FSMA Final Rule on Pre-harvest Agricultural Water

The FDA has issued a final rule that revises certain pre-harvest agricultural water requirements for covered produce (other than sprouts) in Subpart E of the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule. This final rule establishes requirements for systems-based pre-harvest agricultural water assessments that covered farms use for hazard identification and risk management decision-making purposes. As part of the assessment, farms are required to evaluate the following factors to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto produce or food contact surfaces:

Factors	Description
Agricultural water system(s)	• The location and nature of the water source (such as whether it is ground water or surface water) • The type of water distribution system (such as whether it is open or closed to the environment) • The degree to which the system is protected from possible sources of contamination, including: - other users of the water system - animal impacts (such as from grazing animals, working animals, and animal intrusion) - adjacent and nearby land uses related to animal activity, the application of biological soil amendments of animal origin (BSAAOs), or the presence of untreated or improperly treated human waste
Agricultural water practices	• The type of application method (such as overhead sprinkler or spray, drip, furrow, flood, and seepage irrigation) • The time interval between the last direct application of agricultural water and harvest of the covered produce (other than sprouts)
Crop characteristics	• Susceptibility of the covered produce to surface adhesion or internalization of hazards
Environmental conditions	• Frequency of heavy rain or extreme weather events that may impact the agricultural water system (such as by stirring sediments that may contain human pathogens) or that may impact or damage produce. Damage can increase the susceptibility of produce to contamination. • Air temperatures • Sun (UV) exposure
Other relevant factors	• Including, if applicable, results of pre-harvest agricultural water testing to inform the assessment

Assessment Outcomes

Covered farms must use the outcomes of the pre-harvest agricultural water assessment to make written determinations about whether corrective or mitigation measures are needed to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with hazards associated with pre-harvest agricultural water. The following chart summarizes the requirements for actions that must betaken following agricultural water assessment determinations:

If you determine	Then you must
that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)	• Immediately discontinue use(s) *And* • Take corrective measures before resuming use of the water for pre-harvest activities
there is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land for which mitigation is reasonably necessary	• Implement mitigation measures promptly, and no later than the same growing season
there is one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land, for which mitigation is reasonably necessary	• Implement mitigation measures as soon as practicable and no later than the following year *Or* • Test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment
that there are no known or reasonably foreseeable hazards for which mitigation is reasonably necessary	• Regularly (at least once each year) inspect and adequately maintain the water system(s)

Corrective measures

If a covered farm determines that its pre-harvest agricultural water is not safe or of adequate sanitary quality for its intended use(s), it is required to immediately discontinue such use. Corrective measures that a farm could take in order to resume such use include:

- Re-inspecting the entire affected agricultural water system under the farm's control and, among other steps, making necessary changes, or
- Treating the water in accordance with the standards outlined in the Produce Safety Rule.

Mitigation measures

If a covered farm determines that mitigation measures are necessary to reduce the potential for contamination of produce or food contact surfaces with hazards associated with their pre-harvest agricultural water, it has various options to choose from, including:

- Making necessary changes such as repairs.
- Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, with supporting scientific data and information.
- Increasing the time interval between harvest and the end of the storage period and/or conducting other activities during or after harvest to allow for microbial die-off or removal, with supporting scientific data and information.
- Changing the method of water application to reduce the likelihood of produce contamination (such as changing from overhead spray to subsurface drip irrigation for certain crops).
- Treating the water in accordance with the standards outlined in the Produce Safety Rule, or
- Taking alternative mitigation measures supported by scientific data and information.

Reassessment

A covered farm is required to conduct a reassessment each year in which the farm applies pre-harvest agricultural water to covered produce (other than sprouts), and anytime there is a significant change in its agricultural water systems, agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that make it reasonably likely that a hazard may be introduced into or onto covered produce or food contact surfaces through direct application of pre-harvest agricultural water. For example, a change from an untreated ground water source to an untreated surface water source, or a change in agricultural water use practices, are significant changes that require a reassessment. The reassessment must evaluate the impacts of those changes on the factors discussed above, any new hazards identified, and the written determination of whether corrective or mitigation measures are needed to reduce the potential for contamination of produce or food contact surfaces.

Records

Covered farms are required to maintain written records of their pre-harvest agricultural water assessments, including descriptions of factors evaluated and their written determinations. Farms that test their pre-harvest agricultural water as part of their assessments are required to maintain certain documentation related to their test results and procedures. Additionally, supervisors are required to review the written pre-harvest agricultural water assessments and the determinations made based on the outcomes of the assessments.

Exemptions

Covered farms may be eligible for an exemption from conducting a pre-harvest agricultural water assessment if they can demonstrate that their pre-harvest agricultural water for covered produce (other than sprouts):

- meets certain requirements that apply for harvest and post-harvest agricultural water (including the prohibition on the use of untreated surface water, the microbial quality criterion and if applicable, testing requirements for untreated ground water).
- is received from a public water system or supply that meets requirements established in the rule (provided that the farm has public water system results or certificates of compliance demonstrating that the water meets relevant requirements); or
- is treated in accordance with the standards outlined in the Produce Safety Rule.

Additionally, in order to be eligible for an exemption, it must be reasonably likely that the quality of the previously described water will not change prior to the water being used as agricultural water (for example, due to the manner in which the water is held, stored or conveyed).