



# **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: overheard 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

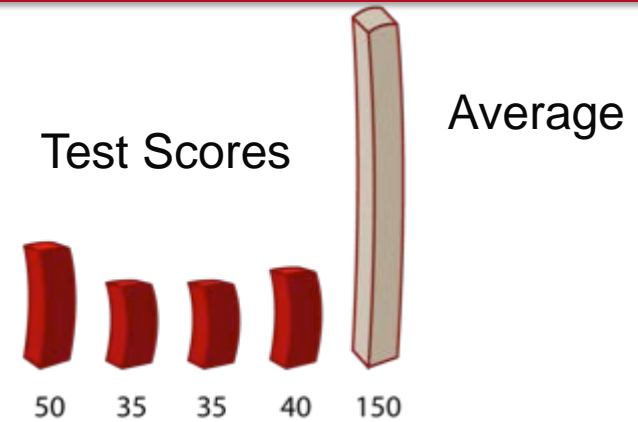
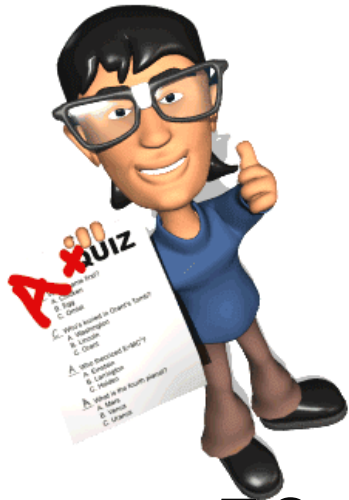




# Geometric Mean

What it is?

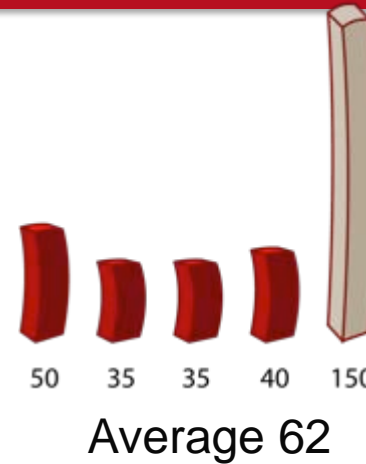
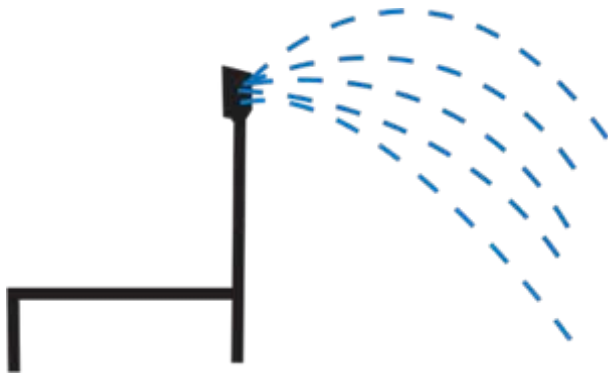
How do you calculate it?



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

## Arithmetic Mean AVERAGE

- 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.



$$GM = (50 \times 35 \times 35 \times 40 \times 150)^{1/5} = 51.65$$

## Geometric Mean

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



Step 1

- Find log of each number
- $\log 50 = 1.69$ ;  $\log 1.54$  etc.

Step 2

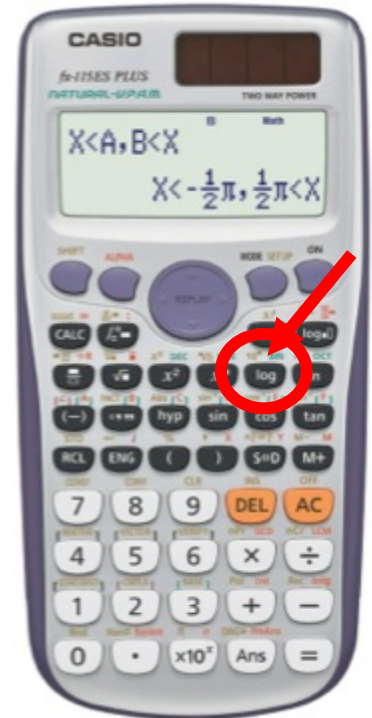
- Add logs of all numbers
- $1.69 + 1.54 + 1.54 + 1.60 + 2.17 = 8.54$

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<sup>th</sup> percentile of water quality distribution
- A value that should not be exceeded by 10% of samples taken (**410** CFU/100mL)

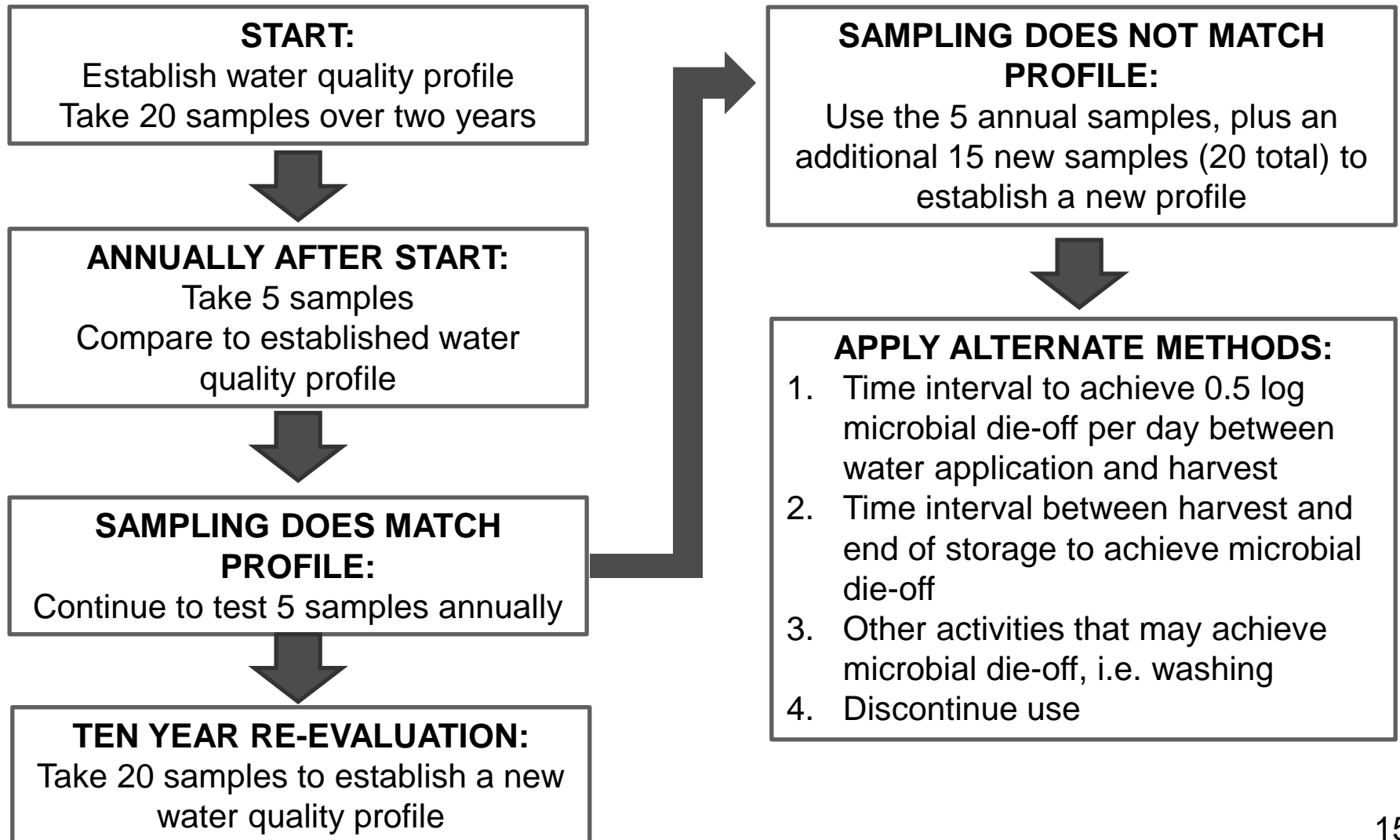


# Establishing a Baseline

- 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



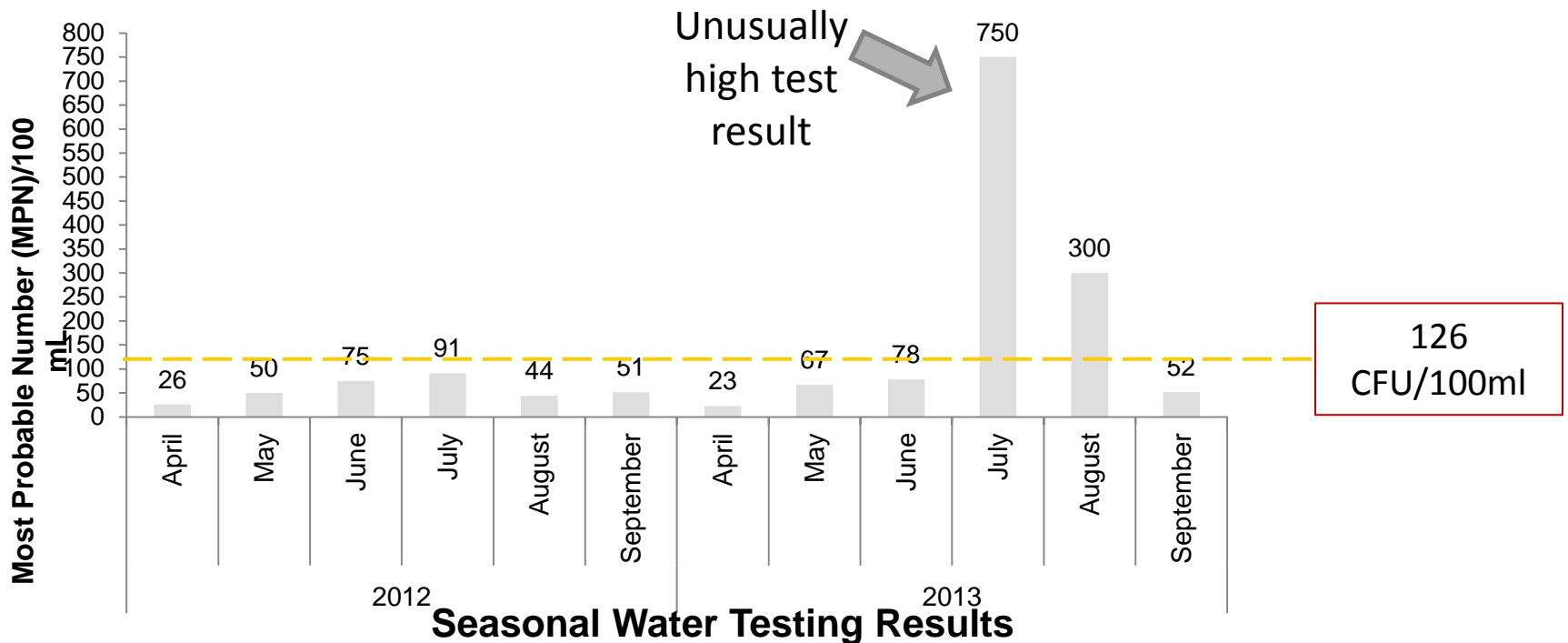
# Establishing a Surface Water Quality Profile





# Visualizing Water Quality Trends

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







# 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





# 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 manner proven safe and appropriate for intended use



## Agricultural Water – Proposed Microbial Standards

