

FSMA Final Rule on Pre-harvest Agricultural Water: Factors for Agricultural Water Assessment to Consider

Agricultural Water Assessment

The FDA published 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.

The following chart summarizes the factors that covered farms are required to consider as part of the assessment. The requirements can be found in the Federal Register.

Agricultural Water System(s)

Description	Additional Information and Examples
Location and nature of the water source (for example, whether it is ground water or surface water)	<ul style="list-style-type: none"> • Ground water obtained from deep underground aquifers, with properly designed, located and constructed wells, generally yields water that is higher quality. Surface waters, which are more exposed to the environment and runoff, may be more susceptible to contamination.
Water distribution system used (for example, whether it is open or closed to the environment)	<ul style="list-style-type: none"> • Some water used for growing is conveyed through open distribution systems, such as canals and laterals, that can be subject to introduction of hazards from runoff, animal intrusion, direct discharge and seepage. • Other water might be distributed through a closed system, such as through piping, which, if it is constructed and functioning properly, can help protect water from the introduction of hazards. However, hazards can enter a closed system if the system is not maintained properly. • Covered farms with open and closed components in their agricultural water distribution systems must consider the individual properties and characteristics of each component when conducting a pre-harvest agricultural water assessment.

Description	Additional Information and Examples
<p>The degree to which the system is protected from possible sources of contamination, including:</p> <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Other users: a covered farm must consider the potential for known or reasonably foreseeable hazards to be introduced by other users of the water source or distribution system. For example, a farm that draws water for crop protection sprays from a pond that is also used for recreational swimming must consider whether the use of the source for recreational swimming could introduce hazards into the agricultural water system. • On-farm Animal impacts: Both wild and domesticated animals can be a source of pathogens that can contaminate produce. A farm may become aware of potential animal impacts on its pre-harvest agricultural water systems through inspections and maintenance performed on the water source or distribution system or through findings from visual observations. • Animal activity on adjacent and nearby land¹¹: Animal activities that may introduce contamination into water sources or distribution systems include, but are not limited to, livestock feeding operations of any size, dairy production, fowl production, barnyards, or significant wildlife intrusion or wildlife habitat. Examples of factors to consider when evaluating the likelihood of potential hazards being introduced into a water system from animal activity include: <ul style="list-style-type: none"> - the location and proximity of animal activities relative to the water system, including whether animals have direct access to the water system (such as for loafing or drinking) - whether any fencing, containment, or other measures are employed to prevent animal access to the water system - the presence and location of potential animal attractants and habitats (such as heavy vegetation, wooded areas, water sources, or standing water) - whether earthen diversion berms, ditches, or other barriers are present to help minimize the influence of runoff or airborne transmission (e.g., fugitive dust) on the water system. - whether any systems or structures are in place to handle, convey, or store animal waste (such as animal stalls, composting piles, pits, manure lagoons, or other waste containment structures or systems) that may serve as a possible source of contamination to the water system. • Application of BSAAOs on Adjacent and Nearby land*: Factors to consider when evaluating the likelihood of potential hazards being introduced into a water system from BSAAOs may include: <ul style="list-style-type: none"> - the location and proximity of areas where BSAAOs are held or applied to land in relation to the water system - the measures, if any, an upstream farm uses to control runoff

* By “adjacent” land, we are referring to land sharing a common border with the farm’s land... By “nearby” land, we are referring to a broader category of land, including land that does not adjoin the farm’s land but has the potential to affect the covered farm’s agricultural water system(s) based on the land’s location.

Description	Additional Information and Examples
	<p>and/or tailwater returns into the water system</p> <ul style="list-style-type: none"> - whether the BSAAOs are treated and to what extent - whether any systems or structures are in place to handle, convey, and store BSAAOs (such as composting piles, pits, manure lagoons, or other waste containment structures or systems) that may serve as a possible source of contamination to the water system. <ul style="list-style-type: none"> • Impact of untreated or improperly treated human waste on adjacent and nearby land*: Examples of potential sources of contamination from untreated or improperly treated human waste from adjacent or nearby land include wastewater treatment plants, toilet facilities (portable and fixed), sewage systems, septic tanks, and drain fields. Factors to consider when evaluating the likelihood of potential hazards being introduced into a water system from human waste may include: <ul style="list-style-type: none"> - whether and how the human waste is treated - whether the source of human waste is discharged directly into the water system - the proximity of the potential source of human waste to the water system - the topography between the potential source of human waste and the water system - whether there are any physical measures in place between the potential source of human waste and water system that would reduce the likelihood of hazards being introduced <p><i>* There are a variety of resources available that may provide insight as to the presence and nature of impacts that can affect the quality of agricultural water. For example, information may be acquired through visual observation; from local extension agents, industry associations, water management authorities, or irrigation districts; or from online resources such as mapping tools. Farms may benefit from looking to a variety of resources to assist in their understanding of their agricultural water systems.</i></p> <p><i>We recognize that even with the variety of resources available, farms may face uncertainty around evaluating factors associated with activities on adjacent or nearby land. Due to the nature of the risks associated with animal activity, BSAAO, and untreated or improperly treated human waste in these instances, farms should consider accounting for an increased likelihood of hazard introduction to the water systems from adjacent or nearby lands, in addition to the other information evaluated as part of an assessment, when making decisions around the safe use of their water.</i></p>

Agricultural Water Practices

Description	Additional Information and Examples
The type of application method	<ul style="list-style-type: none"> • Commonly used pre-harvest agricultural water application methods include overhead sprinkler (or spray), surface and subsurface drip, furrow, flood, and seepage irrigation. • Different irrigation methods present different risks based on the extent to which the irrigation water is directly applied to the harvestable portion of the crop. • For example, overhead sprinkler irrigation is generally thought to increase the risk of contamination as compared with furrow and subsurface drip irrigation of certain crops.
The time interval between the last direct application of agricultural water and harvest of the covered produce (other than sprouts)	<ul style="list-style-type: none"> • Generally, bacterial pathogens in water that is applied early in the growing season maybe subject to die-off from several environmental forces, such as UV exposure, temperature, and humidity – whereas pathogens present in agricultural water that is applied shortly before • harvest may not be exposed to the same environmental conditions to allow for die-off to occur. • In considering the application interval prior to harvest, a farm that uses multiple water application methods for its produce – e.g. furrow irrigation and crop protection sprays – must consider the timing of both types of applications.

Crop Characteristics

Description	Additional Information and Examples
Characteristics that make covered produce vulnerable to contamination, such as susceptibility to surface adhesion or internalization of microbial hazards	<p>Farms are required to evaluate whether the produce has any characteristics that make it vulnerable to contamination, such as whether it is susceptible to surface adhesion of bacteria or internalization of microbial hazards.</p> <p>This includes considering internalization of hazards due to physical damage from weather events (such as freezing of an epidermal peel or hail damage) or biological damage (such as from phytopathogens).</p> <p>In addition, farms must consider other physical characteristics (such as whether the produce has a large, rough surface that may increase the susceptibility to surface adhesion of bacteria); growth characteristics (such as whether it grows on or near to the ground); and other properties (such as porosity) that may affect the probability and degree of contamination.</p>

Environmental Conditions

Description	Additional Information and Examples
<p>Farms are required to evaluate the potential impacts of environmental conditions that may impact the water system or covered produce. This includes seasonal rainfall patterns, the frequency of extreme weather events (such as heavy winds or rain), and other relevant agro- ecological conditions (such as temperature, sunlight (UV exposure)).</p>	<ul style="list-style-type: none">• Survival of pathogens in the environment is influenced by complex physical, chemical, and biological interactions.• Changes in temperature and seasonality are expected to impact persistence of foodborne pathogens in the environment. In general, the survival of pathogens in water sources decreases with increasing temperatures.• Airborne transmission – particularly when dry, windy conditions exist – may result in contamination of the environment, including agricultural water and the growing area.• Seasonal changes in rainfall – particularly heavy rainfall and flooding events – can greatly affect surface water quality and may result in the stirring up of sediments, which have been known to harbor pathogens.• Rainfall events can also result in runoff, which can contain pathogens, into the growing area or agricultural water system.• Weather events, such as freezing or hail, can result in physical damage to the epidermal barrier or produce (e.g., punctures or bruising), that may allow for survival of pathogens on produce.

Other Relevant Factors

Description	Additional Information and Examples
<p>Farms must consider any other factors relevant to identifying conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces.</p>	<ul style="list-style-type: none">• Relevant factors may include whether a farm tests its water to help inform its agricultural water assessment.