

FDA Final Rule Pre-Harvest Water

Introduction

Pre-harvest water use refers to the application of water on crops before they are harvested. It plays a crucial role in agriculture, but it can also pose risks to food safety if the water is contaminated. Here is a brief history of pre-harvest water use in terms of regulation and risks to food safety.

Early Regulations: In the past, regulations about pre-harvest water use were limited. There was a general understanding of the importance of clean water for crop irrigation, but specific guidelines and standards were not widely implemented. Pre-harvest water was always considered a free input without regulation.



Emergence of Food Safety Concerns: Over time, instances of foodborne illness outbreaks linked to contaminated produce raised concerns about the safety of pre-harvest water. Pathogens like E. coli, Salmonella, and Listeria can be present in water sources and will potentially contaminate crops during irrigation.

Implementation of Regulations: Regulatory bodies, such as the U.S. Food and Drug Administration (FDA) in the United States, have developed regulations to address pre-harvest water safety. In 2015, the FDA's Food Safety Modernization Act (FSMA) introduced new regulations, including the Produce Safety Rule, which set standards for water quality used in irrigation.

The New Rule

The produce safety rule from 2015 has recently been updated effective July 5, 2024, to require a water system assessment including risk analysis and mitigation requirements for pre-harvest water inputs. So now, all aspects of farm irrigation will have to be evaluated for potential risks to contamination along with mitigation measures.

Large farms	9 months after effective date	April 7, 2025
Small farms	1 year, 9 months after effective date	April 6, 2026
Very small farms	2 years, 9 months after effective date	April 5, 2027

In order to achieve compliance with the new pre-harvest water regulations, stakeholders need to undertake several key steps. These steps include:

1. **Water Assessments:** Stakeholders need to conduct thorough assessments of their water sources and systems used in food production. This involves identifying potential hazards and evaluating the quality and safety of the water. Factors considered include location, distribution, system protection from contamination, application method, post irrigation harvest, crop characteristics, weather extremes, temperature, and UV exposure.

2. **Preventive Controls:** Once potential hazards are found, stakeholders must implement expedited mitigation measures as preventive controls to minimize or eliminate risks. This may include implementing treatment methods, such as filtration or disinfection, to ensure water quality meets the required standards. If water has been found to be unsanitary, all use must immediately stop until the root cause has been evaluated and corrective actions completed.

3. **Monitoring Programs:** Stakeholders must establish robust monitoring programs with a supervisory review of the written pre-harvest agricultural water assessment and the outcomes on an annual basis. Descriptions of factors evaluated and the rationale for the determination of risk is required as part of the pre-harvest water assessment.
4. **Recordkeeping:** Comprehensive recordkeeping is essential to show compliance with the FSMA water regulations. Stakeholders must maintain accurate and up-to-date records of water assessments, monitoring results, corrective actions, and any other relevant documentation.
5. **Training and Education:** It is crucial for stakeholders to provide appropriate training and education to their employees about the importance of water safety and the specific requirements of the FSMA water regulations. This ensures that all individuals involved in food production understand their roles and responsibilities in maintaining water quality.
6. **Verification and Validation:** Regular verification and validation of water management practices and controls are necessary to ensure ongoing compliance. This may involve conducting internal audits, third-party inspections, or laboratory testing to confirm the effectiveness of the implemented measures.

Exemptions

There are exemptions for operations that use water from a public system, treat the water according to the produce safety rule, or follow certain requirements on prohibition of untreated surface water and testing for untreated ground water.

How to Assess your Operation

The FDA has launched a user-friendly tool called “Agricultural Water Assessment Builder” which prompts users to answer questions specific to their operation. Stakeholders can find this tool on the FDA’s website at <https://agwaterassessment.fda.gov/>. Users will be asked questions on their agricultural water system components, animal impact, human waste, potential sources of hazards, crop characteristics, environmental conditions and more. At the end, users can save or print their information for use in their risk analysis and mitigation measures as part of their food safety program.

How RQA Can Help

RQA works with growers and their supply chains to ensure their policies, procedures and training reflect regulatory requirements. Have your unique pre-harvest written assessment created for you and your specific operation by one of our seasoned experts who will guide you through the regulatory process. Expert risk assessment and on-going training support will promote a healthy food safety culture within your organization. RQA’s review of your water system and site risks will ensure your written plan is compliant with all regulations. Recall or crisis simulation exercises are custom tailored and ensure team members become knowledgeable with a plan of action. Call or email today to see how RQA can help.

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Reference Links

Agricultural Water Assessment Builder: www.agwaterassessment.fda.gov

Fact Sheet on the Final Rule: www.fda.gov/media/178221/download?attachment

FSMA Final Rule on Pre-Harvest Agricultural Water:
www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-pre-harvest-agricultural-water

Annual Agricultural Water Assessments and Risk Based Outcomes: www.fda.gov/media/178219/download?attachment

Timeline Graph of Food Safety Recall Events and New Regulation from 2000-2024

