

# Food Safety Modernization Act (FSMA) Water Standards of the Produce Safety Rule

- Act signed into law January 2011
  - Addresses an integrated food safety system
- 7 FSMA rules designed to be:
  - Preventive, science-based controls
  - Apply domestically and internationally
  - Affect from farm-to-fork



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- 2015 ISDA formed a FSMA Advisory Committee
  - Objective – determine level of participation in implementing FSMA at the State level
- 2017 committee decided to implement Produce Safety Rule at the State level
- Developed legislation followed by the promulgation of rules



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- Produce Safety Rule covers the on-farm activities of:
  - Growing, harvesting, packing and holding
  - Raw Ag Commodities (RACs) generally consumed raw
  - Water standards and testing ←
  - Animal intrusion
  - Health and hygiene of personnel
  - Biological soil amendment of animal origin

# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- 2019 marked the beginning of on-farm inspections of produce generally consumed raw
- To date ISDA has inspected 86 farms covered by Produce Safety Rule
- March 18, 2019 – FDA issued an extension of compliance dates for Subpart E – Agricultural Water
  - THE COMPLIANCE DATES FOR THE AGRICULTURAL WATER PROVISIONS (SUBPART E) ARE DELAYED TO JANUARY 26, 2024, FOR VERY SMALL BUSINESSES, JANUARY 26, 2023, FOR SMALL BUSINESSES, AND JANUARY 26, 2022, FOR ALL OTHER BUSINESSES.



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- Water Standards Definitions
  - Colony Forming Unit (CFU) – unit used to estimate concentration of microorganisms in sample
  - Geometric mean (GM) – measures a central tendency or in general an average
  - Standard Threshold Value (STV) – measures the amount of variation in the *E. coli* levels
  - Log reduction – estimates how many live bacteria will be eliminated by an activity (such as washing)





# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- Inspect all water systems under your control at least once annually (beginning of season)
- Test all water sources for general *E. coli* using EPA criteria for recreational water
  - Geometric mean not greater than 126 CFU per 100 mL, and
  - Standard Threshold Value (STV) of not more than 410 CFU per 100 mL
- Samples taken as close as practicable to pre-harvest, representative of use



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- Untreated Surface Water
  - Microbial Water Quality Profile (rolling data set) of 20 samples, used to calculate GM and STV
    - Span of 2 – 4 years
    - Yearly thereafter, 5 new samples
      - Combine with 15 most recent samples of the rolling data set
      - Recalculate new microbial water quality profile



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- Untreated Ground Water – used for growing produce
  - Microbial Water Quality Profile (rolling data set) – 4 samples, used to calculate GM and STV
  - Yearly thereafter, 1 new sample
    - Combine with 3 most recent samples of the rolling data set
    - Recalculate new microbial water quality profile





# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- Untreated Ground Water used for No detectable *E. coli* activities
  - Example of activities include:
    - Ice, cleaning and sanitizing, handwashing, or water that touches harvested produce
  - Microbial Water Quality Profile (rolling data set) – 4 samples, used to calculate GM and STV
- If 4 sample data set meet zero tolerance for *E. coli*:
  - Yearly thereafter, 1 new sample
    - Combine with 3 most recent samples of the rolling data set
    - Recalculate new microbial water quality profile
- If *E. coli* detected, stop use, must resume 4 sample testing until no detection



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- What if water does not meet standards (126 CFU GM/410 CFU STV)
  - Corrective actions might include:
    - Die off rate – applying amount of time between last irrigation and harvest or between harvest and end of storage (maximum of 4 days)
    - Treating water
    - Re-inspecting water system



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- [How do I calculate a Geometric Mean and Statistical Threshold Value](#)
- [Equivalent Testing Methodology for Agricultural Water](#)



Food Safety Modernization Act

FSMA ▾

Produce Safety Rule

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News/Updates

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# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- Alternatives to water standards
  - Apply to individual or individual facility
  - Must have adequate data or information to support alternative
  - Alternative must provide the same level of public health protection
- Can only be used for:
  - Microbial quality standard (126CFU)
  - Die off rate and maximum time interval
  - Number of samples for initial survey for untreated surface water
  - Number of samples for annual survey for untreated surface water



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

- Variance
  - Must relate to a regional condition
  - Applies to the region submitting the petition
  - Supply scientific data demonstrating procedures/process ensure same level of public protection
  - Submitted by a State or Foreign Country
  - FDA can approve, deny, modify or revoke a variance





# BSU Water Study Project Goals

- This project will address whether the number and frequency of samples outlined by the FDA is necessary for each producer along a given irrigation canal or stretch of river.
- Will collect the FDA required baseline dataset of 20 *E. coli* samples over two years at 60 sites
- Total suspended sediment and dissolved oxygen will also be measured at each location
- Water quality and geospatial data will be provided to each participating irrigation district



# BSU Water Study Draft Sampling Plan

- After contacting irrigators and irrigation districts across the western part of the Treasure Valley, two irrigation districts, Riverside and Farmers Co-Op have decided to participate in the study
- Working in coordination with the irrigation districts ensures that our samples will be beneficial to the greatest number of users while collecting statistically robust data to analyze
- The detailed sampling plan is currently being developed to be reviewed by the irrigation districts



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## General Sampling Plan:

3, 5-mile reaches, 5 miles apart on each canal with 10 samples, 0.5 mi apart



# Food Safety Modernization Act Water Standards of the Produce Safety Rule

Produce Safety Rule Questions Contact

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