

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 90 th 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

Original Proposal



Supplement to the Original
Proposal



Final Produce Safety Rule



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 90th 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

Agricultural Water - Final



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)