Produce Safety Rule Update:

Subpart E – Agricultural Water

Review, Requirements, Reassessment

February 27, 2018
Review of Relevant Criteria

• Current industry practices

• 2014 Memo: Review of Water Quality Standards
  – Relevant World Health Organization recommendations
  – EPA’s 1986 and 2012 criteria for recreational water
Current Industry Practices

• GAPs
  – Voluntary Program
• Third-party audits
• Buyer requirements
• Commodity-specific guidelines
World Health Organization

- Guidelines for the use of reclaimed wastewater for irrigation of root crops and leafy crops
- Approach is to present several options for managing risks of reclaimed wastewater – “Health Protection Measures”
- Tolerable disease burden should be no greater than that adopted for drinking water
- Based on our evaluation:
  - Illustrations are only examples of how to apply the guidelines, and;
  - they do not represent specific criteria
EPA Criteria

• Fecal indicator organisms have been used to predict the presence of pathogens that can cause gastrointestinal (GI) illness

• 1986 AWQC
  – 126 CFU/ 100 ml *E. coli* (GM, n=5)
  – 235 CFU/ 100 ml *E. coli* SSM

• 2012 RWQC
  – 126 CFU/ 100 ml *E. coli* rolling GM over 30 days
  – 410 CFU/ 100 ml *E. coli* STV for 90th percentile
Summary

• Waters evaluated by EPA can be reasonably representative of agricultural surface waters typically used in produce production

• 36 NGI/1000 primary recreators

• $10^{-6}$ DALY per produce consumer per year
Agricultural Water – Proposed

• Specific criteria for quality of water used for certain purposes, and analytical testing
  – 235 CFU generic *E. coli* per 100 ml standard
    • For direct contact with covered produce (other than sprouts) during growing
    • Alternatives permitted that provide same level of public health protection
  – No detectable generic *E. coli* standard
    • For highest risk uses
Agricultural Water – Proposed

• Frequency of water testing
  – At the beginning of each growing season
  – Every 3 months thereafter during the growing season
  – **No requirements to test when:**
    • Farm receives water from a Public Water System or a public water supply that meets microbial requirements; or
    • Farm treats the water
  – **For untreated surface water**
    • Where runoff into the source is likely: test every 7 days during growing season
    • Where runoff into the containment is minimized: test at least 1x/month during growing season
Agricultural water – Proposed

• Follow-up action required:
  – when a farm determines or has reason to believe that its agricultural water is not safe and of adequate sanitary quality for its intended use; or
  – when water tested does not meet microbial standards
  – Then required to either re-inspect agricultural water system, identify conditions likely to introduce pathogens to produce or food-contact surfaces, make changes, & retest water; OR
  – Treat water
Agricultural Water –
Microbial Quality Standard

- Public Comments
  - More restrictive than necessary to protect public health
  - Not appropriate for all commodities
  - Many water sources do not meet standard
  - Provisions for alternatives insufficient
Agricultural Water – Microbial Quality Standard

• **FDA Action in Supplemental Proposal**
  Updated standard for water used during growing by direct application:
  – Geometric mean of no more than 126 CFU generic *E. coli* /100 mL
  – Statistical Threshold Value (STV) (approximates the 90\textsuperscript{th} percentile) not to exceed 410 CFU generic *E. coli* /100 mL
Agricultural Water –
Microbial Quality Standard

- FDA Action in Supplemental Proposal
  Updated standard for water used during growing by direct application:
  - New provisions to achieve the microbial quality standard after accounting for microbial die-off, removal:
    - Apply time interval in days between last irrigation and harvest using 0.5 log/day reduction rate (or other appropriate alternative rate); and/or
    - Apply time interval in days between harvest and end of storage using an appropriate reduction rate (e.g., removal during commercial washing or natural die-off during extended storage)
Agricultural Water – Frequency of Testing

• **FDA Action in Supplemental Proposal**
  – Tiered approach to testing untreated surface water used during growing by direct application method:
    • Baseline survey of water quality profile, during time period(s) as close as practical to harvest (over 2 years) to determine appropriate use
    • Annual verification survey to verify water quality
    • Re-establish water quality profile once every 10 years using annual data (or sooner, if necessary)
Agricultural Water – Frequency of Testing

• FDA Action in Supplemental Proposal
  – Tiered approach to testing untreated ground water
    • Baseline testing 4 times during growing season or year
    • Annual verification testing once during growing season or year
Agricultural Water - Final

Water used during growing activities for produce other than sprouts

• Frequency of testing dependent on water source
  – Lower frequency for untreated groundwater
  – Higher frequency for untreated surface water

• Microbial Water Quality Profile (MWQP)
  – Initial survey to develop MWQP
    • Minimum of 2 years, but no more than 4 years
  – Annual survey to update MWQP using a rolling dataset
  – Re-characterize MWQP under certain conditions

• Enables farms to understand their water source to determine appropriate use
Stringency of microbial criteria is dependent on use:

• For activities e.g. post-harvest wash, sprout irrigation
  – No detectable generic *E. coli*

• For growing activities such as non-sprout irrigation
  – GM of 126 CFU/100 mL or less generic *E. coli* and STV of 410 CFU/100 mL or less generic *E. coli*
    • Allows for microbial die-off in-field, between last irrigation and harvest, of up to 4 consecutive days
    • Allows for microbial reduction or removal post-harvest, including through commercial practices or storage
Same Level of Public Health Protection

• Are the relevant data and information in support of the use of a measure sufficient to make a determination?

• Are there any unique considerations relevant to the level of public health protection provided by that measure?

• Was the evaluation of scientific and technical evidence conducted by competent individuals using an appropriate process?

• Is the determination of “same level of public health protection” properly documented?
Current Status

• Reassessment
• Compliance dates
• Outreach activities
Reassessment

• FDA is considering how it might simplify agricultural water requirements
• What input will FDA consider?
• Stakeholder engagement

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm546089.htm
Agricultural Water Compliance Dates

• Proposed rulemaking to extend compliance dates for agricultural water to 2022 for the largest farms (other than sprouts)
  – Comment period closed November 13, 2017
• As we continue to work with stakeholders on issues regarding the agricultural water requirements, we do not intend to take enforcement action on agricultural water requirements for produce (other than sprouts)
• Farms may choose to continue with current water testing programs
Outreach Activities

• Summits and meetings
• Technical experts
• Farm visits
Summits and meetings

• CPS Agricultural Water Testing Methods Colloquium
  – April 6-7, 2017 in Irvine, CA
Equivalent Testing Methodology

• Currently, 9 methods included in this list
• We will consider adding more in the future

https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm575251.htm
Summits and meetings

• CFSF: Agricultural Water Standards and Testing Protocols
  – October 3, 2017 in Washington, DC

• PSA Agricultural Water Summit
  – February 27-28, 2018 in Covington, KY
Contact Information

Chelsea Davidson
(Chelsea.Davidson@fda.hhs.gov)

- & -

Kruti Ravaliya
(Kruti.Ravaliya@fda.hhs.gov)