Agricultural Water: 2015 Produce Safety Rule

Presenters

Samir Assar

Director, Division of Produce Safety

Center for Food Safety & Applied Nutrition, FDA

Kruti Ravaliya

Consumer Safety Officer, Division of Produce Safety,

Center for Food Safety & Applied Nutrition, FDA

Overview of Agricultural Water Requirements in 2015 Rule

- Safe and adequate sanitary quality of water
- Inspection of water system under farm's control
- Water treatment, if a farm chooses to treat water
- Tiered approach to water testing
- Specific microbial criteria for water used for certain purposes
- Corrective measures
- Records requirements

2015 Requirements

For water used during growing activities for produce, other than sprouts

- Frequency of testing dependent on water source
- Microbial Water Quality Profile (MWQP)
  - Initial survey, annual survey to update MWQP, and re-characterize MWQP under certain conditions
- Enables farms to understand their water source to determine appropriate use
- Microbial criteria: for agricultural water directly applied to growing produce during pre-harvest activities, the criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV)
  - The GM of samples is 126 or less CFU of generic E. coli per 100 mL of water and the STV of samples is 410 CFU or less of generic E. coli in 100 mL of water.

2015 Requirements

Corrective Measures

- If water exceeds GM/STV, farms would take corrective measures as soon as practicable, but no later than the following year.
- Options include:
  - Microbial die-off between last irrigation and harvest and/or between harvest and end of storage
    - Could also apply a calculated log reduction during activities such as commercial washing
  - Re-inspecting the ag water system, and, among other steps, making necessary changes
  - Treating the water.

Initial Stakeholder Engagement

- 2015:
  - FDA conducted a webinar with over 400 participants, in which FDA SMEs discussed the significant provisions of the Rule and answered questions
  - SMEs discussed the regulation at a series of public meetings held in the US and abroad
- 2016-2017
  - Outreach and education to inform stakeholders about the PSR requirements through speaking engagements and participation in conferences convened by a broad range of stakeholders
  - Educational farm visits with state partners across the US

Initial Stakeholder Feedback

- industry stakeholders found certain provisions of subpart E to be the difficult to understand, translate, and implement in their operations, for example:
  - Inflexible, “one-size-fits-all” approach;
  - Too complicated to understand and implement
  - Difficult to implement

FDA Actions

- Reassessment
  - In 2017, FDA announced intent to consider ways to simplify the requirements
- Additional Stakeholder Engagement, including:
  - PEW/Robert Wood Johnson Foundation Collaborative Forum
  - PSA Ag Water Summit
  - Education farm visits
  - Listening sessions
  - Comments submitted to various dockets
- Compliance date extension
  - To address questions about implementation and identify opportunities to enhance flexibility, we issued a proposed compliance date extension in 2017, which was finalized in 2019

Collaborative Forum

- Sponsored by PEW Charitable Trusts and the Robert Wood Johnson Foundation.
- Several alternatives identified, including:
  - retaining pre-harvest testing requirements and issuing companion guidance
  - replacing pre-harvest testing requirements with a qualitative standard and issuing companion guidance
  - adopting private industry standards in short-term while researching -analyte(s) and numerical thresholds;
  - performing quantitative microbial risk assessment to identify index and/or indicator organisms
- Other areas identified for consideration included qualitative standards, data sharing, and the need for additional guidance

Produce Safety Alliance Water Summit

- FDA subject matter experts joined more that 250 other participants to discuss implementation challenges around subpart E
- Summit participants identified several complex factors associated with agricultural water, including:
  - variability in water source quality
  - method of water application to the crop
  - commodity characteristics that influence vulnerability to contamination
  - regional climatic effects.
- Summit participants identified agricultural water assessments as a promising approach for science-based management decisions that could take the complexities of each farm into account.
- Participants also recognized that additional educational tools would be needed

Other information

- Recent produce-related outbreak investigations
  - Highlighted the role of pre- harvest agricultural water as a potential contributing factor in the introduction and spread of contamination to produce.
  - Highlighted issues associated with activities conducted on adjacent and nearby land
  - Underscored decades of scientific research on pre-harvest agricultural water as a potential contributing factor in the introduction and spread of contamination to produce


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