Frequently Asked Questions: Agricultural Water Requirements under the FSMA Produce Safety Rule

Below are frequently asked questions relating to the agricultural water requirements in Subpart E (§§ 112.40-112.50) of the FSMA Produce Safety Rule. See also FSMA Final Rule on Pre-harvest Agricultural Water and Requirements for Harvest and Post-Harvest Agricultural Water in Subpart E. The full text of the requirements can be found at 21 CFR part 112.

General

1. If water is not intended to contact covered produce, do the requirements for agricultural water in subpart E apply?

It depends. "Agricultural water" refers, in part, to water used in covered activities on covered produce where water is intended to, *or is likely to,* (emphasis added) contact covered produce or food-contact surfaces. (See § 112.3). If water is intended to, *or is likely to,* contact covered produce or food contact surfaces, then it meets the definition of "agricultural water," and the provisions of subpart E apply. Examples include water used during growing activities such as irrigation water applied using direct water application methods, and water used for preparing crop sprays.

2. What requirements in subpart E apply based on specific use of agricultural water?

As provided in § 112.40, if a covered farm[1] uses agricultural water for a covered activity listed in the first column, then the farm must meet the requirements in the second column. The farm also must meet the requirements in the third column, if applicable.

If a covered farm uses agricultural water for this covered activity	Then the farm must meet these requirements	If applicable, the farm also must meet these requirements
(a) Growing covered produce (other than sprouts)	§ 112.41 (quality standard) § 112.42 (inspections and maintenance) § 112.43 (agricultural water assessment) § 112.50 (records)	§ 112.45 (measures) § 112.46 (treatment) § 112.47 (who may test) § 112.151 (test methods)
(b) Sprout irrigation water	§ 112.41 (quality standard) § 112.42 (inspections and maintenance) § 112.44(a) (microbial quality criterion) § 112.50 (records)	§ 112.44(b) (testing untreated ground water) § 112.45 (measures) § 112.46 (treatment) § 112.47 (who may test) § 112.151 (test methods)
(c) Harvesting, packing, or holding covered produce	§ 112.41 (quality standard) § 112.42 (inspections and maintenance) § 112.44(a) (microbial quality criterion) § 112.44(d) (additional management and monitoring) § 112.50 (records)	§ 112.44(b) (testing untreated ground water § 112.45 (measures) § 112.46 (treatment) § 112.47 (who may test) § 112.151 (test methods)

[1] Throughout this guidance, in each answer that addresses covered farms, we use the complete phrase "covered farm" in the first instance and then, for readability, simply use "farm."

3. Are covered farms required to consider any buildings or equipment in meeting the requirements in subpart E?

Yes. The definition of "agricultural water system" includes, in part, "any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities" (§ 112.3). As such, to the extent that any building, structure, or equipment is a component of a covered farm's agricultural water system, the farm must inspect and maintain those components to the extent that they are under the farm's control in accordance with § 112.42 and, if applicable, consider those components in conducting an agricultural water assessment pursuant to § 112.43.

For example, in evaluating the degree of protection of an agricultural water system from possible sources of contamination, farms should consider whether buildings or structures that are part of its agricultural water system protect other components of the agricultural water system from possible sources of contamination (such as where a well house or storage shed might protect wells and/or water application equipment from debris, trash, domesticated animals, or other possible sources of contamination).

4. What does "adjacent or nearby lands" mean for the purposes of meeting subpart E requirements?

For the purposes of subpart E, by "adjacent" land we are referring to land sharing a common border with the covered 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 farm's agricultural water systems(s) based on the land's location. For example, agricultural water may be affected by agricultural practices and runoff from those operations into surface water sources or open distribution systems that are used for agricultural water even if the operations' lands are not adjacent to a farm's land.

5. What are some examples of adjacent or nearby land uses that may be relevant for meeting subpart E requirements?

Many activities on adjacent or nearby lands may create or pose conditions that are reasonably likely to introduce known or reasonably foreseeable hazards to agricultural water systems. Examples include, but are not limited to, other agricultural operations (such as land used for growing operations, animal grazing, dairy production, poultry production, barnyards, commercial animal feeding operations, and farms with working animals); composting sites; lands used for recreational activities (such as campgrounds); wastewater treatment facilities (or other potential sources of human waste like toilet facilities and sewage disposal systems); urban/suburban development activities; and lands with significant wildlife intrusion or habitat.

Inspections and maintenance of agricultural water systems

6. What is the difference between inspections and maintenance of agricultural water systems in § 112.42(a) and (b), respectively?

Inspection of an agricultural water system under a covered farm's control is generally the first opportunity for ensuring that the system will deliver water that is safe and of adequate sanitary quality for its intended use. Inspection of a farm's agricultural water system provides an opportunity to identify and characterize activities and situations that may lead to contamination of the farm's agricultural water. Further, inspection results provide the farm with historical knowledge of its water systems, their quality, and factors that may affect their quality. Requirements related to inspection of agricultural water systems can be found in § 112.42(a).

Regular maintenance of a farm's agricultural water systems is imperative to ensure the continued safety of a farm's water. If not regularly maintained, portions of an agricultural water system may fail, corrode, collect debris, or otherwise become a source of contamination. Requirements related to maintenance of agricultural water systems can be found in § 112.42(b).

7. Are covered farms required to inspect portions of agricultural water systems that are not under their control under § 112.42(a)?

Covered farms are not required to inspect portions of an agricultural water system that are beyond their control under § 112.42(a). However, the extent to which a farm controls its agricultural water system(s), and certain factors over which the farm may have little or no control, will likely influence the identification or characterization of potential hazards associated with the farm's agricultural water system(s). Evaluating these factors as part of the farm's inspection under § 112.42(a) will help the farm determine the appropriate and safe use of the agricultural water from its agricultural water system(s).

8. What are some examples of relevant information related to inspections of agricultural water systems under § 112.42(a)?

Section 112.42(a) requires that at the beginning of a growing season, as appropriate, but at least once annually, a covered farm must inspect all of its agricultural water systems, to the extent they are under the farm's control, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. This includes consideration for:

- The nature of each agricultural water source (for example, whether it is ground water or surface water)
    - For example, surface water sources are subject to a great number of external forces that shape their overall composition, chemistry, and microbial water quality (e.g., erosion, run-off, dust, suspended sediments). In contrast, ground water sources typically contain microorganisms, including pathogens, much less frequently, due to the natural filtering mechanism of soil. However, ground water can be compromised and its microbial water quality degraded, such as if wells are improperly constructed, poorly maintained, improperly located;
- The extent of the farm's control over each agricultural water source
    - For example, a farm may have more control over a ground water source such as a small spring if the expanse of the spring is under the farm's control and the farm is able to protect the spring from the influence of surface activities. The farm may have greater access to and control of on-farm surface water sources such as

impoundments, catches, and ponds, than it would for flowing surface waters that only course through but do not originate on the farm's land;

- The degree of protection of each agricultural water source
    - For example, protection could include covers, containments, earthen berms or other barriers that help protect the water system from possible sources of contamination (such as barriers that help minimize the influence of runoff on the water system);
- The use of adjacent and nearby land
    - For example, runoff from an upstream field may flow into the farm's agricultural water system. While the farm may have little or no control of the other agricultural water user's practices, the requirement to consider those nearby uses of which the farms is aware will help the farm determine appropriate and safe use of that water; and
- The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches the covered farm
    - For example, if the farm uses water from a river and is downstream from a wastewater treatment plant that discharges into that river, the farm must consider the likelihood that the wastewater treatment plant introduces hazards into the water before it reaches the farm. For example, the farm would consider the likelihood of accidental discharge of untreated municipal sewage into the river.

9. Are covered farms required to eliminate pooling of water in their growing fields as part of agricultural water system maintenance under § 112.42(b)?

We acknowledge the potential for small pools of water to temporarily form in field areas or at the base of plants after irrigation. Small amounts of water of this nature are temporary and occur in the normal course of irrigation practices. We are not suggesting that it will always be possible to eliminate pooling. However, pooled water that remains for extended periods of time can be a source of contamination and pooled water in close proximity to the crop may serve as an attractant for pests and other animals, which may in turn introduce hazards into the pooled water that may contaminate produce. Thus, covered farms are required, as necessary and appropriate, to implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards resulting from contact of covered produce with pooled water (§ 112.42(b)(4)). For example, protective barriers (such as plasticulture), equipment adjustments, mounding soil, and staking are methods that, depending on the circumstances, may be appropriate to reduce the potential for pooling or to separate the pooled water from the covered produce.

Pre-harvest agricultural water assessments

General

10. When must pre-harvest agricultural water assessments for covered produce (other than sprouts) be performed?

Preparing an agricultural water assessment towards the beginning of the growing season may be of benefit for covered farms, as doing so may allow for early identification of conditions for which measures under § 112.45 may be reasonably necessary. However, we recognize that flexibility is needed to account for certain situations, such as for crops that have year-round growing seasons, and for farms that may have multiple crops with year-round or staggered growing seasons throughout the year. As such, § 112.43(a) requires that farms prepare an agricultural water assessment at the beginning of the growing season, as appropriate, but at least once annually.

Additionally, a farm must conduct a reassessment whenever a significant change occurs in the farm's agricultural water system, water use practices, crop characteristics, environmental conditions, or other relevant factors that make it reasonably likely that a known or reasonably foreseeable hazard will be introduced into or onto covered produce (other than sprouts) or food contact surfaces. A reassessment conducted under § 112.43(e) due to a significant change must evaluate any factors and conditions affected by the change.

11. How far upstream are covered farms required to consider potential sources of hazards when preparing a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

Due to the variability that exists in agricultural water systems and across different growing regions, covered farms' consideration of potential sources of hazards to their agricultural water systems will vary widely, include factors that may be outside of a farm's control, and will likely depend on each farm's unique agricultural water systems and growing operations. As such, we do not consider it appropriate to prescribe a distance for which farms must consider factors that have the potential to impact their water quality when preparing an agricultural water assessment for covered produce (other than sprouts) under § 112.43.

There are a variety of resources available to farms that may provide information as to the presence and nature of impacts that might affect the quality of their agricultural water. See question 12.

12. How can covered farms obtain information on potential sources of hazards that are not under their control when preparing a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

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 a covered farm's agricultural water. For example, information can be acquired through visual observation, from local extension agents and/or industry associations, or from online resources such as mapping tools, which may provide helpful information on topography and proximity to potential sources of hazards. Depending on the water source being used, there may also be organizations or water management authorities, such as irrigation district managers, that can serve as a source of information. Farms may benefit from looking to a variety of resources to assist in their understanding of other water users and adjacent and nearby land uses to further inform their agricultural water assessments and risk management determinations.

13. What is the difference between agricultural water systems inspections and maintenance under § 112.42 and pre-harvest agricultural water assessments for covered produce (other than sprouts) under § 112.43?

The requirements for pre-harvest agricultural water assessments for covered produce (other than sprouts) in § 112.43 supplement the requirements for inspection and maintenance of agricultural water systems in § 112.42. While § 112.42 entails inspecting and maintaining components of an agricultural water system to the extent that they are under the farm's control, and applies for all uses of agricultural water (not just water used for pre-harvest activities for covered produce (other than sprouts)), § 112.43(a) requires farms to conduct a more comprehensive assessment of possible sources and routes by which known or reasonably foreseeable hazards are reasonably likely to be introduced into its pre-harvest agricultural water for non-sprout covered produce.

While results of inspections and maintenance under § 112.42 can be used to inform an agricultural water assessment under § 112.43(a) (or the need for a reassessment under § 112.43(e)), meeting the requirements in § 112.42 does not eliminate the need for a farm to prepare an agricultural water assessment in accordance with § 112.43.

For example, a covered farm using an on-farm pond as a pre-harvest agricultural water source would consider the results of any inspections and maintenance performed (under § 112.42) as part of its pre-harvest agricultural water assessment (under § 112.43). For hazard identification purposes, under § 112.43, a covered farm would assess each pre-harvest agricultural water system it uses for non-sprout covered produce from water source to point of application. A covered farm could not satisfy the agricultural water assessment requirements in § 112.43 solely based on inspection activities conducted under § 112.42, because the agricultural water assessment requires consideration of a broader range of factors, including agricultural water practices, crop characteristics, and other relevant factors.

Exemptions

14. If the quality of water from an "exempt" source changes prior to being used as pre-harvest agricultural water for covered produce (other than sprouts), is the covered farm eligible for an exemption from the requirements to prepare an agricultural water assessment under § 112.43(b)?

No. A covered farm is only exempt from preparing a written agricultural water assessment if the farm can demonstrate that the water meets the requirements in § 112.43(b)(1)(i), (ii), or (iii) and it is reasonably likely that the relevant quality of 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) (§ 112.43(b)(2)). (The requirements in § 112.43(b)(1)(i), (ii), and (iii) refer to a farm demonstrating that its water meets certain requirements that apply for higher-risk uses of water (such as harvest and post-harvest agricultural water); is received from a public water system or supply that meets certain requirements; or is treated in accordance with the rule, respectively.)

For example, if a farm receives water from a Public Water System that furnishes water meeting the microbial requirements in 40 CFR part 141 (§ 112.43(b)(1)(ii)) and conveys that water through a closed distribution system that allows for water quality to be maintained, the farm may be eligible for an

exemption, provided all requirements are met (including the requirement that the farm have results or certificates of compliance demonstrating that relevant requirements are met). However, if the farm conveys that water through an open canal system prior to using it as pre-harvest agricultural water for non-sprout covered produce and it is reasonably likely that the quality of water will change prior to use of the water, the farm is not eligible for an exemption from the requirement to prepare an agricultural water assessment.

15. Is a covered farm required to use agricultural water for pre-harvest purposes AND harvest/ post-harvest purposes in order to be eligible for an exemption from the requirements to prepare an agricultural water assessment for covered produce (other than sprouts) under § 112.43(b)(1)(i)?

No. While the provisions referred to in § 112.43(b)(1)(i) apply to water that is used for purposes outlined in § 112.44(a) (such as water used for harvest and post-harvest purposes), a farm that only uses agricultural water for pre-harvest activities may still be eligible for this exemption, provided all applicable requirements are met.

Agricultural water systems

Location and nature of each water source

16. Will surface water sources used for pre-harvest agricultural water for covered produce (other than sprouts) always be considered "high risk" and result in a determination that measures under § 112.45 are reasonably necessary?

The risk associated with agricultural water will vary from source to source. Even within a single type of water source (e.g., surface water), the associated risk may vary depending, in part, on the nature and likelihood of hazards being introduced. For example, if a farm has two different holding ponds—one that is at a higher elevation than surrounding lands, and the other that is at a lower elevation—both are considered surface water sources. However, the holding pond at the higher elevation may be more well-protected from the introduction of hazards via runoff than the other holding pond, and may therefore present less risk when used as pre-harvest agricultural water.

Further, the risk associated with agricultural water will depend on how and when agricultural water is applied to covered produce, characteristics of the covered produce, and environmental conditions. As such, farms are required to evaluate these various factors under § 112.43(a) as part of their agricultural water assessments to assist them in determining whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water. Given the variability that exists across industry in water systems, operations, and conditions, not every surface water source will require that corrective or mitigation measures be implemented under § 112.45.

Type of water distribution system

17. How must a covered farm account for a water distribution system consisting of both open and closed components when preparing a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

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 for covered produce (other than sprouts) under § 112.43(a)(1). For example, open distribution systems, such as systems of canals and laterals, can be subject to the introduction of hazards such as via runoff, animal intrusion, direct discharge, or seepage. Closed distribution systems, such as piped distribution systems, can help protect the water from the potential introduction of hazards during conveyance. However, hazards may be introduced into closed piping systems, such as where interconnected with other systems without adequate backflow protection.

Degree of protection from possible sources of contamination

18. What are some examples of relevant information related to animal activities to consider as part of a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

Animal activities that may introduce contamination into sources or distribution systems include, but are not limited to, livestock feeding operations of any size, dairy production, poultry production, barnyards, or significant wildlife intrusion or wildlife habitat.

Examples of relevant factors for evaluating the degree of protection of agricultural water systems from potential sources of contamination associated with animals under § 112.43(a)(1)(iii) include, but are not limited to, the following:

- The presence and location of any animal activities, such as whether there are areas in which animals might be in close proximity and/or have direct access to pre-harvest agricultural water systems (such as for loafing or drinking). Included in this is consideration for any fencing, containment, or other measures that may affect animal access to agricultural water systems;
- The presence and location of potential attractants and habitats (such as heavy vegetation, wooded areas, water sources, or standing water) that may draw animals to agricultural water systems;
- Whether runoff into agricultural water systems from lands currently or historically associated with animals is likely to occur, including whether there are earthen diversion berms, ditches, or other barriers that minimize runoff;
- Whether animals have access to areas relevant to agricultural water systems at times when pre-harvest agricultural water is being applied to non-sprout covered produce; and
- 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 agricultural water systems. Included in this, for example, is whether vehicles carrying animal waste follow traffic patterns that may result in the introduction of known or reasonably foreseeable hazards from the animal waste to agricultural water systems.

19. What are some examples of relevant information related to biological soil amendments of animal origin (BSAAOs) to consider as part of a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

Section 112.3 of the produce safety regulation defines "biological soil amendment of animal origin" (BSAAO) to mean "any biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal by products including animal mortalities, or table waste, alone or in combination. The term biological soil amendment of animal origin does not include any form of human waste."

Examples of relevant factors for evaluating the degree of protection of agricultural water systems from potential sources of contamination associated with BSAAOs include, but are not limited to, the following:

- The location and proximity of areas where BSAAOs are held or applied to land in relation to agricultural water systems;
- Whether runoff or tailwater returns into agricultural water systems from areas where BSAAOs are held or applied to land is likely to occur, including whether there are earthen diversion berms, ditches, or other barriers that minimize runoff;
- Whether the BSAAOs are treated and to what extent;
- Whether BSAAOs are applied to the land during times when pre-harvest agricultural water is being applied to non-sprout covered produce; and
- 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 agricultural water systems. Included in this, for example, is whether vehicles carrying BSAAOs follow traffic patterns that may result in the introduction of known or reasonably foreseeable hazards from the BSAAOs to agricultural water systems.

20. What are some examples of relevant information related to untreated or partially treated human waste to consider as part of a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

An evaluation of the hazards associated with untreated or improperly treated human waste includes consideration of potential sources of contamination such as wastewater treatment plants, toilet facilities (portable and fixed), sewage systems, septic tanks, and drain fields.

Examples of relevant factors for evaluating the degree of protection of agricultural water systems from potential sources of contamination associated with untreated or partially treated human waste include, but are not limited to, the following:

- Whether and how the human waste is treated;
- Whether the source of human waste is discharged directly into the agricultural water system;
- The proximity of the potential source of human waste to the agricultural water system;
- The topography between the potential source of human waste and the agricultural water system; and

- Whether there are any physical measures in place between the potential source of human waste and agricultural water system that would reduce the likelihood of hazards being introduced.

21. Are there potential sources of hazards beyond other water users, animals, BSAAOs, and human waste that are appropriate to consider as part of a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

Section 112.43(a)(1)(iii) requires that as part of an agricultural water assessment, covered farms must evaluate the degree of protection of the agricultural water system from possible sources of contamination. While other water users, animal impacts, and adjacent and nearby land uses related to animal activity, BSAAOs, or presence of untreated or improperly treated human waste are provided as examples of possible sources of contamination, the list of examples in § 112.43(a)(1)(iii) is not exhaustive. For example, if applicable to the circumstances, the farm must consider the following potential sources of contamination as part of its agricultural water assessment:

- Upstream maintenance activity (such as dredging) within a canal system that may affect the microbial quality of the water;
- Urban development activities from which runoff may introduce hazards to the agricultural water system; and
- Human activities (such as recreational vehicle parks) that may introduce hazards to the agricultural water system.

Agricultural water practices

22. If a covered farm is uncertain what the time interval between last application of agricultural water and harvest will be, how should the farm consider that in preparing its pre-harvest agricultural water assessment for covered produce (other than sprouts)?

We recognize that there may be some instances in which there is uncertainty as to what the time interval between last application of agricultural water and harvest will be. In such instances, covered farms may use their previous experience and knowledge of agronomic practices to provide an estimate in their agricultural water assessment as to what the expected interval might be. For example, if a farm knows that the last water application generally occurs 1 to 2 weeks before harvest, even though the precise interval may vary and not be known until right before harvest, the farm may note that in its agricultural water assessment and use that information alongside other factors evaluated in § 112.43(a) in making decisions regarding use of its pre-harvest agricultural water.

Crop characteristics

23. What are some examples of relevant information related to crop characteristics to consider as part of a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

Under § 112.43(a)(3), a covered farm is required to evaluate whether the covered produce (other than sprouts) 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. For example:

- Surface properties of a crop (such as produce like leafy vegetables that have large surface area) and topographical features (such as produce like netted melons that have rough surfaces) can foster attachment or entrapment of pathogens, if present in agricultural water;
- Growth characteristics of a crop (for example, near to the ground) can affect the probability and degree of contamination. Further, the possibility of splash dispersal to such crops may become problematic during periods of rainfall; and
- Physical damage from weather events (such as freezing of an epidermal peel or hail damage) or biological damage (such as from phytopathogens) can increase susceptibility to internalization of hazards.

24. If a covered farm grows multiple types of covered produce, is it required to consider the characteristics of each individual crop as part of a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

Covered farms have the flexibility to evaluate crop characteristics in § 112.43(a)(3) as appropriate given their pre-harvest agricultural water uses and growing operations. While some farms may be growing multiple types of crops using the same agricultural water system, in some instances, crops may have similar characteristics such that the farm may group them based on broad similarities. For example, a farm that grows multiple types of leafy greens may assess the characteristics of all types at once, noting, for example, the large, rough surface area that may increase the likelihood of contaminants being trapped and surviving for extended periods of time. Similarly, a farm that grows oranges, mandarins, and lemons may assess the characteristics of citrus fruit in general. To the extent that a single commodity may have a unique factor that sets them apart from the others, the farm may choose to note that unique characteristic within its agricultural water assessment, rather than establishing a separate evaluation for that one crop. For example, a farm might explain whether one type of leafy green is particularly susceptible to physical damage that has the potential to result in survival and/or growth of pathogens, if introduced.

Environmental conditions

25. What are some examples of relevant information related to environmental conditions to consider as part of a pre-harvest agricultural water assessment for covered produce (other than sprouts)?

Under § 112.43(a)(4), covered farms are required to consider environmental conditions, including the frequency of heavy rain or extreme weather events that may impact the agricultural water system (such as by stirring sediments) or covered produce (such as damage to edible leaves) during growing activities, air temperatures, and sun exposure. For example:

- 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, although exceptions may be observed in certain geographic areas and/or on certain farm environments;
- **Seasonal changes in rainfall**, particularly heavy rainfall and flooding events, can greatly affect surface water quality and may result in **sediments**, which can serve as reservoirs for pathogens, being dispersed within the water column;

- **Airborne transmission** may also result in contamination of the environment (such as agricultural water and growing areas), particularly when dry, windy conditions are present;
- **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; and
- **Survival of pathogens and other microorganisms** on produce commodities prior to harvest is dependent upon several environmental factors, including **sunlight (UV) intensity, moisture level, and temperature**. Generally, pathogens and other microbes die-off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool and wet conditions.

26. How can covered farms obtain information on environmental conditions for their pre-harvest agricultural water assessments for covered produce (other than sprouts)?

In many instances, covered farms will be able to use their previous experience and knowledge of their growing region to assess the environmental conditions for their agricultural water assessment. For example, many farms already take weather and climatic conditions into account when making management decisions for the crops they grow, and when and how those plants are planted and harvested. We do not expect farms to obtain detailed reports of local conditions, conduct complex scientific analyses of weather events, or travel to weather stations in order to obtain such information. Rather, knowledge of general trends, such as the identification of wet seasons, average monthly temperatures, and seasonal trends in sun exposure, will likely provide farms with adequate information for their agricultural water assessment. If a farm is new to the growing region, the farm can obtain relevant information on environmental conditions from internet resources (such as average monthly temperatures and rainfall), cooperative extension, and other local resources.

27. How can covered farms account for unpredictable weather in their pre-harvest agricultural water assessments for covered produce (other than sprouts)?

In most instances, covered farms will be able to use their previous experience and historical knowledge of their growing region to assess not only general "routine" trends in environmental conditions (e.g., yearly seasonal patterns in sun exposure), but also those conditions that might happen on a less frequent basis, but that nonetheless have the potential to impact their agricultural water systems or covered produce (e.g., hurricanes, heavy winds, or rains that otherwise may occur on occasion). By recognizing these events within their agricultural water assessments, farms will be able to develop a plan to ensure the safety and quality of their pre-harvest agricultural water in the instance that such events do occur.

However, we recognize that farms will not be able to anticipate every environmental condition that occurs. Unanticipated environmental conditions that go beyond what was considered as part of a farm's assessment (such as unexpected flooding that may introduce new hazards into a surface or ground water source, or an earthquake, which may affect a farm's piped distribution system) are significant changes that warrant a reassessment under § 112.43(e)(2). The reassessment must evaluate any factors and conditions that are affected by such change, including the factors in § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under § 112.43(c).

Reassessment

28. What are some examples of "significant changes" that warrant a reassessment under § 112.43(e)?

Section 112.43(e) requires, in part, that a covered farm must conduct a reassessment whenever a significant change occurs in its agricultural water system(s), agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that impacts hazard identification or a risk management determination as described in § 112.43(c). For example:

- A **change from an untreated ground water source to an untreated surface water source**, or the **installation and use of a new water distribution system**, is a significant change that requires a reassessment, as the degree of protection and likelihood of hazards being introduced are likely to differ and may impact risk management determinations;
- Some **changes in the use of adjacent or nearby land**—such as if adjacent or nearby land is used for a new dairy production operation—are significant changes, as the new use of that land may differ in its potential to introduce hazards into the agricultural water system;
- **Changes in agricultural water practices**, including the method or timing of water application, are significant changes that require a reassessment, as different practices present different risks to the crop;
- **Growing a different type of covered produce** than previously grown is a significant change, as the unique characteristics associated with the crop might affect whether it is vulnerable to contamination from agricultural water; and
- Some **environmental conditions**, such as unexpected flooding that may introduce hazards into a surface or ground water source and is not already accounted for in an agricultural water assessment, are significant changes that require a farm to conduct a reassessment.

The reassessment must evaluate the impacts of those changes on the factors in § 112.43(a), any new hazards identified, and the outcome and determination under § 112.43(c).

Testing as part of an assessment

29. If a covered farm tests its pre-harvest agricultural water as part of a pre-harvest agricultural water assessment for covered produce (other than sprouts), what sampling frequency and microbial criteria is the farm required to use?

Section 112.43(d)(3) requires that for covered farms that test their pre-harvest agricultural water as one part of an assessment, the frequency of testing samples and any microbial criterion (or criteria) applied must be scientifically valid and appropriate to assist in determining, in conjunction with other factors evaluated under § 112.43(a), whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with their agricultural water used in growing covered produce (other than sprouts).

Farms have the flexibility to use any sampling frequency and microbial criterion (or criteria), as long as the requirements in § 112.43(d)(3) are met. For example, this could include sampling frequencies that a

farm establishes based on its historical data and/or knowledge of water quality variability within its source. Sampling approaches that take into consideration other site- or region-specific data or information may also be appropriate.

While the sampling frequencies and microbial criteria used for pre-harvest agricultural water in the 2015 produce safety final rule are examples of approaches that farms may choose to use, they are not required to do so. Further, if a farm has scientifically valid data or information to support use of a sampling frequency and/or microbial criterion (or criteria) that is more reflective of its unique conditions than that used in the 2015 produce safety final rule, the farm must use that information under § 112.43(d)(3).

30. If pre-harvest agricultural water for covered produce (other than sprouts) meets the microbial criteria that a covered farm establishes under § 112.43(d)(3), does that mean measures under § 112.45 are not reasonably necessary?

Whether or not agricultural water meets a microbial criterion (or criteria) established in accordance with § 112.43(d) is not the sole determinant of whether corrective or mitigation measures are reasonably necessary under § 112.45. Rather, results from pre-harvest agricultural water testing serve as an additional source of information that covered farms may use to further inform their agricultural water assessments.

For example, if a farm tests its water as one part of an assessment per § 112.43(c)(4), in addition to determining whether the water meets the criterion (or criteria) established in accordance with § 112.43(c)(3), the farm can look at test results collected over time for potential insight into changes in water quality that might indicate hazards being introduced into the water system. Even if the water does not exceed the criterion (or criteria) the farm establishes, the farm may find, for example, that migratory birds are causing water quality to degrade when present in the area. As another example, the farm may find when looking at historical data that test results had at one time consistently shown lower levels of generic *E. coli* than more recent data, potentially indicating that a change occurred that is affecting the farm's water system.

In such circumstances, even if the water does not exceed the criterion (or criteria) the farm establishes, the trends in water quality changes over time show a potential source(s) of contamination to a farm's agricultural water. A farm must consider this information, along with other factors, in conducting its agricultural water assessment.

31. Can a covered farm consider historical data if testing its pre-harvest agricultural water for covered produce (other than sprouts) as part of an assessment?

We recognize the value in utilizing historical test results, particularly when it comes to analyzing trends in water quality over time, which may help to further inform a covered farm's agricultural water assessment. Historical data may be particularly useful in situations in which potential hazards are introduced into a water system intermittently, such that a farm is able to compare data over time to further inform its conclusions of whether measures are reasonably necessary under § 112.45. For example, if a farm is concerned that the quality of its water may be affected by rain due to runoff into a water source and/or stirring up of sediments, the farm may use water quality data collected over time

to determine if water quality is degraded following rain events compared to baseline (i.e., limited or no rain) conditions.

Assessment outcomes

32. If a potential source of contamination is identified in preparing a pre-harvest agricultural water assessment for covered produce (other than sprouts), does that alone mean that measures under § 112.45 are reasonably necessary?

If a covered farm identifies a potential source of contamination under § 112.43(a)(1), it is not a foregone conclusion that measures under § 112.45 are reasonably necessary. Rather, farms must make their written determinations on outcomes in light of all of the information evaluated under § 112.43(a)(1) through (5). This includes information on:

- The agricultural water system (including the source, water distribution system, and degree of protection from possible sources of contamination);
- Agricultural water use practices;
- Crop characteristics;
- Environmental conditions; and
- Other relevant factors, including test results, where appropriate.

33. For pre-harvest agricultural water for covered produce (other than sprouts), what is the difference between situations in which corrective measures are reasonably necessary and situations in which mitigation measures are reasonably necessary?

For pre-harvest agricultural water for covered produce (other than sprouts), "corrective measures" refer to those that covered farms must implement 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. See §§ 112.43(c)(1) and 112.45(a).

Conversely, "mitigation measures" provide more flexibility in the timing of decisions as compared to the immediate action required under §§ 112.43(c)(1) and 112.45(a), in that the mitigation measures must be implemented as soon as practicable and no later than 1 year after the date of the farm's agricultural water assessment or reassessment, except that mitigation measures in response to known or reasonably foreseeable hazards related to animal activity, BSAAOs, or the presence of untreated or improperly treated human waste on adjacent or nearby lands must be implemented promptly, and no later than the same growing season as such assessment or reassessment. See §§ 112.43(c)(2), 112.43(c)(4)(i), and 112.45(b).

34. What are some examples of situations in which the outcome in § 112.43(c)(1) is appropriate for pre-harvest agricultural water for covered produce (other than sprouts) (that is, when pre-harvest agricultural water is not safe and of adequate sanitary quality for its intended use)?

There are some conditions that, absent information or circumstances indicating otherwise (such as if the farm is not using pre-harvest agricultural water during the time period of interest), are likely to result in the outcome in § 112.43(c)(1), in which the water is not safe or is not of adequate sanitary quality for its intended use(s) and the farm is required to immediately discontinue use of the water and take corrective measures under § 112.45(a) before resuming such use. For example:

- Incidents in which raw sewage is introduced to an agricultural water system (for example, leakage of sewage from a ruptured pipe or improper release of sewage from a sewage treatment facility into an agricultural water system);
- Situations where a significant amount of animal waste is introduced to an agricultural water system (such as might result from a manure lagoon overflowing into an agricultural water system); and
- The presence of dead and decaying animals in an agricultural water system (for example, a well in which an animal has died, or a canal in which sheep have entered and drowned).

However, these examples are not the only circumstances in which the outcome under § 112.43(c)(1) will apply, nor do circumstances need to be as clear-cut as these in order for § 112.43(c)(1) to be appropriate.

35. How can a covered farm account for uncertainty related to adjacent and nearby land uses when making determinations on assessment outcomes for pre-harvest agricultural water for covered produce (other than sprouts) in § 112.43(c)?

We recognize that covered farms may face uncertainty around evaluating information related to animal activity, BSAAOs, and untreated or partially treated human waste from adjacent and nearby lands, such as if upstream users are not willing to share information. Due to the nature of the risks associated with these uses of adjacent and nearby lands, in the event of uncertainty, farms should consider the increased likelihood of hazard introduction from adjacent and nearby land uses, in addition to other information evaluated in § 112.43(a)(1) through (5), in determining whether measures under § 112.45 are reasonably necessary.

Harvest and post-harvest agricultural water

36. Does the microbial criterion of "no detectable generic *E. coli* per 100 mL of water" in § 112.44(a) apply throughout use of water for harvest and post-harvest purposes?

We consider the microbial criterion in § 112.44(a) to apply to water as it is being added to a dump tank, flume, or wash tank. Additional management and monitoring practices that apply for agricultural water used for harvest and post-harvest purposes can be found in § 112.44(d).

37. Does "managing water" under § 112.44(d)(1) mean that covered farms are required to treat non-single-pass water (including recirculated water or reused water) that they use for harvest and post-harvest purposes?

Section 112.44(d)(1) requires, in part, that covered farms must manage water used in harvesting, packing, and holding covered produce as necessary. Recognizing the wide-range of handling procedures, washing line set-ups, and commodity-specific practices where agricultural water directly contacts

covered produce during or after harvest activities, we are not requiring treatment of water. Instead, we have provided flexibility for farms to implement measures appropriate to their practices to comply with § 112.44(d)(1), which may include disinfection treatment for non-single-pass water.

38. Does the requirement to maintain and monitor water temperature in § 112.44(d)(3) apply for all commodities when agricultural water is used for harvest and post-harvest purposes?

Section 112.44(d)(3) requires that covered farms must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance. Thus, the requirement is tailored to apply only to appropriate commodities and practices, and only as needed to minimize the potential for infiltration of pathogens.

Corrective and mitigation measures

39. Can covered farms wait until the end of the relevant time period to implement mitigation measures for their pre-harvest agricultural water for covered produce (other than sprouts)?

The ends of the allowable timeframes for implementing mitigation measures in §§ 112.43(c)(4)(i) and 112.43(c)(2) (i.e., "no later than one year after the date of the agricultural water assessment" and "no later than the same growing season as the assessment," respectively) are included 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 (for example, 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. Moreover, these end points are important in that they provide a basis after which, if a farm does not implement mitigation measures, the farm is required to discontinue such use of the water until the farm has implemented adequate mitigation measures in accordance with § 112.45(b)(2).

However, inclusion of these end points in § 112.43(c)(4)(i) and 112.43(c)(2) does not permit farms 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 under § 112.45(b). Rather, farms must implement mitigation measures "as soon as practicable" or "promptly," respectively, as applicable to their circumstances.

40. How can a covered farm manage risks associated with hazards that affect pre-harvest agricultural water for covered produce (other than sprouts) if those hazards are outside the farm's control?

We recognize that covered farms may not always have control over a potential source of known or reasonably foreseeable hazards (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 measures in § 112.45 in the recognition that not every measure will be an appropriate or viable option for every farm, including those that a farm can implement whether or not the farm has control over the potential source of hazards at the point where hazards may be introduced to an agricultural water system.

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, the farm might determine that changing the water application method is appropriate to reduce the likelihood of contamination of the covered produce.

41. How can a covered farm determine the effectiveness of measures they implement under § 112.45?

There are various actions covered farms may take to verify the effectiveness of their corrective and mitigation measures. Examples include:

- If a farm takes measures that involve making necessary changes under § 112.45(a)(1) or 112.45(b)(1)(i), such as repairing a leak within the farm's piped distribution system in order to protect it from possible sources of contamination, re-inspection of the agricultural 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 as a mitigation measure under § 112.45(b)(1)(iv), 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.
- When treating agricultural water (§ 112.45(a)(2) and 112.45(b)(1)(v)); applying a time interval between last direct water application and harvest to allow for microbial die-off (§ 112.45(b)(1)(ii)); or applying a time interval between harvest and end of storage and/or using other activities during or after harvest to allow for microbial die-off and/or removal (§ 112.45(b)(1)(iii)), the farm is required to maintain scientifically valid data or information to support use of those measures (see § 112.50(b)(8) and (10)).
- A farm may choose to test their water to assist them in evaluating the efficacy of corrective or mitigation measures that they implement. However, we emphasize that farms must not rely on test results alone in making decisions around the safe use of their agricultural water.

If a 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, consistent with § 112.41 (§ 112.45(b)(2)).

42. In what situations might making necessary changes to agricultural water systems as a corrective or mitigation measure under § 112.45(a)(1) and (b)(1)(i), respectively, be appropriate?

Taking measures under § 112.45(a)(1) (which includes, but is not limited to, re-inspecting the affected agricultural water system and making necessary changes) and § 112.45(b)(1)(i) (which entails making necessary changes (for example, repairs) for pre-harvest agricultural water for non-sprout covered produce) generally are more relevant when the farm has some control over the potential source of known or reasonably foreseeable hazards. However, this may not always be the case. For example, even if a source of hazards is outside of a farm's control, depending on the circumstances, measures such as building a berm to reduce runoff, installing a windbreak, or making repairs to a well-head may be

appropriate to reduce the potential for known or reasonably foreseeable hazards being introduced into its agricultural water system.

43. What kind of information must be used to inform a time interval between last direct application of pre-harvest agricultural water and harvest of covered produce (other than sprouts) as a mitigation measure under § 112.45(b)(1)(ii)?

Scientific data and information used in support of a time interval between last direct application of agricultural water and harvest of the covered produce under § 112.45(b)(1)(ii) 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). Evaluating various factors under § 112.43(a), such as the timing of water applications, environmental conditions, and crop characteristics, will help farms identify conditions relevant to establishing an increased time interval between last direct water application and harvest in accordance with § 112.45(b)(1)(ii).

We consider the scientific data and information used to support the approach to a pre-harvest time interval established for the 2015 produce safety final rule as an example of adequate supporting scientific data and information farms may use in accordance with § 112.45(b)(1)(ii). As such, if a farm does not test its pre-harvest agricultural water but increases the time interval between last direct application of water and harvest as an appropriate mitigation measure, the farm may choose to increase its time interval to a minimum of 4 days, based on the data used to support the approach in the 2015 produce safety final rule. If a farm tests its pre-harvest agricultural water and increases the time interval between last direct application of water and harvest as a mitigation measure, the farm may choose to use a microbial die-off rate of 0.5 log per day, for potentially less than 4 days between last direct water application and harvest, to achieve a calculated log reduction to meet the criteria the farm establishes in accordance with § 112.43(d)(3).

Prior to using one of these approaches, however, the farm should consider whether the studies evaluated in support of pre-harvest microbial die-off in the 2015 produce safety final rule are reflective of conditions relevant to the farm. If a farm has scientifically valid data or information to support use of an increased time interval that is more reflective of its unique conditions, the farm must use that information in establishing an appropriate time interval under § 112.45(b)(1)(ii).

44. What are examples of the type of information that can be used to inform a time interval between harvest and end of storage and/or use of other activities during or after harvest as a mitigation measure for pre-harvest agricultural water for covered produce (other than sprouts) under § 112.45(b)(1)(iii)?

Covered farms that increase the time interval between harvest and the end of storage and/or conduct other post-harvest activities as a mitigation measure in accordance with § 112.45(b)(1)(iii) must establish parameters for such practices as appropriate to their circumstances (for example, in consideration of commodity characteristics, storage time and conditions, and/or other relevant production practices), as supported by scientifically valid data and information.

For example, a farm that uses commercial washing as a mitigation measure under § 112.45(b)(1)(iii) must do so as appropriate to its circumstances. The appropriateness of using commercial washing as a mitigation measure may be affected by the characteristics of the covered produce being washed (such as where commodity characteristics may protect potential contaminants from removal); the method of commercial washing (such as through a single-pass system vs. one that uses recirculated water); and any monitoring or management practices the farm has in place to reduce the potential for the agricultural water to serve as a source or route of contamination to covered produce (for example, the practices specified in § 112.44(d)).

45. In what situations might changing the water application method as a mitigation measure for pre-harvest agricultural water for covered produce (other than sprouts) under § 112.45(b)(1)(iv) be appropriate?

The appropriateness of changing the water application method as a mitigation measure in § 112.43(b)(1)(iv) is a function of multiple factors, including the water application method, characteristics of the crop (such as whether the harvestable portion grows near, on, or in the ground), and any relevant practices the farm may have in place. For example, changing the water application method for root crops may not be an appropriate mitigation measure, as it may be difficult to effectively minimize contact between agricultural water and the harvestable portion of the crop while allowing the crop access to water needed to survive and grow. However, for non-root crops, changing the water application method may be effective as a mitigation measure under § 112.45(b), if making the change minimizes the water that is in direct contact with the harvestable portion of the crop. For example, changing from overhead to microjet irrigation for some tree fruit (such as citrus) or from microjet to drip irrigation for some covered produce that grows near the ground (such as bell peppers) may reduce the likelihood of contamination of the covered produce in accordance with § 112.45(b)(1)(iv). Additionally, 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 under § 112.45(b)(1)(iv).

46. Are covered farms required to treat pre-harvest agricultural water as a corrective or mitigation measure under § 112.45?

Covered farms are not required to treat their agricultural water. Rather, farms have a range of options to consider based on the practices and conditions specific to the farm, treatment of water being only one such option.

Treatment of agricultural water

47. If a covered farm treats agricultural water, is it required to use chemical treatment?

No. If a covered farm treats agricultural water, § 112.46 allows for non-chemical methods of treatment. For example, physical treatment of agricultural water (including using a pesticide device) or any other suitable treatment method can be employed provided the method is effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the microbial quality criterion in § 112.44(a), as applicable (§ 112.46(a)).

With respect to chemical treatments, we also note that like all registered pesticide products, registrations for antimicrobial products are specific to the use that was considered as part of the registration process, and thus the products may be legally used for the specified registered use only. For example, among the antimicrobial products registered with EPA as sterilizers are certain registered antimicrobial products for use in the treatment of irrigation water systems or irrigation ponds to control bacterial and algae growth. However, because these antimicrobial products are not authorized by EPA for use to control human pathogens or indicator organisms, they cannot be used to treat irrigation water to comply with relevant requirements in subpart E.

48. What is an example of an effective monitoring program for agricultural water treatment under § 112.46(c)?

If a covered farm treats agricultural water, § 112.46(c) requires that the covered farm must monitor the treatment using an adequate method and frequency to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use(s) and, if applicable, also meets the microbial quality criterion in § 112.44(a).

An example of an effective monitoring program for use of a chemical treatment method would measure the level of active compound as well as those factors that may affect its activity, such as pH, temperature, and contact time. For example, adequate monitoring of water treated with hypochlorite in a post-harvest wash must include, at a minimum, monitoring the level of active antimicrobial (free available chlorine) and pH, since it is known that hypochlorite activity is reduced both by organic material (e.g., soil, plant debris) and pH values outside its effective range (pH 6.0–7.5). The concentration of active disinfectant and pH must be adjusted, as necessary, taking into account variations in water quality in order to maintain the effectiveness of the treatment. In addition, the frequency at which farms monitor agricultural water treatment must be adequate to ensure that the conditions for proper treatment are consistently met and adjusted, as necessary, to result in water that is safe and of adequate sanitary quality for its intended use and/or meets the microbial quality criterion in § 112.44(a), as applicable.

Who may test

49. If public data are available for a water source that a covered farm uses as agricultural water, can the farm use those data if testing agricultural water for subpart E purposes?

Section 112.47(a) provides that the requirements related to agricultural water testing under §§ 112.43(c)(4)(ii) and 112.44 may be met using results from testing performed by a covered farm or a person or entity acting on the farm's behalf; or, data collected by a third party or parties, provided the water sampled by the third party or parties adequately represents the farm's agricultural water source(s) and all other applicable requirements are met. As such, for example, if a covered farm that tests pre-harvest agricultural water under § 112.43(c)(4)(ii) uses data collected by a third party, such data must reflect sampling that occurred immediately prior to or during the covered farm's growing season and must be representative of the water the farm uses in growing covered produce (other than sprouts) (§ 112.43(d)(1)).

Test methods

50. What test methods are covered farms required to use if testing their agricultural water for subpart E purposes?

If testing agricultural water for generic *E. coli,* covered farms are required to use EPA's "Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC)" (December 2009) (§ 112.151(a)); or, a scientifically valid method that is at least equivalent to Method 1603 in accuracy, precision, and sensitivity (§ 112.151(b)(1)). We have provided a list of testing methodologies that meet the requirements in § 112.151(b)(1) on our website at: Equivalent Testing Methodology for Agricultural Water – Produce Safety rule (21 CFR 112).

If testing pre-harvest agricultural water for any other indicator of fecal contamination, index organism, or other analyte pursuant to § 112.43(d), farms must use a scientifically valid method (§ 112.151(b)(2)).

Agricultural water records

51. Can existing records related to agricultural water, such as those a covered farm might maintain for purposes of third party food safety standards, be used to fulfill agricultural water record requirements in subpart E?

Under § 112.163(a), covered farms are not required to duplicate any existing records, including those for agricultural water, if those records contain all of the required information and satisfy the relevant requirements. Similarly, if a farm has records containing some but not all of the required information, § 112.163(b) provides the flexibility to keep any additional information required either separately or combined with existing records. As such, farms have flexibility as to how they maintain records, so long as all relevant requirements are met.

52. Can records related to agricultural water system inspections under § 112.42(a) be used to fulfill records related to pre-harvest agricultural water assessments under § 112.43?

Records of a covered farm's agricultural water system inspection in § 112.50(b)(1) may not be appropriate to fulfill, in full, the requirement to maintain records of written agricultural water assessments in § 112.50(b)(2), as the requirements in § 112.43 for agricultural water assessments require consideration of a broader range of factors than those considered for water system inspections under § 112.42(a). See also question 13.

53. Under § 112.50, are covered farms required to use peer-reviewed journal articles as "scientifically valid data or information" in support of various requirements in subpart E?

We use the term "scientifically valid" to mean an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. Use of peer-reviewed literature is just one component of what we mean by the term "scientifically valid;" however, we continue to believe that peer-reviewed literature may be an important source of information.