

Agricultural Water Assessment

The FDA is proposing to revise some of the 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 proposal, if finalized, would replace the pre-harvest microbial quality criteria and testing requirements for such produce in the Produce Safety Rule with requirements for systems-based pre-harvest agricultural water assessments. If finalized, covered farms would be required to conduct pre-harvest agricultural water assessments once annually, and whenever a change occurs that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto produce or food contact surfaces.

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

Agricultural water system(s)

Description	Additional Information and Examples
Location and nature of the water source (including whether it is ground water or surface water)	<ul style="list-style-type: none"> Groundwater 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 and 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.
<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 would 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 would need to consider whether the use of the source for recreational swimming could introduce hazards into the agricultural water system. 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 land*¹: 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. <ul style="list-style-type: none"> In evaluating adjacent and nearby land uses, a farm could, for example, consider the effects of any fencing, containment, or other measures employed to prevent animal access to water sources or distribution systems, or earthen diversion berms, ditches, or other barriers to help minimize the influence of runoff or airborne transmission (e.g. fugitive dust) on sources and distribution systems. Information on adjacent and nearby land uses could be acquired through visual observations, discussions with local extension agents or associations, online resources or other means as appropriate. 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 distance between the fields and the water source the measures, if any, an upstream farm uses to control runoff whether the BSAAOs are treated and to what extent how BSAAOs are handled, conveyed, and stored on the land whether runoff is likely to occur Impact of untreated or improperly treated human waste on adjacent and nearby land*: An evaluation of the hazards associated with untreated or improperly treated human waste from adjacent or nearby lands could include consideration of potential sources of contamination, such as wastewater treatment plants, toilet facilities (portable and fixed), sewage systems, septic tanks, and drain fields. In considering whether hazards associated with human waste from adjacent or nearby lands might be introduced to water systems, farms might consider: <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>* We recognize that 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 when making decisions around the safe use of their water.</i></p>

¹ By “adjacent” land, we are referring to land sharing a common border with the water source or distribution system. By “nearby” land, we are referring to a broader category of land, including land that does not adjoin the water source or distribution system but has the potential to affect the covered farm based on the land’s location.

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 may 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 – would 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	<ul style="list-style-type: none"> • A farm would be 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. • This would include 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). • In addition, farms could 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 near to the ground); and other properties (such as porosity) that may affect the probability and degree of contamination.

Environmental conditions

Description	Additional Information and Examples
Farms would be required to evaluate the potential impacts of weather conditions, including 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)).	<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.

Other relevant factors

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

This chart summarizes requirements found in the proposed rule. To read and submit comments on the proposed requirements, please see Docket No, FDA-2021-N-0471.