

FSMA Final Rule on Pre-harvest Agricultural Water: Corrective and Mitigation Measures for Pre-harvest Agricultural Water for Non-Sprout Covered Produce

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. Depending on the outcomes of a covered farm’s assessment, the farm may be required to implement corrective or mitigation measures to reduce the potential for contamination of covered produce or food contact surfaces as a result of the use of pre-harvest agricultural water. The following chart summarizes measures corrective and mitigation measures discussed in the final rule.

Corrective Measures

For pre-harvest agricultural water for covered produce (other than sprouts), “corrective measures” refer to those that covered farms must implement in order to resume use of water if the water is not safe or is not of adequate sanitary quality for its intended use. Corrective measures are used in circumstances where it is necessary to take immediate action to protect public health, in that farms are required to immediately discontinue use of the water and implement corrective measures prior to resuming that use. Options for corrective measures include:

Corrective Measure	Additional Information
<p>Re-inspecting the entire affected agricultural water system to the extent that it is under your control and, among other steps, making necessary changes and taking adequate measures to determine if your changes were effective</p>	<ul style="list-style-type: none"> • For example, if a dead animal in a canal, results in the water being not safe or not of adequate sanitary quality for its intended use, examples of steps the farm could take to resume use of the water include, at a minimum: <ul style="list-style-type: none"> - Removing the dead animal and any related hazards identified during the re-inspection and allowing time for contaminants to clear the canal and bypass the point at which the farm draws water. - Re-inspecting the entire water system potentially affected by the dead animal to the extent it is under the farm’s control to identify any relevant conditions (such as additional dead animals and/or carcass materials that may have contaminated the farm’s water distribution system, if applicable). - Cleaning any necessary equipment that may have been contaminated (such as the water distribution system impacted by the dead animal). and - Visually verifying that all carcass materials have been removed.
<p>Treating the agricultural water</p>	<ul style="list-style-type: none"> • Treatment must be applied in accordance with requirements in the Produce Safety Rule, including those related to treatment effectiveness, delivery, and monitoring. • Examples of treatment methods that farms can use (provided all requirements are met) include: <ul style="list-style-type: none"> - Physical treatment - An EPA-registered antimicrobial pesticide product - Other suitable method

Mitigation Measures

“Mitigation measures” provide more flexibility in the timing of actions compared to those discussed above. Mitigation measures must be applied promptly and no later than the same growing season as the assessment or reassessment for some hazards, specifically for adjacent and nearby land uses related to:

- Animal activity
- The application of biological soil amendments of animal origin (BSAAO), or
- The presence of untreated or improperly treated human waste

For other hazards, mitigation measures must be implemented as soon as practicable and no later than one year after the date of the farm’s agricultural water assessment or reassessment.

Mitigation measures include:

Mitigation Measure	Additional Information
Making necessary changes (such as repairs)	<ul style="list-style-type: none"> • Making changes to water systems (such as repairs) can help prevent the systems from being a source of contamination to covered produce or food contact surfaces. • It is generally preferred that sources of hazards be addressed at the point where they are introduced to an agricultural water system. • Even if a source of hazards is outside of a farm’s control, there are steps farms may be able to take to reduce the potential that hazards will be introduced into their water systems. Examples include: <ul style="list-style-type: none"> - Building a berm to reduce runoff - Installing a windbreak - Repairing a well-head to ensure it is protected from hazards
Increasing the time interval between last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off	<ul style="list-style-type: none"> • Supporting scientific data and information must be relevant to the farm’s conditions (such as the region, crop, and environment), and be characterized in a manner that addresses the likely biphasic nature of microbial die-off (i.e., rapid short-term die-off and a gradual long-term die-off). • Information evaluated as part of an assessment will help farms identify conditions relevant to establishing an appropriate interval. This includes information related to: <ul style="list-style-type: none"> - The timing of water applications - Environmental conditions - Crop characteristics
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	<ul style="list-style-type: none"> • Supporting scientific data and information must be relevant to the farm’s conditions (for example, in consideration of commodity characteristics, storage time and conditions, and other relevant production practices). • Examples of post-harvest activities that may result in microbial die-off or removal include commercial washing or controlled atmosphere storage (among others), if supported by scientific data and information.
Changing the method of water application to reduce the likelihood of produce	<ul style="list-style-type: none"> • The appropriateness of changing the water application method is a function of multiple factors, including the water application method, characteristics of the crop (such as whether the harvestable portion

Mitigation Measure	Additional Information
contamination	<p>grows near, on, or in the ground), and any relevant practices the farm has in place.</p> <ul style="list-style-type: none"> • Changing the water application method may be effective if it minimizes water that is in direct contact with the crop (for example, changing from overhead to microjet irrigation for some tree fruits). • However, it may not be appropriate for root crops, as it may be difficult to effectively minimize contact between water and the crop while supporting the crop’s growth and survival. • There may be instances where multiple practices—such as the use of plastic mulch along with changes in water application methods—together serve as effective mitigation measures.
Treating the agricultural water	<ul style="list-style-type: none"> • Treatment must be applied in accordance with requirements in the Produce Safety Rule, including those related to treatment effectiveness, delivery, and monitoring. • Examples of treatment methods that farms can use (provided all requirements are met) include: <ul style="list-style-type: none"> - Physical treatment - An EPA-registered antimicrobial pesticide product - Other suitable method
Taking alternative mitigation measures	<ul style="list-style-type: none"> • Alternative measures must be supported by scientific data and information • Covered farms are not required to notify or seek approval from FDA regarding use of an alternative mitigation measure

How can covered farms manage hazards that are not under their control?

We recognize that covered farms may not always have control over a potential source of hazards at the point where hazards are introduced to an agricultural water system (such as may occur for hazards that originate from adjacent or nearby land uses or from other water users). The rule incorporates a range of options for corrective and mitigation measures, including those that a farm can implement even if it does not have control over a potential source of hazards. For example, even if a source of hazards is outside of a farm’s control, measures that divert runoff away from the farm’s water system or otherwise protect the system from potential hazards (such as repairing a well-head or fixing a leak in a piped system) may be appropriate to use as mitigation measures. As another example, depending on the circumstances, a farm might determine that changing the water application method is appropriate to reduce the likelihood of contamination of covered produce.

Can covered farms wait until the end of the relevant time period to implement mitigation measures for their pre-harvest agricultural water?

We incorporated ranges for the relevant timeframes for implementing mitigation measures in the recognition that covered farms may not be able to immediately implement mitigation measures in every circumstance. For example, some mitigation measures, such as making necessary changes (such as repairs) or changing the method of water application, may take time to implement, as they might entail changes to current, or adoption of new, infrastructure and equipment on the farm.

However, this does not mean that farms are permitted to wait until the end of the year after the date of the assessment or the end of the same growing season as the assessment (as applicable) to implement mitigation measures. Rather, farms must implement mitigation measures “as soon as practicable” or “promptly,” as applicable to their circumstances.

How can covered farms determine the effectiveness of their mitigation measures?

There are various ways covered farms can verify the effectiveness of their mitigation measures. For example:

- If a farm takes measures that involve making necessary changes, such as repairing a leak within the farm's piped distribution system to protect it from possible sources of contamination, re-inspection of the water system to visually confirm that the repair was successful may be sufficient.
- If a farm changes the method of water application to reduce the likelihood of contamination of covered produce, the farm might regularly monitor the system while the covered produce is being irrigated to confirm that the water application method is limiting contact with the produce as intended.
- If a farm treats agricultural water; applies a time interval between last direct water application and harvest; or applies a time interval between harvest and end of storage and/or uses other activities during or after harvest, the farm is required to maintain scientifically valid data or information to support use of those measures.
- While not required to do so, a farm may choose to test its water to help evaluate the effectiveness of any mitigation measures the farm implements.

If a covered farm determines that its mitigation measures are not effective to reduce the potential for contamination of the covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards, it must discontinue use of the agricultural water until it has implemented mitigation measures adequate to reduce the potential for such contamination.