN/100 ml



GM – 156
STV – 407





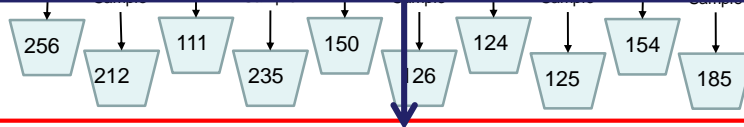
Water Quality Profile Does Not Meet Standard – Example 1

1st 3rd 5th 7th 9th Water

0.1 log reduction ml needed

Option 1 (Preharvest) – assume 0.5 log reduction per day;
1 day preharvest interval needed

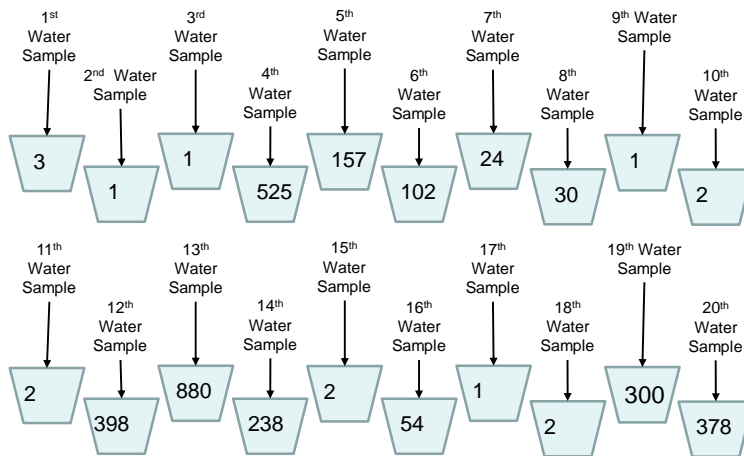
Option 2 (Postharvest) – need to hold product or
 implement validated process (i.e. washing) to get 0.1 log reduction



GM – 156
STV – 407



Water Quality Profile Does Not Meet Standard – Example 2

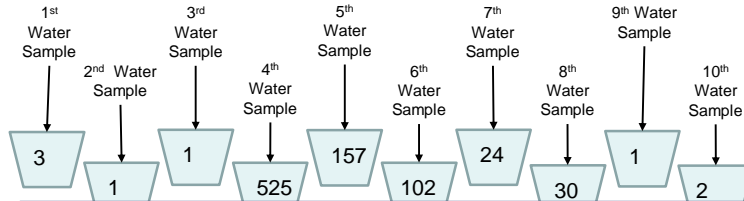


GM – 20
STV – 540

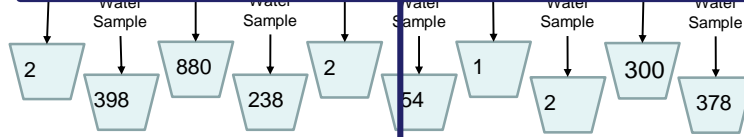




Water Quality Profile Does Not Meet Standard – Example 2



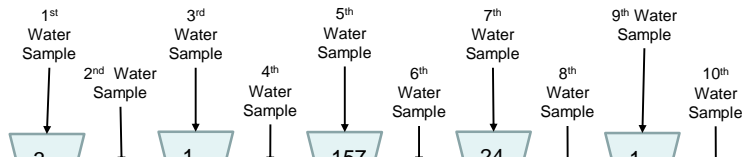
Need to decrease this number to 410



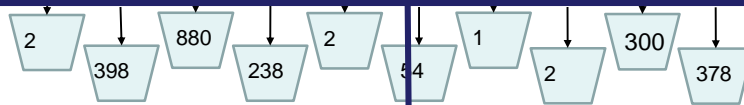
GM ↓ 20
STV – 540



Water Quality Profile Does Not Meet Standard – Example 2



STV = 540 MPN/100 ml (2.7 log MPN/100 ml)
Rule = 410 MPN/100 ml (2.6 log MPN/100 ml)
2.7 – 2.6 = 0.1 log MPN/100 ml



GM ↓ 20
STV – 540





Water Quality Profile Does Not Meet Standard – Example 2

1st Water 3rd Water 5th Water 7th Water 9th Water Sample

0.1 log reduction needed

Option 1 (Preharvest) – assume 0.5 log reduction per day;
1 day preharvest interval needed

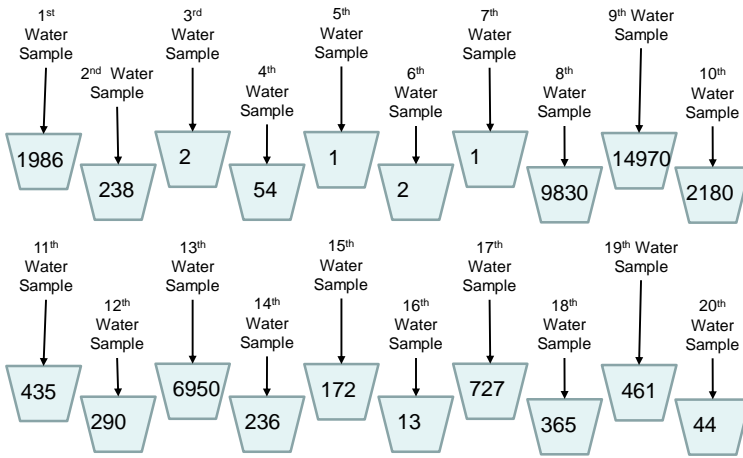
Option 2 (Postharvest) – need to hold product or
 implement validated process (i.e. washing) to get 0.1 log reduction



GM – 20
STV – 540



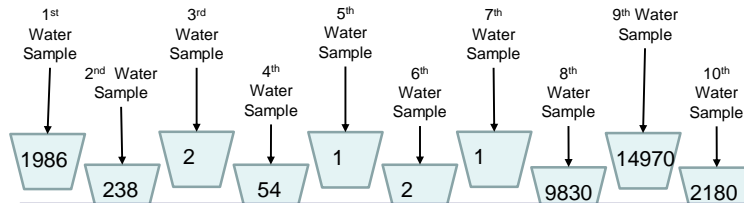
Water Quality Profile Does Not Meet Standard – Example 3



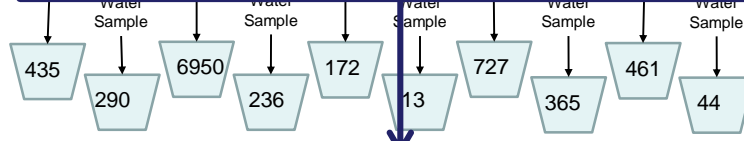
GM – 157
STV – 7,198



Water Quality Profile Does Not Meet Standard – Example 3



Both numbers need to decrease to 126 and 410, respectively



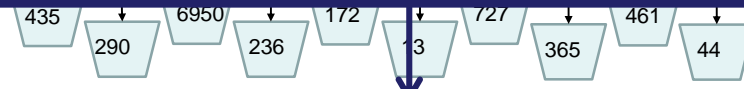
**GM – 157
STV – 7,198**



Water Quality Profile Does Not Meet Standard – Example 3

GM = 157 MPN/100 ml (2.2 log MPN/100 ml)
 Rule = 126 MPN/100 ml (2.1 log MPN/100 ml)
 $2.2 - 2.1 = \mathbf{0.1 \log \text{MPN/100 ml}}$

STV = 7,198 MPN/100 ml (3.8 log MPN/100 ml)
 Rule = 410 MPN/100 ml (2.6 log MPN/100 ml)
 $3.8 - 2.6 = \mathbf{1.2 \log \text{MPN/100 ml}}$



**GM – 157
STV – 7,198**



Water Quality Profile Does Not Meet Standard – Example 3

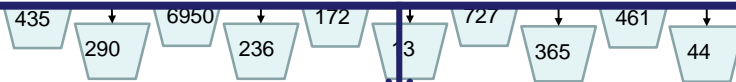
GM = 157 MPN/100 ml (2.2 log MPN/100 ml)
 Rule = 126 MPN/100 ml (2.1 log MPN/100 ml)

$2.2 - 2.1 = 0.1 \text{ log MPN/100 ml}$

Assume you take the more conservative reduction

STV = 7,198 MPN/100 ml (3.8 log MPN/100 ml)
 Rule = 410 MPN/100 ml (2.6 log MPN/100 ml)

$3.8 - 2.6 = 1.2 \text{ log MPN/100 ml}$



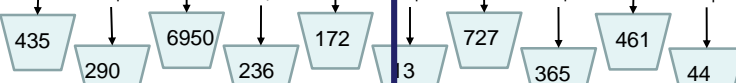
GM – 157
 STV – 7,198



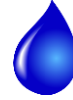
Water Quality Profile Does Not Meet Standard – Example 3

1st 3rd 5th 7th 9th Water

1.2 log reduction needed
Option 1 (Preharvest) – assume 0.5 log reduction per day;
3 day preharvest interval needed
Option 2 (Postharvest) – need to hold product or
 implement validated process (i.e. washing) to get 1.2 log reduction



GM – 157
 STV – 7,198

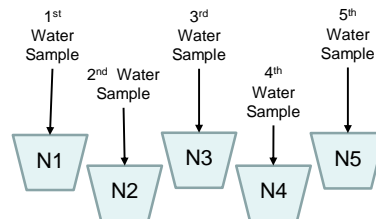


Proposed Produce Safety Rule

- What to do if your water exceeds the counts?
- If options 1 or 2 are not selected:
 - discontinue use of that water source
 - Treat the water



Annual Testing



5 water samples collected per year, as close to harvest as possible

Use these 5 samples to calculate a Geometric mean (GM) and Statistical Threshold Value (STV) to see if data supports the water quality profile





Proposed Produce Safety Rule

- Agricultural Water Testing Frequency
 - If GM and STV values of annual survey do not support water quality profile
 - Develop a new water quality profile of 20 samples
 - Can use annual survey data and combine with most recent baseline/annual survey data from prior years
 - Collect new data with annual survey data



Proposed Produce Safety Rule

- Agricultural Water Testing Frequency
 - If you know or have reason to believe the water quality profile no longer represents your water, you must develop an new water quality profile.
 - Significant changes in adjacent land use
 - Erosion
 - Other impacts outside your control



Proposed Produce Safety Rule

- Agricultural Water Testing Frequency
 - Water quality profile testing must be repeated every 10 years (if not earlier)



Compliance Dates by Business Size

Rule	2014	2015						
		Oct 31	2016	2017	2018	2019	2020	2021
Produce Safety	Proposed	Final	Large	Large	Water	Water		
			Small	Small	Small	Water	Water	
			V. Small	V. Small	V. Small	V. Small	Water	Water

Sup.

- Proposed
- Final
- Large
- Small
- V. Small
- Water

- Small – more than \$250,000 but no more than \$500,000 in produce sales
- Very Small – more than \$25,000 but no more than \$250,000 in produce sales





Training

Standardized curriculum to become
“qualified individual”

- Produce Safety Alliance: 
 - 1 day workshop
 - <http://producesafetyalliance.cornell.edu/>
- UF IFAS will offer courses in 2016
 - Watch for dates this fall
 - Working to generate funding to reduce costs (currently estimated at \$150/person)