Industry Guidance:
Pre-Harvest Agricultural Water, 2nd edition

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IFPA Food Safety Council
Agricultural Water Working Group
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Introduction

The International Fresh Produce Association (IFPA) convened a group of volunteers from among the 140 members of the IFPA Food Safety Council. Volunteers prepared guidance for those seeking to comply with the United States Food and Drug Administration (FDA) revised Subpart E requirements for agricultural water, published in May 2024 under the Food Safety Modernization Act (FSMA) to amend the 2015 Produce Safety Rule. Specifically, working group volunteers were asked to address common points of confusion and provide additional resources to support the produce industry. The resulting briefs and other communications were based on the final provisions of revised Subpart E rule and contents of its preamble as well as scientific evidence applicable to a wide range of cropping systems. As a living document, this content will be updated and revised on an as-needed basis.

How to Use this Document

The document is organized into four topic-specific scenarios and 13 briefs to ensure ease of use. Not all topics included in the revised Subpart E PSR requirements for pre-harvest agricultural water are addressed. Topics that have historically generated more questions from stakeholders were selected for focused discussion and case studies. It is recommended to navigate this document using the Table of Contents, which include hyperlinks to document sections.

In addition to the 13 briefs, a series of four scenarios were created and are presented in general order of complexity. Each scenario is presented within the context of the revised Subpart E final rule to illustrate how the briefs can aid covered farms to meet the requirements of the agricultural water assessment (AgWA). IFPA and the Agricultural Water Working Group recognize that some commodities benefit from existing industry-specific guidance regarding management of agricultural water. This document is intended to complement, not replace, existing commodity-specific resources.

Briefs

As part of revised Subpart E for pre-harvest agricultural water, an AgWA must be conducted for water used to grow produce covered by the PSR. There are ways to be exempt from completing the AgWA. When the AgWA is required, it must be conducted at least once per year to identify potential conditions that may increase the likelihood of human pathogens being in pre-harvest water. The AgWA elements are individually described in the 13 briefs included in this document. For any given scenario, several or many of the briefs may be relevant. Each is designed to provide useful information in a stand-alone format, allowing them to be used 'à la carte' to help build a customized AgWA that is tailored to the unique risk profile of each covered farm. The briefs are organized into two sections:

- Those related to developing a risk profile for the water source, in context of its intended use; and
- Those focused on determining the outcome of the AgWA, including whether corrective or mitigation measures are reasonably necessary.

The AgWA also includes recordkeeping requirements, which are discussed separately {Link to Records Requirements Brief}.

Scenarios

The four scenarios reflect a range of farming practices and varying levels of complexity. They represent situations that may be encountered when assessing the likelihood of hazard introduction and the associated risk to consumers in relation to pre-harvest agricultural water and produce covered by the PSR. Each scenario contains: (1) water source and conveyance methods; (2) potential sources and pathways of pathogen contamination of the water; and (3) how the water is used with covered produce (i.e., fruits and vegetables typically consumed raw) during growing activities (i.e., pre-harvest water use period). Many scenarios also include information, such as microbiological test results, to aid one in understanding, or developing expectations of, overall water quality.

Each scenario is followed by an exercise, in which the regulatory requirements related to developing an AgWA are applied to the information presented in the scenario. Information briefs, related to specific components of the regulatory requirements, are cited in these exercises to demonstrate how the briefs can be used by a farm when performing an AgWA. In each scenario described, the farm is covered by the PSR, so they are not eligible for exemptions described in Subpart A: General Provisions of the regulation (e.g., no qualified exemption or exemption for produce that undergoes commercial processing with a kill step). Conditions that might exempt a covered farm from conducting an AgWA (described in 21 CFR 112.43(b)) can be found in the Understanding Exemptions section of this document.

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Background Information:

Hazard and Risk

A fundamental aspect of effectively managing a pre-harvest agricultural water system—and food safety overall—is understanding the terms **hazard** and **risk**.

- A **hazard** is a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control (definition source: FDA Preventive Controls for Human Foods Rule).
  - The PSR focuses on biological hazards only (although produce must always be safe for consumption). The FD&C Act and most GAP audits include chemical and physical hazards.
  - Examples of biological hazards include pathogenic microorganisms listed. {Microbiological Hazards Table}
  - When describing the purpose of an AgWA to identify hazards, it is important to consider both the presence of a hazard and the conditions that could result in a 'known or reasonably foreseeable hazard.' In other words, this involves evaluating situations that could result in the contamination of non-sprout covered produce or food-contact surfaces by that hazard (see, for example, responses to comments 16 and 29 in the 2024 revision to Subpart E requirements).
- **Risk** is the **probability** of an adverse health effect and the **severity** of that effect resulting from the presence of a hazard(s) in food. There are two components of risk:
  - **Severity** (e.g., health consequence) is tied to the hazard itself. Questions related to severity include:
    - If someone becomes ill, how sick might they get? What is the likelihood of hospitalization or death?
  - **Probability** (i.e., likelihood, or frequency of occurrence) can be assessed by asking these questions:
    - Has this hazard been found before? How often? Under what conditions? At what levels?
    - Have other growers, under similar conditions, found the hazard is likely present in their agricultural water?
    - Does testing data show the presence of the hazard?
    - Are there certain conditions (e.g., rain, season) that might increase the chance the hazard could enter the water system?
    - Will the hazard, if present in the water, reach the produce?
    - Will the hazard, if it reaches the produce, survive so as to be consumed and cause illness?
    - How much of the organism (dose) does it take to make someone sick?

Probability can be impacted through implementation of **controls** (i.e., specific action or practice implemented to prevent or minimize hazards). Some control strategies are within a farm's control and may be implemented as a result of the evaluation discussed below. Other control strategies are outside the control of the grower (e.g., no rain, slope of land). In the revision to Subpart E, FDA defines specific **measures** (e.g., broader standards to prevent contamination or promote safe conditions) that can be implemented to reduce risk. For example:

- Are there measures in place to reduce the likelihood of contamination occurring (e.g., distance, slope, physical barriers like berms, ditches, fences)? How effective are these measures?
- Are there measures in place that would reduce the likelihood that contaminated water would "successfully" make someone sick? For example, is it likely that water would contact the crop? Are there measures that would reduce levels of the hazard in the water (e.g., water treatment)? Are there measures in place that would reduce the level of contamination even if it had been introduced to the crop (e.g., die-off)?

Assessments and **evaluations** refer to the process of combining the likelihood of encountering a hazard with the potential severity of its outcome to determine if corrective or mitigation measures are necessary. Some people choose to assign numbers or scores to probability and severity, some by adding them together, and others through addition. The math is less important than recognizing that risk is a continuum--some situations will be higher risk, others will be lower risk. The risk associated with a hazard may change over time, such as weather or the presence or movement of animals. The best AgWAs document factors that increase or decrease risk. Responsible growers will also be alert to changes in conditions that impact risk. It is possible to identify a hazard and conclude it is not reasonably likely to cause illness (i.e., not a risk). When risk increases, growers should consider using tools available to decrease risk, generally through decreasing one of the following:

- Decrease the probability water will become contaminated;
- Reduce levels of contamination in water if it is contaminated (e.g., water treatment);
- Decrease the probability contaminated water will contact the harvestable portion of the crop; and/or
- Decrease the probability that, if contaminated water contacts the crop, it will persist at a level likely to cause illness.

Reasonably Foreseeable Hazards

This section of the document was adapted from a July 2021 United Fresh Produce Association (now IFPA) article available at: https://www.freshproduce.com/resources/food-safety/reasonably-foreseeable-hazard/.

A "reasonably foreseeable hazard" designation signals the escalation of urgency. In both FDA's investigation report related to *E. coli* O157:H7 and leafy greens, as well as a letter to the Florida Fruit and Vegetable Growers Association related to *Cyclospora*, FDA stated organisms of concern may be known and "reasonably foreseeable hazards." This term appears in the PSR, but it is likely more familiar to those with a background in Hazard Analysis Critical Control Point (HACCP) and individuals who have conducted hazard analyses in accordance with the Preventive Controls for Human Foods Rule (PCHF).

What is a "reasonably foreseeable hazard" in the context of a growing environment? And what is the implication for others in the supply chain? A subgroup of the United Fresh Food Safety Council discussed this topic with FDA. Below is a synopsis of this discussion.

- The term signals the FDA's concern about an issue and indicates an escalation of urgency.
- "Reasonably foreseeable hazards" are not a one-size-fits all. The exact language of the letter regarding *Cyclospora* notes the detection "**may** constitute a known or reasonably foreseeable hazard." In the *E. coli* report, FDA states the strain "**appears to be**" a known or reasonably foreseeable hazard. This means the designation is not absolute. The assessment should be done on a case-by-case, field-by-field basis, versus an incrimination of an entire growing region.
- This term should prompt growers to evaluate potential sources of the hazard, routes of contamination, and implementation of controls. This includes recognizing the importance of adjacent and nearby land and adequately assessing risk. This evaluation should consider if the hazard is reasonably likely to occur based on a farm's individual policies, procedures, and practices. Growers should move beyond a "check the box" approach in conducting this evaluation. The onus is on the grower to demonstrate the adequacy and effectiveness of controls.
- Companies regulated under PCHF that purchase produce from growers using this term should consider its implications for their hazard analysis.
- Regardless of one's role in the produce supply chain, the term "reasonably foreseeable hazard" is clearly here to stay. Its continued use reflects the FDA's ongoing concerns about food safety within the produce industry. With the increasing publication of outbreak investigation reports, it is expected this term will continue to be used to promote greater awareness of potential hazards, enabling more effective risk evaluation and management.

A Systems Approach to Pre-Harvest Water Risk Management

Because there is no kill step for produce to be eaten raw, food safety must be managed by preventive actions across the entire production process and supply chain. Given the variation of practices associated with agricultural production, the degree of mechanization, water sources, water treatments, growing practices, harvesting approaches, among others, a grower must carefully assess risks associated with each step. It is only after this analysis has been completed that the operation can identify the most logical risk corrective or mitigation measures. While this document presents many recommendations, they will not **all** be equally applicable to **all** produce farms. For example, water should be managed differently on a farm where there is no chance of water contact with the crop versus a farm where deliberate or inadvertent water contact occurs.

As previously stated, fundamental to this assessment is a clear understanding of the difference between hazards and risks. Hazards are agents that can cause harm (e.g., bacterial pathogens, pesticides, heavy metals, glass). Risk is the likelihood the hazards *will* cause harm, combined with the severity of injury or illness if exposure occurs. Growers should use recall and outbreak history, scientific research, historical knowledge of events/hazards on the farm, and expert consultation to identify potential hazards. One should then evaluate the likelihood each hazard can occur, move, and survive in their specific production system. The prioritization of risks should guide the selection and implementation of measures as an outcome of the AgWA. As new information becomes available, either publicly or as a result of internal findings (e.g., verification activities), risk and mitigations should be re-assessed (21 CFR 112.43(e)). This is particularly true when managing pre-harvest agricultural water safety because the science informing best practices is continually evolving.

Figure 1: A systems-based approach to food safety risk management may involve 'stacking' multiple mitigations (some are measures described in 21 CFR 112.45) that are appropriate to the identified hazards and likelihood the hazard will cause harm (i.e., there is a risk). The figure below highlights how different combinations of mitigations can be used to achieve an acceptable level of risk with pre-harvest agricultural water. Different pre-harvest agricultural water systems will not necessarily present the same 'stack' of mitigations to meet the risk reduction goal.

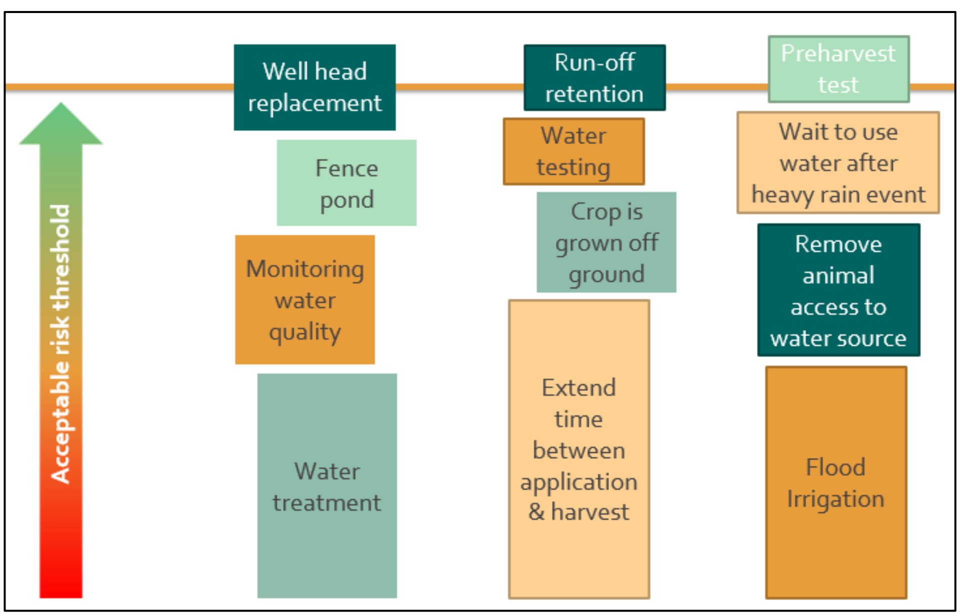


Figure adapted from Dr. Channah Rock, University of Arizona

Comparison: Agricultural Water Systems Inspection and Agricultural Water Assessment

In the 2015 PSR, FDA established the requirement to perform an agricultural water systems inspection (§ 112.42) on all agricultural water systems, including water used for pre-harvest activities (e.g., irrigation, protective spray application) and harvest/postharvest activities (e.g., washing, cooling). In 2024, FDA finalized the requirement for performing an AgWA on pre-harvest water (§ 112.43). A summary of the differences between the agricultural water systems inspection and AgWA requirements is presented below. For more detailed discussion, go to: "FSMA Produce Safety Rule: Agricultural Water Systems Inspection is Different from the Proposed Agricultural Water Assessment" factsheet. Additionally, there are several key definitions relevant to this section: agricultural water, agricultural water system, and AgWA. {Link to Relevant Definitions}

The ***agricultural water systems inspection*** in § 112.42 must include all agricultural water systems, to the extent they are under the grower's control. The intent of this inspection is to identify conditions likely to introduce known or reasonably foreseeable hazards into produce or food-contact surfaces. These water system components include agricultural water source, water distribution system, any building or structural part of the water distribution system, and any equipment used for application of agricultural water to covered produce or food-contact surfaces. The documented agricultural water system inspection must be conducted at the beginning of the growing season, at least once per year, and more often as appropriate. The end goal is to maintain the agricultural water system to reduce the potential for pathogens in the water. The findings of the agricultural water systems inspection can be used to inform the AgWA.

This guidance document primarily focuses on the expectations and requirements outlined in the AgWA. Additional resources on the agricultural water systems inspection can be found in "Supporting Resources."

The AgWA in § 112.43 is intended to supplement the requirements of the agricultural water systems inspection. In contrast to the agricultural water systems inspection, the AgWA focuses on pre-harvest water, which is water meeting the definition of agricultural water and that is used during growing activities for covered produce (other than sprouts). The AgWA requires covered farms to conduct a more comprehensive assessment of possible sources and routes of contamination, including those outside a grower's control. The response to Comment 15 in the 2024 final rule on pre-harvest agricultural water preamble recognizes that farms may have little control over external factors (e.g., weather events, adjacent and nearby lands, other water users). Even so, growers are expected to consider these factors when assessing their water source. The AgWA must be conducted at the beginning of a growing season and at least once per year. Whenever a significant change occurs in the agricultural water system or other elements within the AgWA (§112.43(e), a reassessment must occur. Preamble (2024) Comments 69 and 100 present examples of environmental conditions that might necessitate a reassessment.

Details of the individual components that make up the AgWA can be found throughout this document. The findings from a farm's AgWA will determine what corrective or mitigation measures must be implemented, as directed under § 112.43(c). This is in contrast to the agricultural water system inspection and maintenance requirements under § 112.42, which are not directly linked to the implementation of corrective or mitigation measures [see Preamble (2024), Comment 25]. Reference Corrective/Mitigation Measures section}.

Supporting Resources

1. Produce Safety Alliance. *FSMA Produce Safety Rule: Agricultural Water Systems Inspection is Different from the Agricultural Water Assessment.* February 2025. Available at: https://resources.producesafetyalliance.cornell.edu/documents/AGWA-FSMA-PSR-Agricultural-Water-System-Inspection-is-Different.pdf.

2. Produce Safety Alliance. *Records Required by the FSMA Produce Safety Rule.* February 2025. Available at: https://resources.producesafetyalliance.cornell.edu/documents/Records-Required-by-the-FSMA-PSR.pdf.

Understanding Compliance Dates

The best source of current information about FSMA compliance dates is on the FDA website. Of note, several compliance dates have passed, meaning farms covered under the PSR must be in compliance for most requirements.

Beginning January 26, 2023, the FDA ended enforcement discretion for the postharvest requirements of Subpart E for businesses that do not qualify as small or very small. This means that enforcement of Subpart E requirements for **postharvest** and **harvest water** applications began on the following dates:

- January 26, 2025, for very small businesses;
- January 26, 2024, for small businesses; and
- January 26, 2023, for all other businesses.

The final revision for the pre-harvest agricultural water section of Subpart E was issued in May 2024. The effective date for this section of Subpart E is July 5, 2024. Compliance dates for **pre-harvest agricultural water** under Subpart E are as follows:

- April 5, 2027, for very small businesses;
- April 6, 2026, for small businesses; and
- April 7, 2025, for all other businesses.

Understanding Exemptions

The FSMA PSR includes a variety of coverage conditions and exemptions, mostly in relation to commodities, farm businesses, and specific agricultural water requirements. Importantly, this section does not describe every exemption, only those directly related to Subpart E.

If water never contacts covered produce or food-contact surfaces, any pathogens that might be in the water are extremely unlikely to contact the produce and make consumers sick. Water used in a way that does not contact covered produce or food-contact surfaces is not classified as agricultural water. Subpart E, including the AgWA, applies only to what is defined as agricultural water {reference Relevant Definitions}.

> ***Agricultural Water*[1]**: water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

For water uses that do qualify as agricultural water, the requirements of Subpart E apply. These requirements include ensuring all agricultural water is safe and of adequate sanitary quality for its use (§ 112.41), performing an agricultural water systems inspection (§ 112.42), completing a pre-harvest AgWA and deciding on an outcome (§ 112.43), and taking appropriate actions in response (§ 112.45). If water used as pre-harvest agricultural water meets certain requirements for postharvest water (§ 112.44), the grower *may* be exempt from performing an AgWA. However, the grower would still be bound to the other requirements in Subpart E, including the agricultural water systems inspection requirement {reference Comparison: Agricultural Water Systems Inspection and Agricultural Water Assessment}.

Those "certain requirements" are spelled out in § 112.43(b)(1). An AgWA is not required if:

- The water is untreated ground water and has been tested in the same manner as postharvest water as described in § 112.44(a) and (b).
  - The requirements include a frequency of four samples in one year and one sample per year afterward and a criterion that the water must have no detectable generic *E. coli* in a 100 mL sample.
  - All results of water testing must be recorded in the farm record (§ 112.50(b)(5)) and must be consistent with the testing method requirement in § 112.151.
  - This exemption does not apply to untreated surface water, even if it has been tested and has no detectable generic *E. coli* in a 100 mL sample.
- The water is from a public water supply or a public water system (e.g., most public drinking water).
  - This exemption links to § 112.44(c) and requires that the farm keeps water quality documentation about the public water source.
- The water is treated in accordance with § 112.46.
  - The treatment method may be chemical (e.g., sanitizers) or physical (e.g., slow sand filtration), provided it is proven to produce water that is safe and of adequate sanitary quality for its intended use.
  - Documentation of treatment effectiveness (control parameters) and monitoring are required in § 112.50(b)(10) and (11).

Treated status can also qualify postharvest water for an exemption from being tested for generic *E. coli* (§ 112.44(c)(3)). A final condition for exemption **applies to all three of the above-mentioned situations.**

It is reasonably likely that the water quality will remain unchanged before its use as agricultural water (for example, based on how the water is held, stored, or conveyed*)* (§ 112.43(b)(2)).

Many growers might review how they use water during growing activities and realize that, for the reasons described above, they are already managing risks to produce on the farm by: 1) eliminating contact between agricultural water and covered produce (or food-contact surfaces), or 2) using a water source that has been confidently assessed as very low risk (e.g., water with no detectable *E. coli*, treated according to EPA protocols) and ensuring it is protected from contamination with pathogens on the farm before use.

Supporting Resource

1. U.S. Food and Drug Administration. 2015. *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. Produce Safety Rule Subpart A: General Provisions.* Available at: https://www.ecfr.gov/current/title-21/section-112.3

Pre-Harvest Agricultural Water Scenarios

Scenario 1: Vegetable Farm Using Municipal Water

A vegetable farm in the Midwest region of the United States supplies wholesale markets with fresh tomatoes and cucumbers. The growing area is outdoors. Fields are formed into rows covered with black plastic mulch separated by furrows. On this farm, cucumber vines are not trellised, and the tomato plants are grown on trellises.

All cucumbers that meet quality standards (e.g., undamaged) are harvested. Pooled water has been observed in the growing area during rainfall events, sometimes in contact with cucumbers on the vine. Harvested cucumbers are washed with a brush line and spray bar, followed by application of wax. Tomatoes touching the ground are not harvested. Harvested tomatoes are cleaned along a dry brush line and no water is used in postharvest tomato handling.

- ***Water source*:** Municipal water from a utility that operates in compliance with the U.S. Environmental Protection Agency (EPA) Safe Drinking Water Act requirements for a public water source.
- ***Conveyance of water:*** The municipal water is carried through an enclosed distribution system from the water source directly to the irrigation system and to the packhouse for use as postharvest water.
- ***Potential sources of contamination*:** Animal activity (prints, feces, crop damage, and other indications) are sometimes observed in the growing area. Animals that may enter the growing area include deer, various small rodents, and birds. The area used to mix plant protection products (PPP) is covered and enclosed. Animals are excluded from this enclosed area.
- ***Irrigation method*:** Drip tape is placed under black plastic during bed formation. Drip is the only form of irrigation for these crops.
- ***Foliar application*:** PPP are applied to vines as needed to control insect damage and fungal disease. PPP application can occur up to 24 hours prior to harvest.
- ***Water tests*:** The farm operator has annual drinking water quality reports from the water utility that cover the prior three years. In each report, the utility indicates compliance with total coliform-based testing requirements and standards in the Safe Drinking Water Act (SDWA).

Unpacking the Vegetable Farm Scenario:
Is an AgWA Needed?
An AgWA probably would not be required in this scenario. The water source is drinking water, which meets U.S. EPA requirements for a public water system. Additionally, the quality of water is not likely to change due to the direct conveyance system used.

- ***Irrigation water:*** Irrigation of tomatoes and cucumbers by drip under plastic mulch is a non-contact method and not expected to be within the definition of agricultural water. An AgWA is not required for water that is not defined by FDA as agricultural water.
- ***Foliar spray water:*** Water is used to mix plant protection products (PPP) and applied to the crops before harvest. This use is likely considered agricultural water. Foliar spray water comes from a public water system that meets the requirements of the SDWA and is, therefore, exempt from the AgWA requirement.
  - **Note:** § 112.43(b)(1)(ii) provides an exemption from the need to perform an AgWA on water obtained from a drinking water utility (e.g., a public water system).
- ***Other water:*** Any water used as agricultural water during and after harvest would not be subject to the AgWA requirement. The requirement applies only to pre-harvest water (see § 112.43).

- ***Other relevant requirements***:
  - As described in § 112.42(b)(4), the potential for contamination of covered produce through pooled water must be managed. In this scenario, pooled water may be a carrier of pathogens to produce if, for example, animal feces were located nearby in the growing area. This possibility should be considered even if the water is not considered 'agricultural water.'
  - Note that FDA provides guidance related to flooding[1]. In that document, exposure of the edible portion of the crop to natural flood water is considered an adulteration event. It states: *"pooled water (e.g., after rainfall) that is not reasonably likely to cause contamination of the edible portions of fresh produce is not considered flooding."*
  - If the exemption for water from a public water system were used (§ 112.43(b)(1)(ii)), a certificate of compliance from the public water system or other documentation is required under § 112.50(b)(6) and § 112.44(c).

§ 112.43(b)
Exemptions. You do not need to prepare a written agricultural water assessment for water that you directly apply during growing activities for covered produce (other than sprouts), if your water meets the criteria in paragraphs (b)(1) and (2) of this section.
(1) You can demonstrate that the water:
i. {relates to no detectable *E. coli* standard}
ii. Meets the requirements in §112.44(c) for water from a public water system or public water supply…
(2) It is reasonably likely that the quality of the water… will not change prior to the water being used as agricultural water (for example, due to the manner water is held, stored, or conveyed).

§ 112.44(c)
Exemptions. There is no requirement to test agricultural water that is used as sprout irrigation water or for harvesting, packing, or holding covered produce when:
(1) You receive the water from a public water system, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations…

Supporting Resources

[1] US Food and Drug Administration. *Guidance for Industry: Evaluating the Safety of Flood-affected Food Crops for Human Consumption*. October 2011. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-evaluating-safety-flood-affected-food-crops-human-consumption.

Scenario 2: Blackberry Farm Using Spring Water and River Water

A blackberry farm has two orchards located in a subtropical highland climate in Mexico. Canes are managed to keep the berries growing at least 45 centimeters off the ground.

Farm 1:

- ***Water source***: Spring water 6 miles upstream that is used by several growers.
  - The condition and degree of protection of the spring are not known at the point of use.
- ***Conveyance of water:*** The conveyance method for the water changes during delivery to the irrigation system.
  - Water is piped for the first 5 miles from the spring to the blackberry farm.
  - Water moved over the last mile is through open channels.
- ***Potential sources of contamination***: Wild animal activity, including migratory birds and deer, can be observed in the growing area and along the open channel.
- ***Irrigation method***: Water is pumped from the channels into a small open storage tank at the entrance of the farm. From the storage tank, the water is pumped through a filter to screen for gross debris then passes through drip irrigation lines or into furrow irrigation (one or the other for each growing area) to the growing canes.
  - Drip irrigation is used on 70% of the farm.
  - Drip irrigation lines sometimes spring leaks that spray water, which can contact berries on the canes, even above the 45 cm line.
- ***Foliar application***: Water is treated with chlorine prior to mixing PPP for foliar application (**Note**: this practice may not be appropriate; see the exercise section below). Treatment records are in the farm's records.
- ***Water tests***: The water source, prior to chlorination, is tested multiple times per year. Test results for generic *E. coli* range from not detected (<1 CFU/100 mL) to 10 CFU/100 mL.
  - Records of the date of sample collection and the results of analysis are kept in the farm's record.

Farm 2:

- ***Water source:*** River water.
- ***Conveyance of water:*** River water is diverted to an unprotected open channel. The length of channel from the river to the growing area has not been measured (possibly miles).
- ***Potential sources of contamination***: Domesticated animals (e.g., cows, goats, dogs) are active in the riverbank area. Dead animals and garbage from human activity have been found after heavy precipitation events in channels accessible to the public.
- ***Irrigation method***: Irrigation water is brought from the channel using an irrigation gate into a system of furrows between the rows of canes.
- ***Foliar application***: Spring water from Farm 1 is loaded into a tanker truck, treated with chlorine, and trucked to Farm 2 prior to mixing PPP for foliar application. Treatment records are in the farm's record.
- ***Water tests***: River water has been tested at the point of use and typically has about 400 MPN generic *E. coli*/100 mL during the dry season. Concentrations as high as >100,000 MPN generic *E. coli*/100 mL have been measured during the rainy season.

~~Unpacking the~~ Blackberry Farm Scenario Excercise

Is an AgWA Needed?

An AgWA would likely not be required in the blackberry farm because the method of application does not allow intentional contact with the harvestable portion of the plant (the fruit). However, the water is still required to be of adequate quality under the Food Drug & Cosmetic Act as incidental contact may occur. In addition, although testing quantified levels of generic *E. coli* is not required in the final rule, FDA has acknowledged that meeting the EPA recreational water requirements is an acceptable metric when evaluating agricultural water quality.

- ***Irrigation water***:
  - For both Farm 1 and Farm 2, the combination of production practices and method of application means the use likely does not meet the definition of agricultural water {Link to Relevant Definitions}
  - The canes are managed so that furrow and drip irrigation water does not normally touch the harvestable portion of the crop (above 45 cm).
  - Although the Food, Drug, & Cosmetic Act requirements about adulteration still apply, the requirements of the PSR likely do not apply to this use of the water.
- ***Foliar spray water:***
  - For both Farm 1 and Farm 2, foliar spray water applied prior to bloom is from the spring. The water is treated with chlorine before mixing.
  - It becomes crucially important for the farm to determine whether their use of chlorine to treat the water meets the requirements of § 112.46.
    - {see Link to Treatment of Agricultural Water Brief}
    - including the requirement to ensure the treatment is effective and
    - monitor the treatment} because treated water is exempt from the AgWA requirement of § 112.43 (see exemption in § 112.43(b)(3)).
    - Records needed
  - In particular, ensure that the label for any plant protection product (PPP) permits mixing with the water treatment chemical {Link to Treatment of Water- The Label is the Law Brief}.
- ***Other relevant requirements:*** The river water used for irrigation at Farm 2 has a history of generic *E. coli* concentration measurements around 400 MPN/100 mL with higher measurements also recorded.
  - 100,000 MPN/100 mL is high in relation to U.S. EPA recreational water standards.
  - EPA recreational water quality standards (geometric mean less than 126 CFU/ 100 mL and statistical threshold values varying from 235 to 576 CFU/100 mL depending on the type of recreation)

Preamble, Proposed Revision to Subpart E (page 69145, column 3):

"… if a farm uses drip tape in a way that water does not normally contact the harvestable portion of the crop, unintentional contact may still occur if the drip tape begins to leak sprays water on the crop. Although not considered agricultural water for purposes of subpart E, the farm should consider whether the source of water may have caused the produce to become adulterated under section 402 of the FD&C Act …"

Systems approach broadens perspective:
Many farms are accustomed to thinking about regulatory requirements in isolation. The PSR uses a systems approach in which the requirements have flexibility and are inter-dependent. The effect is to require deeper thinking about the big picture. Covered farms are expected to think independently and prevent contamination of covered produce by building upon the core requirements of the PSR. For instance, in the blackberry farm scenario:

- The definition of agricultural water and the meaning of treated water are based on effective avoidance of contact and effective removal of pathogens, respectively.
- While a farm may be exempt from specific requirements of the PSR, they must still minimize the potential for adulteration under 21 CFR § 112.11 and not allow adulterated food into commerce under the FD&C Act.

Furthermore, the river catchment area has animal activity, dead animals, and trash particularly at high flow conditions when *E. coli* concentrations are higher. In this instance, where the farm knows this water has high E. coli counts and other concerns (i.e., dead animals), they should really monitor and minimize plant contact. If the water is applied pre-bloom, the risk of fruit contamination is lower. If the water is applied at bloom or after, it is now agricultural water. The farm should also pay attention to incidental contact with the water (e.g., spraying from a damaged dripline, secondary contact through tools or clothing contacting water, splash) that contacts covered produce or food-contact surfaces. The farm should consider whether any product that contacts this water is adulterated as described in the FD&C Act {Link to Relevant Definitions}.

Supporting Resource

1. U.S. Food and Drug Administration. 2024. *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water. Final Rule 2024*. Available at: https://www.govinfo.gov/content/pkg/FR-2024-05-06/pdf/2024-09153.pdf

Scenario 3: Hydroponic Operation Using Well Water

A two-acre enclosed growing operation [controlled environment agriculture (CEA)] produces leafy greens using a deep-water raft system. Overall, ten indoor float ponds are used to grow baby leaf lettuce. Rafts measure 5 feet by 3 feet and are made of polystyrene. Grooves in the polystyrene hold a small quantity of peat to aid in the seeding and gemination processes.

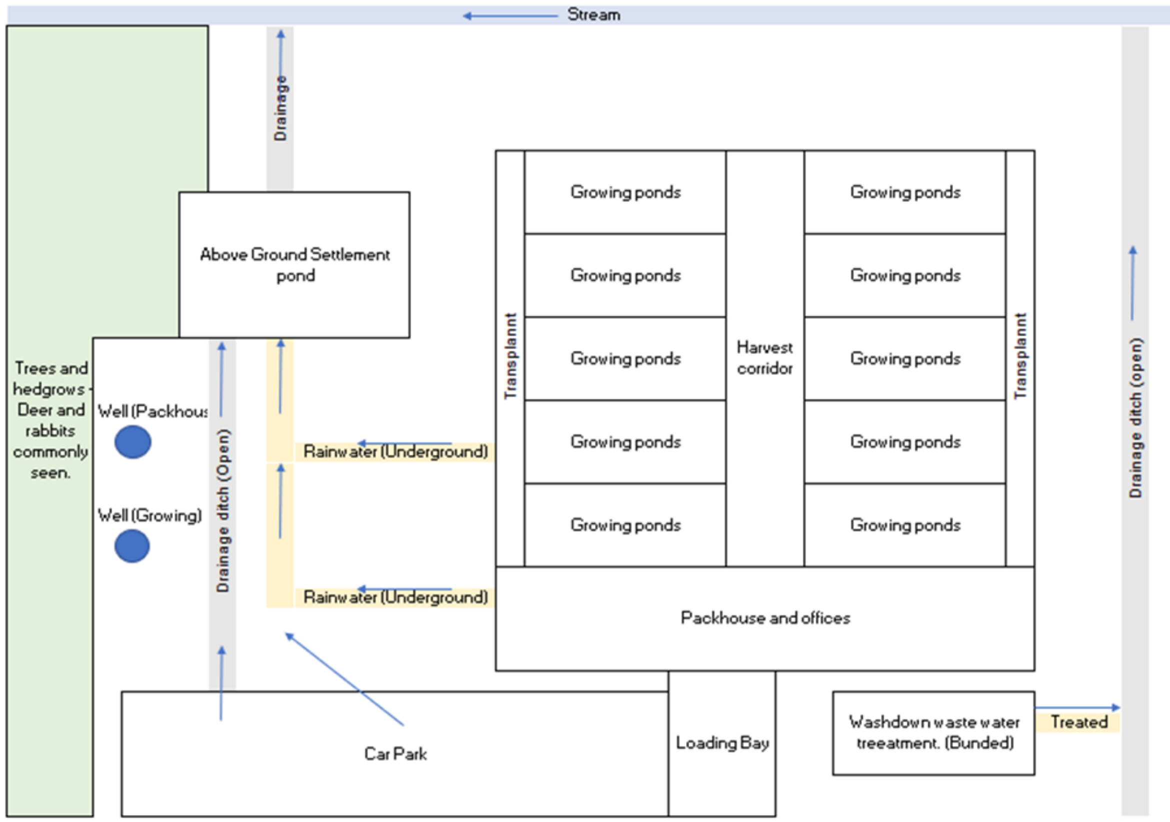
Plants grow to approximately 4 inches in height prior to harvest. A harvesting conveyor belt and packing machine are common equipment used for rafts from all 10 ponds. Workers lift rafts for harvest at 4 a.m. and the remainder of the harvest system is fully automated. The harvested product is transported by conveyors to the packinghouse, which is chilled. Product remains in bins until 6 a.m. when the packing crew arrives.

- ***Water source and conveyance*:** Water for this operation comes from two wells.
  - Each well is approximately 100 feet from the greenhouse.
  - Well 1 supplies the indoor float ponds used for growing. Well 1 is about 200 feet deep, with a 1-foot concrete pad over the grouted bore hole and sanitary seal well cap over the well head. A bed of 2" gravel surrounds the concrete pad.
  - Well 2 is used by the packinghouse and situated about 50 feet from a vehicle parking lot. Aside from noted differences, Well 2 is similar to Well 1.
  - Water for the growing operation (pre-harvest uses) is pumped from Well 1, with no header tank, directly through a sediment filter.
  - Water for the packing operation (postharvest uses) is pumped from Well 2 via a header tank. Packinghouse water is filtered to remove sediment, then chlorinated in the tank (to 4 ppm active ingredient) prior to distribution for use in sanitation hoses, at handwashing sinks, and for toilet flushing.
  - Water condensate is collected within the growing facility but is disposed down the sanitary sewer and not used for production of produce.
  - Water quality parameters, such as hardness and pH, are monitored in relation to the efficacy of the nutrient solution used for plant growth.

Water Treatment:
Water is not considered treated unless the treatment method is effective to make the water "safe and of adequate sanitary quality for its intended use." (see § 112.46). In-line sieves and filters that are used to achieve coarse filtration and remove particulates may also remove a limited number of pathogens. However, generally they are not effective to achieve the intent of § 112.46.

- ***Potential sources of contamination*:**
  - Rainwater runoff from the 2-acre roof area is directed via below-ground piping to a settlement pond, from which it flows to a local stream.
  - Wildlife (deer, rabbits) are observed in the fields around the enclosed area, particularly to the west where the adjacent property is forested.
- ***Irrigation method*:**
  - Plants grow on rafts. Roots are submerged in a nutrient solution (the indoor float pond water). The harvestable portion of the crop (the leaves) is above the raft, out of the water.
- ***Foliar application*:** Plants are continuously misted during growing to manage humidity for product quality. The water used for misting is the same as the source water for the indoor float ponds.
- ***Water tests*:** Each well is tested on a monthly schedule. Generic *E. coli* test results are generally below detection levels (<1 CFU/ 100 mL). Total coliform results tend to be <100 CFU/100 mL. Concentrations have historically been higher, particularly when samples were collected immediately after rain.

Diagram of the Hydroponic Operation



Unpacking the Hydroponic Operation Scenario:

Is an AgWA Needed?

- ***Irrigation water:***
  - The water in the indoor float tanks used for irrigation has nutrients added and is not intended to touch the harvestable portion of the crop located above the raft. Employee training is in place to remove floats impacted by water splashing. However, incidental water contact may occur through the growing and harvest process without the knowledge of employees.
- ***Foliar spray water:***
  - Water used to mist the product is in contact with the harvestable portion of the crop.
  - This water is taken from the well and is not treated.
- ***Other uses of water:***
  - The farm in this scenario should consider whether water from the growing ponds constitutes agricultural water used during harvest or postharvest.
  - For example, practices related to raft removal and harvest may result in contact with water that drips from roots or the raft with the harvested crop or food-contact surfaces (e.g., the conveyor belt).

In summary, an AgWA is required in this scenario. The water used to mist produce is in direct contact with the baby leaf lettuce meeting the definition of agricultural water. Water used for irrigation in the deep-water raft system is not intended to contact the harvestable portion of the crop, but incidental contact may occur during growing and harvesting operations.

What Would Be in the AgWA?

- ***Nature of the water source and degree of protection***:
  - Are wells operated and maintained to prevent contamination from external sources (e.g., rainwater, reservoir and water from rain events)? {Link to Location and Nature of Each Water Source Brief}
  - Are animals excluded from the area surrounding the well head and is runoff water diverted away from the well pad? {Link to Degree of Protection Brief}
  - Monitoring records show uptick in coliform bacteria after rain events indicating well integrity issues.
- ***Water Irrigation practices and delivery system***:
  - Is the agricultural water system designed, built, and operated in a way that protects water from contamination from the environment inside the controlled environment farm (e.g., animal access, employee contact with water, water collection tanks exposed to the environment, and equipment/system cleaning process and frequency).
  - Are deep-water growing reservoirs inspected at a specified frequency to assess potential to increase risk to water quality?
  - What is the timing of foliar application in relation to harvest?
  - Does the crop contact irrigation water in any other way? For example, do leaves hang over the raft into the water? {Link to Crop Characteristics Brief}
  - Does the harvest process allow for water to contact food-contact surfaces or the harvestable portion of the crop?
- ***Crop characteristics***:
  - Are the leafy greens damaged in any way such that pathogens (if in the mist water or through incidental contact) could be internalized? {Link to Crop Characteristics Brief}
- ***Environmental conditions***:
  - How do conditions from the growing environment impact growth or die-off of pathogens of concern (e.g., warm temperatures, humidity, lack of UV light, and nutrient-rich leaf exudates might reduce potential for die-off)? {Refer to call-out box: In-Field Die-Off in the Tree Fruit Farms scenario}
  - Is the sampling program representative of the water being used for irrigation and foliar application? {Link to Other Relevant Factors Brief}

    Outcome: The outcome of the AgWA is a conclusion, or determination, about whether measures are reasonably necessary to mitigate the potential for contamination of covered produce (or food-contact surfaces) with pathogens (§ 112.43(c). In this *Hydroponic Operation Using Well Water* scenario, a likely determination based on the AgWA would be that the potential for contamination is low. However, the operation might decide that mitigation measures are warranted to keep risk at that level and to maintain best practices.

The operation might consider the following measures as a prudent margin of safety if not already in place:

- Because they are testing their water, they may also want to consider whether conditions within their specific operation are appropriate to use pathogen die-off as a mitigation measure for this scenario between the last application of agricultural water (misting) and harvest. {Link to Allowances for Die-off and Removal Brief}
- Using a water treatment that is validated to control human pathogens of concern at a frequency that is reasonable for the specified water use may reduce the likelihood of cross-contamination. {Link to Treatment of Agricultural Water Brief}

Scenario 4: Tree Fruit Farms Using Surface Water

Three tree fruit orchards use the same source of irrigation water in the same general growing area.

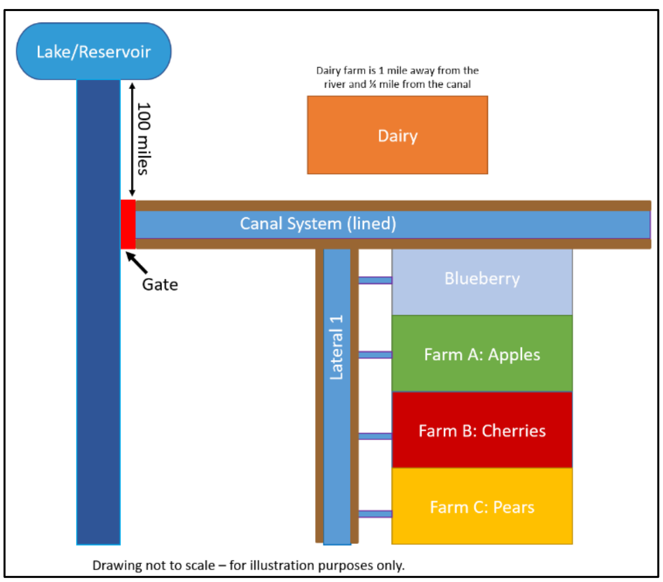
- Grower A produces apples.
- Grower B produces cherries.
- Grower C produces pears.

Scenario information

- ***Water source*****:** The common water source for all three orchards is a lake/reservoir in a mountainous region about 100 miles from the irrigation district.
- ***Water conveyance:***
    - Water is initially carried from the reservoir to the orchards by a natural river channel.
    - River water is then diverted to a main (lined) canal.
    - The main canal feeds unlined laterals that serve an irrigation district.
    - All three orchards draw from the same lateral, in upstream-to-downstream order of **Grower A**, **Grower B**, **Grower C**.
    - The main canal and lateral canals flow between protective berms.
- ***Potential sources of contamination*****:**
    - A 200-head dairy farm, approximately ¼ mile from the main canal at a location 1 mile upstream from the **Grower A** turnout.
        - Per State law, the existence of the dairy farm is public-domain information due to a confined animal feeding operation (CAFO) General Permit requirement.
        - The General Permit process includes routine inspection and sampling for contamination of groundwater in proximity to regulated CAFOs.
        - While the wind does occasionally blow during the harvest season, general wind patterns indicate that dust contamination from the CAFO is not a concern.
    - A blueberry growing operation, immediately upstream from **Grower A**.
        - The blueberry grower's practices include the application of biological soil amendments of animal origin (BSAAO) to the growing area.
        - **Grower A**, due to conversation with the blueberry grower, knows that the BSAAO used are properly composted according to National Organic Program (NOP) requirements.
            - PSR requirements for treated BSAAO are similar to the NOP requirements.
        - The blueberry grower has not been through a PSR inspection; however, the blueberry farm is certified annually by an NOP auditor that is accredited by USDA.
    - Animal intrusion
        - The reservoir and river are not enclosed or fenced to prevent intrusion; the main and lateral canals are fenced in some areas.
        - Wildlife may access waterways over approximately 100 linear miles beginning with the reservoir, continuing along the river and canals to the individual farms.
            - Animal activity is highest near the reservoir and wildlife pressure is lower in the dryer, flatter land around the growing areas.
    - Recreational activity
        - Recreation is a minor use for the reservoir (e.g., swimming, fishing, and boating), and there is less recreation in the river.
        - People are prohibited from accessing the canals.

- *Irrigation method*: Each grower uses canal water for irrigation water with different application methods and timing.
    - **Grower A** exclusively uses drip irrigation in their apple orchard.
    - **Grower B** uses micro sprinklers in their cherry orchard and the water typically does not contact the fruits, even those growing on the lower branches.
    - **Grower C** uses under-tree sprinklers in their pear orchard and the water does reach fruit growing on the lower branches of most trees.
- *Foliar application*: Each grower has different reasons and timing for foliar applications of water.
    - **Grower A** uses overhead-sprayed water from the canal to cool apples when temperatures rise above a threshold (90°F). The last application of cooling water occurred in August.
    - **Grower B** uses water from the canal to mix plant protection products (PPP) in the production of cherries. Depending on the year, Grower B may spray for fruit fly control or to control mildew infections up to 3 days prior to harvest. In addition, PPP may be sprayed to reduce cherry cracking if rain occurs close to harvest.
    - **Grower C** uses water from the canal to mix PPP in the production of pears. Many applications occur weeks or more before harvest; however, removal of pear psylla pest residue sometimes requires a soap-and-water spray within one to two days of harvest.
- *Water tests*: Each grower that uses water from the canal system periodically collects samples for testing.
    - Results for generic *E. coli* are typically less than 100 CFU/100 mL at all three testing sites. The concentration has never exceeded 126 CFU/100 mL in 10 years of data collection by each grower.

Scenario 4 – Map of scenario for illustrative purposes



Climate information: May

Grower B harvests cherries in May.

The growing region is characterized by an average of approximately 4 days of light rainfall (cumulative 0.5 inches precipitation) during the month of May. The area around the reservoir (water source) is characterized by approximately 14 days of rain (cumulative 2 inches precipitation) during the month of May. The growing area is further characterized by relative humidity at approximately 50%, and a UV index[1] of approximately 5 during the late growing season and harvest period for cherries. Temperatures average a high of 74°F and a low of 46°F.

Climate information: August

- **Grower A** last sprays cooling water on apples in August, at least a month prior to harvest in October and **Grower C** harvests pears in August.
    - The growing region is characterized by an average of approximately 3 days of light rainfall (cumulative 0.2 inches precipitation) during the month of August.
    - The area surrounding the reservoir is characterized by approximately 7 days of rain (cumulative 1.5 inches precipitation) during the month of August.

- The growing area is further characterized by relative humidity at approximately 40%, and a UV index[1] of approximately 5 during the late growing season and harvest period for apples and pears.
- Temperatures average a high of 89°F and a low of 57°F.

Tree Fruit Farm Scenario Exercise:
Is an AgWA Needed?
For each grower, an AgWA would be needed in this scenario based on the provisions of the final rule.

- The use of irrigation water is within the definition of agricultural water for **Grower C** (pears under canopy sprinklers).
- All three growers use foliar sprays, for various reasons, in a way that contacts the harvestable portion of the crop and meets the definition of agricultural water.
- The water used for all applications is untreated surface water. No exemptions to the AgWA requirement apply.

What Would Be in the AgWA, if Needed?
In this scenario the AgWA would be different in some ways for **Grower A, Grower B,** and **Grower C**, even though each uses the same source of agricultural water. The written assessments for each grower will likely also include **consistent components** relevant to this scenario, such as:

- *Nature of the water source and degree of protection*: {Link to Degree of Protection Brief}
  - The main canal is lined, meaning it is less prone to subsurface seep into the canal. Subsurface seep might be a concern at locations near, for example, the dairy farm's unlined manure pond if present in the scenario. Growers should be aware of state laws that may require manure ponds or lagoons to be lined.
  - Both main and lateral canals run between earthen berms, meaning surface water is prevented from running into the canals during rainfall events. Surface water contamination due to run off might be a concern, particularly near blueberry fields after the application of BSAAO.
  - Four factors that might introduce pathogens to the water source are related to known animal activity, human waste, or BSAAOs. Each assessment should include potential introduction of human pathogens by each of these factors:
    - The dairy farm,
    - Recreational water users, and
    - The BSAAO used by the blueberry grower.
    - Wildlife feces are likely in the water
- *Agricultural water practices*:
  - Although agricultural water use practices are different for each grower, each assessment should describe uses that constitute agricultural water and timing of application relative to harvest.

- *Crop characteristics*:
    - Each crop grows above ground in a tree, meaning less potential for exposure to pooled water or wet soil.
    - Each crop is characterized by pH that generally does not support the growth of foodborne pathogens (see call out box).
- *Environmental conditions*:
    - Specific environmental conditions were described in the scenario and would be relevant for each grower to include in their assessment:
        - Rainfall affects the amount of run-off, which can carry contamination and stir up pathogens that may be in the sediment [7].
        - Die off is expected to be much more rapid in hot, dry weather compared to cool, wet weather without much sunlight [2].
        - Longer-wavelength ultraviolet irradiation, of the type found in natural sunlight, kills bacterial, viral, and (in many cases) protozoan pathogens [8]. A UV index of 5 is considered a moderate level of sunshine [1].
- *Other relevant factors*:
    - Commercial washing after harvest is typical for each crop in this scenario. The washing step may be validated to provide log reduction of human pathogens (see call-out box).
    - The AgWA for each grower might include results of testing for generic *E. coli*. Because each grower does their own testing, their results could lead to different determinations.

Effect of pH:
The surface of various commodities has a typical pH. The effect of pH may not destroy human pathogens, but it can reduce growth. For the most part, human pathogenic bacteria will not grow at a pH lower than 3.9 (pathogenic *E. coli and Salmonella*) [3, 4] to 4.4 (*L monocytogenes)* [5].
The pH of apples and cherries is less than 4.0 and the pH of pears is less than 4.6 [6].

Commercial washing:
Postharvest commercial washing may lead to some removal of pathogens. This is a factor many growers will consider. When evaluating the pathogen-removal benefit of postharvest washing, it is essential to understand whether the treatment is, instead, meant to manage cross contamination. Available validation data may not evaluate log removal, which means removal of pathogens from the crop itself.
A commercial washing step -- even if it is validated to provide a certain log reduction – is unlikely to be effective as a mitigation measure if pathogen concentrations on produce are high. However, commercial washing may be part of a system-wide strategy to managing risk from potential contamination.

The written assessments likely will include **components that are different** for each grower, based on the differences in crops and water use patterns. These components may include:

- *Nature of the water source and degree of protection*:
    - Each grower may note that there is potential for the lateral canal to be influenced by the BSAAO that are land-applied by the blueberry grower. However, only **Grower A** talked with the blueberry grower and knows the BSAAO are treated.
    - The potential effect of the dairy on water quality is mitigated by regulatory oversight and testing, as well as the fact that the main canal flows between raised berms and is lined. These protections would prevent dairy water entry through surface or subsurface flow paths. The potential for contamination of the water source via dust is minimal due to prevailing wind direction.

- *Agricultural water practices*:
  - Each grower has different uses of agricultural water; an assessment is required only for agricultural water.
    - Less water contact reduces the likelihood of pathogen introduction to the crop.
  - Each grower has different timing of application of agricultural water.
    - More time from application to harvest generally means human pathogens, if on the crop, are more likely to die or be physically removed.
- *Crop characteristics*:
  - Apples and pears (unlike cherries) are commonly stored in unmodified atmosphere for extended periods (months). Some are stored under controlled atmosphere conditions to prolong shelf life. Human pathogens may die off during this interval.
  - In-field die off versus persistence (related to timing of agricultural water application) can be affected by environmental conditions and crop surface characteristics [10].
- *Environmental conditions*:
  - Each grower will evaluate environmental conditions during key timeframes for their crop and region. Environmental conditions close to harvest are particularly important to focus on because they affect water use and human pathogen die-off characteristics.
- *Other relevant factors*:
  - Although in this scenario the water test results for each grower were similar, in other scenarios each grower may have different test results. For example, land use between two orchards may affect the quality of water in the lateral canal.

In-field die-off:
Delicious and Gala apples are typically harvested in early season, a period when cooling water is applied (when needed) by overhead spraying. In-field die off under these conditions was measured to result in 2.8-log (99.8%) to 2.9-log (99.9%) removal of generic *E. coli* within 10 hours of contact [9].

In this example, the evaluation started at sundown and UV was therefore not a major mechanism of removal. Removal under actual (daytime) use conditions may be higher.

Die-off rates are variable and should be evaluated in context of crop and environmental conditions. Similar studies to those described here may be available for other crops, varieties, and regions.

Outcome: The outcome of the AgWA is a conclusion, or determination, about whether measures are reasonably necessary to correct or mitigate the potential for contamination of covered produce (or food-contact surfaces) with pathogens (Section § 112.43(c)).

Concentrations of generic *E. coli*:
Each grower monitors the water for generic *E. coli* but what do they do with the information?

- In the preamble of revised Subpart E of the final rule, FDA acknowledges the U.S. EPA recreational water criterion of 126 CFU/100 mL (geometric mean) and an STV of 410 or less CFU/100 mL of generic *E. coli* established in the 2015 PSR is scientifically valid to use when evaluating your agricultural water quality; however, it is no longer required and should only be used as one part of the assessment.
- Monitoring data is valuable information when historical data and/or knowledge of the water source suggest variability. When sampling, each farm should determine a frequency and criteria that are relevant and appropriate based on their operation and risk assessment (Section § 112.43(a)(5)). In the final rule and guidance provided in the preamble (2024) comments 93 and 95 provide examples of sampling frequencies and criteria for testing.
- **Note:** Using testing data is just one piece of information to support decision-making and cannot be relied upon alone to identify a potential hazard. As an example, testing may indicate higher levels of

generic *E. coli* in water but would not be sufficient evidence to point to any hazard as the cause without further observation and assessment.

Grower A: Apple Orchard Outcome

- Various factors in Grower A's assessment would likely lead to the conclusion that no additional measures are necessary to mitigate the potential for pathogens on the apples due to water use. Irrigation water does not touch the crop, and the last application of foliar spray is months prior to harvest. Environmental conditions during that timeframe are conducive to in-field die-off.
- Two factors to consider:
    1. Knowledge that BSAAO used by the blueberry farmer is treated, and
    2. The permitting system (with monitoring) for the dairy farm supports a determination that the potential for pathogen introduction from those operations is low.
- Test results for generic *E. coli* are relatively low (<126 CFU/100 mL) which supports a determination of low potential for pathogen introduction from conditions, such as unobserved, but likely, wildlife access to the waterways.
- Grower A could also reference research showing a significant in-field die-off of generic *E. coli* within the first 12 hours, that typical apple wash conditions achieve nearly a 1-log reduction, and that storage can further decrease *E. coli* levels on apples. [12].

Grower B: Cherry Orchard Outcome
Various factors likely would lead to a determination that measures to mitigate the potential for pathogens on the cherries due to water use **may be necessary**, depending on timing of foliar spray application.

- Although irrigation water does not touch the cherry crop, the last application of foliar spray can be relatively close to harvest (sometimes less than 4 days).
- Only Grower A spoke with the blueberry grower, so Grower B is unaware that the BSAAO used by the blueberry grower is treated. Depending on local conditions, Grower B may have concerns that practices at the blueberry operation could introduce pathogens into the water.
- Like Grower A, Grower B may use results of water tests to address concern about unobserved animals accessing the water source.
- Environmental conditions near harvest are consistent with the expectation of substantial levels of pathogen die-off over a 4-day (or more) period between application and harvest.

Systems approach:
Traditional audit schemes tend to utilize check lists and evaluate each consideration independently. The PSR, including the agricultural water assessment, uses a systems approach in which each consideration may affect others. The cumulative effect of these system interactions is crucial to the assessment.

For instance, in-field die-off can be a powerful mitigation measure. However, simply leaving 4 days between application and harvest is not a universally effective approach.
- Understanding effects of environmental factors and crop characteristic help evaluate whether in-field die-off will occur.
- Understanding water quality (e.g., the concentration of *E. coli*) can help determine when in-field die-off is sufficient.

Considering these factors, **Grower B** may determine that no mitigation measures are needed during years when water does not contact produce close to harvest. If **Grower B** must use irrigation water to apply sprays close to harvest, they might decide to test their water close to harvest to ensure that water quality has not changed. Alternatively, the grower may choose to use water from another source, such as municipal water or a source where a water quality assessment has confirmed that no conditions require mitigation.

Grower C: Pear Orchard Outcome:
Various factors would likely lead to the conclusion that measures to mitigate the potential for pathogens on the pears due to water use **may be necessary.**

- Irrigation water contacts the pears close to harvest (sometimes less than 4 days)
- Application of foliar sprays contacts the pears close to harvest (sometimes less than 4 days)
- Only **Grower A** talked with the blueberry grower, so **Grower C** does not know that the BSAAO applied by the blueberry grower is treated.

To mitigate risk due to the potential that pathogens were introduced to agricultural waters before use growing pears, **Grower C** might choose to take a combination of these actions or other actions:

- Change their irrigation method to microsprinklers or drip, or in some other way avoid contact of irrigation water with pears. {Link to Agricultural Water Systems Practices Brief}
- Use an alternative water source (e.g., untreated ground water with water test results, or municipal water) to mix PPP applied as foliar sprays. {Link to Agricultural Water Practices Brief}
- Pay close attention to and document the cumulative expected removal of pathogens (if present) by the following factors when making decisions about whether to harvest the pears. {Link to Allowances for Die-off and Removal Brief}
    - In-field die-off between water application and harvest under ambient environmental conditions during harvest.
    - Removal of pathogens by commercial washing after harvest in context of any validated sanitizer added, or other treatment steps.
    - Die-off during extended storage, based on validated data that is reflective of storage conditions for the pears from the orchard.
    - Testing water closer to harvest can better inform food safety decision-making during postharvest handling.

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11. U.S. Food and Drug Administration. 2024. *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water* (Revision to Subpart E). Federal Register 89(88): 37448. See Page 37490.
12. Killinger, K. et al. 2015. *Assessment of Apple Packing for Listeria Risk*. Washington Tree Fruit Research Commission.

Pre-Harvest Agricultural Water Briefs

Brief 1: Elements of an Agricultural Water Assessment (§ 112.43(a))

§ 112.43(a)
Elements of an agricultural water assessment. Based in part on the results of any inspections and maintenance you conducted under § 112.42, at least once annually you must prepare a written agricultural water assessment for water that you apply to covered produce (other than sprouts) using a direct application method during growing activities. The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces …"

Brief description:
Following the annual inspection and routine monitoring and maintenance of the agricultural water system (as required in § 112.42), growers must conduct and document an AgWA at least once a year. This assessment applies to water directly applied to covered produce (e.g., irrigation and crop protection sprays) during pre-harvest growing activities.

How does this requirement reduce risk?

The AgWA includes a description of the agricultural water system. Several factors that affect vulnerability of the agricultural water system include:

1) **Water Source --** source is groundwater or surface water;
2) **Distribution System --** water distribution system is an open or closed conveyance; and
3) **System Protection --** the water system is protected from potential sources of contamination:
    a. Other users of the water system
    b. Condition of storage areas used for irrigation equipment.
    c. Location of water and equipment relative to human waste, animal operations, or other sources of fecal material, such as commercial animal feeding operations.

What does compliance look like?

The assessment must include specific elements described in this brief. In addition, maps and photographs may accompany the written part of the assessment. Maps can highlight permanent fixtures, such as gates, reservoirs, returns, and other permanent above-ground components of the irrigation system.

Once the system is described, evaluate components to better understand whether the quality of agricultural water is adequate for the intended use. Some key factors are summarized here and discussed in greater detail in other briefs.

While developing the AgWA, it is important to remember that the potential for hazard introduction can be affected by the following:

- *Water Source*: Is the agricultural water from public or municipal sources, wells, untreated surface water, treated water, or recycled water? {Link to Location and Nature of Each Water Source Brief}
- *Distribution system*: Is the agricultural water from closed (e.g., pipes) or open delivery systems (e.g., canals)? Do you use overhead sprinkler, drip, furrow, flood or seepage irrigation?

- *System Protections and conditions observed*: What has been observed and recorded during pre-season and pre-harvest assessments? Is there any evidence of animal intrusion or adjacent land activities of concern? Were there any weather events, such as heavy rain or extreme heat, that caused damage to edible parts of the crop? Has there been application of biological soil amendments of animal origin adjacent to the production field? {Link to Degree of Protection Brief}
- *Crops to irrigate*: Consider crop characteristics that will impact surface adhesion or internalization of pathogens from agricultural water, and where the commodity grows (e.g., in the tree or the ground) {Link to Crop Characteristics Brief}
- *Other factors:* Comparison against microbial criteria established for the intended use. {Link to Link to Testing of Agricultural Water Brief}

In addition, risk from hazards that have been introduced to the water despite all efforts to prevent introduction can be mitigated by operational decisions.

- *Use/Application method*: Is the agricultural water to be used for direct contact during germination, growing, or foliar application? Other direct contact applications include aerial chemigation, hand wash water, or harvest equipment cleaning.
    - What is the timing relative to harvest? {Link to Allowances for Die-off and Removal Brief}.
    - Is the water treated prior to use? {Link to Treatment of Agricultural Water Brief}.
    - Is the water used without direct contact, such as ground chemigation, drip irrigation, furrow irrigation, dust abatement, cleaning non-food-contact farm equipment? {Link to Agricultural Water Practices Brief}.
    - Water that is not used in direct contact with covered produce or food-contact surfaces is not agricultural water {Link to Relevant Definitions}. Non-contact use is considered inherently lower risk.

Example Scenario:

Answering basic questions can help a grower evaluate risk factors and take mitigation actions when needed. For example, one day before a scheduled irrigation event and close to harvest, a grower might observe animal loading and unloading at an adjacent Concentrated Animal Feeding Operation (CAFO) and strong winds blowing dust toward the water source and unharvested fields. In this case, the grower may want to consider taking actions, such as testing and/or treating the water, adjusting the scheduled harvest day, or testing the unharvested crops. As the grower continues to identify similar situations, it is ideal to communicate and explore the feasibility of the CAFO to adjust the timing or avoid animal movement during windy days, if possible.

Brief 2: Location and Nature of Each Water Source (§ 112.43(a)(1)(i))

Brief description:
This issue brief discusses the location and nature of agricultural water sources, and how these characteristics can influence the introduction of potential food safety hazards to water sources as relates to § 112.43(a)(1).

How does this requirement reduce risk?

> **§ 112.43(a)(1)**
> *Elements of an agricultural water assessment. …* The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce … or food contact surfaces, based on an evaluation of the following factors:
> (1) Each agricultural water system you use for growing activities for the covered produce, including ***the location and nature of the water source (whether it is ground water or surface water)***, the type of water distribution system …, and the degree of protection from possible sources of contamination ….

The type (nature) of the water source is a key determinant in assessing the potential for contamination with human pathogens. Public water, ground water, and surface water have very different inherent vulnerability to introduction of food safety hazards. Understanding these vulnerabilities is key to reducing risk. The following suggestions are provided to assist in the collection of valuable information about each type of water source.

Public water supplies, particularly those regulated under the Safe Drinking Water Act may have the lowest inherent risk. However, they are not risk free. The annual water quality report from the water supply or municipality is a good place to look for information about these systems.

Ground water sources are generally less vulnerable compared to surface water sources, depending in part on:

- Depth of the aquifer: deeper wells often are less exposed than shallow ones.
- The location, construction, and maintenance of the well: the location and construction should avoid intrusion of runoff (e.g., from animal operations) into the well during flooding or by way of potential subsurface flow.
- Groundwater sources suspected of being under the influence of surface water should be further evaluated.

For *surface water* sources, it is important to understand potential sources of pathogens and pathways of contamination to the lake, pond, reservoir, river, canal, or other body of water. Assess the likelihood that water could be contaminated from origin to point of entry to the farm water distribution system by considering:

- The topography and possibility of runoff into the waterway during rainfall and runoff
- Points of discharge from industry, including waste treatment
- Human activity (domestic or recreational)
- Wildlife pressure
- Other agricultural activities, such as livestock operations.

Obtaining a more complete collection of information may be a simple or complex investigation. Consider reaching out to local irrigation districts or public water authorities to gather additional information that may be useful to the risk assessment process.

- Shared data from public testing programs (keep copies when available)
- Maintenance of waterway conveyances (e.g., canal dredging)
- Other environmental impacts that are being monitored by public agencies (e.g., in-stream flow after heavy rain events).

Virtual and physical scouting also may provide important information. Growers might look at satellite imagery to track the water flow from its origin to the farm, and to identify potential sources of contamination along the way. Topography may not be obvious from imagery so, when possible, travel physically along the waterway to document what is visible and where animal activity or land uses have potential to impact water quality. Scouting targets include:

- Identification of potential human waste sources (e.g., failing septic systems, areas of heavy recreational water use)
- Observation of domesticated animal and wildlife activity in or near the water source
- Any other potential sources of contamination

What does compliance look like?

Consider documenting information about the nature and location of each water source, as well as potential impacts of animals and land uses. Note that not all these may be known for a given water source. Additional information gives one more confidence in determining risk levels.

Public water supply:

- The annual water quality report or results of water testing done by the water supplier.

Ground water:

- Information about the construction, maintenance, and location of the well including:
    - Depth of extraction
    - Type of soil, including whether the soil profile includes protective layers
    - Presence and type of casing, grouting, well pad, and other wellhead protection
- Confirmation during routine or for-cause water system inspections that:
    - An effective sanitary seal is in place.
    - The well bore is protected from tampering and potential contamination.
    - The well head is protected from down-hole intrusions (e.g., land slope prevents pooling).
    - Human and animal activity in the vicinity of the well is minimized.
- Determination if the ground water source is under the influence of surface water.
- Understanding whether wells drawing from the same aquifer may affect aquifer water quality
    - Human and animal activity in the recharge area, particularly surrounding well heads
    - Condition of other wells sourcing from the same aquifer

Surface water:

- Source of the water (e.g., spring, municipal, well, river, lake, dam)
- Distance and conditions from the water source to the point of use
- Human and animal activity (feces) affecting the source during agricultural production
- Potential effect of weather events, such as heavy precipitation or strong winds, on the quality of the water during production, particularly close to application and harvest

Documentation may include reports, monitoring logs, and other supporting material relevant to understanding the nature of the water source and potential impacts from animals or land uses. These might include Extension fact sheets, evaluation tools, case studies, or recordkeeping templates, among others.

Example Scenario:

A farm might draw water from a shallow well that is situated in sand near a river. By understanding the nature of this water source, the farm can better manage risk by implementing appropriate protections {Link to Degree of Protection Brief}. For example, if the well was not properly sited, there may be a subsurface connection between the well and the river that causes the well water to rise and become turbid during rain events. If the well was not properly cased and grouted, subsurface water flow could bypass any protective layer and carry contaminants from the surface down the bore hole to mix with the aquifer water.

Understanding the nature of the water source provides context to evaluate what sources and flow paths of potential hazards to be alert to as part of the assessment.

Supporting References

U.S. Environmental Protection Agency. Summary of the Safe Drinking Water Act 42 U.S.C. §300f et seq. (1974) Available online at https://www.epa.gov/laws-regulations/summary-safe-drinking-water-act

The following links provide valuable resources to better understand well construction and location.

- https://www.epa.gov/privatewells/learn-about-private-water-wells
- https://www.cdc.gov/healthywater/drinking/private/wells/location.html
- https://www.watersystemscouncil.org/water-well-help/well-diagram/
- https://wellowner.org/resources/basics/well-system-components/
- https://extension.psu.edu/resources-for-water-well-spring-and-cistern-owners

The following references provide information to help one better understand surface water contamination pathways.

1. Hansen, S., T. Messer, A. Mittelstet, E.D. Berry, S. Bartelt-Hunt, and O. Abimbola. 2020. *Escherichia coli* concentrations in waters of a reservoir system impacted by cattle and migratory waterfowl. *Sci. Total Environ.* 705:135607.
2. Jokinen, C.C., Hillman, E., Tymensen, L. 2019. Sources of generic *Escherichia coli* and factors impacting guideline exceedances for food safety in an irrigation reservoir outlet and two canals. *Water Res.* 156:148-158.
3. Leaman, S.M., Salas, S., Mandrell, R.E., Suslow, T.V., Jay-Russell, M.T., Davis, D.A. 2022. Environmental risk factors in the human pathogen transmission pathways between animal operations and produce crops. *Food Protection Trends*. 42(5):362-376.
4. Navarro-Gonzalez, N., Wright, S., Aminabadi, P., Gwinn, A., Suslow, T.V., Jay-Russell, M.T. 2020. Carriage and Subtypes of Foodborne Pathogens Identified in Wild Birds Residing near Agricultural Lands in California: a Repeated Cross-Sectional Study. *Appl Environ Microbiol.* 86(3):e01678-19.
5. Olds, H.T., Corsi, S.R., Dila, D.K., Halmo, K.M., Bootsma, M.J., McLellan, S.L. 2018. High levels of sewage contamination released from urban areas after storm events: A quantitative survey with sewage specific bacterial indicators. *PLoS Med.* 15(7):e1002614.
6. Taylor, E.V., Nguyen, T.A., Machesky, K.D., Koch, E., Sotir, M.J., Bohm, S.R., Folster, J.P., Bokanyi, R., Kupper, A., Bidol, S.A., Emanuel, A., Arends, K.D., Johnson, S.A., Dunn, J., Stroika, S., Patel, M.K., Williams, I. 2013. Multistate outbreak of *Escherichia coli* O145 infections associated with romaine lettuce consumption, 2010. *J Food Prot.* 2013 Jun;76(6):939-44.

Brief 3: Type of Water Distribution System (§ 112.43(a)(1))

Brief description:
This section discusses the importance of the type of water distribution system and how it can influence the potential introduction of pathogens into the irrigation water, as related to section § 112.43(a)(1).

§ 112.43(a)(1)
*Elements of an agricultural water assessment. …*The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce…or food contact surfaces, based on an evaluation of the following factors:
(1) Each agricultural water system you use for growing activities for the covered produce, including the location and nature of the water…, ***the type of water distribution system (for example, open or closed conveyance),*** and the degree of protection from possible sources of contamination…

How does this requirement reduce risk?

Various types of distribution systems used to carry water from each water source to the point of use have inherently different vulnerability to contamination. Understanding the type of distribution system is important to evaluating steps that can be taken to reduce the possibility that pathogens will be introduced to the water system.

- Open distribution systems like canals are more vulnerable to contamination from animal intrusion, runoff, piped discharge, and seepage (if unlined).
- Closed distribution systems like piping, if properly built and maintained, can protect the water from the introduction of hazards.
- When closed piping systems are interconnected with other systems that may carry contaminated water, hazards may be introduced if flow is not managed. For example, backflow prevention may allow one-way flow of uncontaminated water into other systems and reduce risk of contaminating reverse-flow.

What does compliance look like?

The farm should consider the following activities and documentation:

- Conduct a ground assessment following the entire path of the distribution system from where the water enters the operation to the point of use.
- Document the type of distribution systems, distances and potential sources of contamination, and the context of surrounding human and animal activity (feces) from the beginning of the distribution system to the point of use. {Link to Degree of Protection Brief}

When open (e.g., canals): The potential of contamination will depend on the construction and level of protection for the canal or other open conveyance, runoff during the rainy season or other irrigation activities in the area, potential of animal intrusion, relative locations of discharges, and vulnerability to subsurface seepage. Also consider existing slopes that can accelerate movement of feces into the distribution system, particularly through runoff.

When closed (e.g., piping): Consider the maintenance and location of the system. Specifically, evaluate where and how contamination could enter the piping system or other conveyance (e.g., can water seep in during periods of pressure loss?). Investigate the potential existence of interconnection with other systems and install functional backflow prevention devices when appropriate.

Documentation might include a detailed map of the distribution system with all the components, connections, contamination sources, backflow prevention devices, distances. The map should indicate any prevention measures in place or concerns to be addressed.

Example Scenario:

On-farm evaluations of water distribution systems have detected specific conditions related to the nature of the distribution system that might allow the introduction of pathogens to the system. Examples of observed water distribution system risks:

- Seepage from contaminated sources into unlined water canals.

- Blending of dairy wastewater effluent with district water in distribution pipes in the absence of backflow prevention devices.
- Eroded well pads and housing, leading to run-off into the well.

Supporting Resources and References

1. Jokinen, C.C., Hillman, E., Tymensen, L. 2019. Sources of generic *Escherichia coli* and factors impacting guideline exceedances for food safety in an irrigation reservoir outlet and two canals. *Water Res.* 156:148-158.
2. Leaman, S.M., Salas, S., Mandrell, R.E., Suslow, T.V., Jay-Russell, M.T., Davis, D.A. 2022. Environmental risk factors in the human pathogen transmission pathways between animal operations and produce crops. *Food Protection Trends.* 42(5):362-376.
3. Olds, H.T., Corsi, S.R., Dila, D.K., Halmo, K.M., Bootsma, M.J., McLellan, S.L. 2018. High levels of sewage contamination released from urban areas after storm events: A quantitative survey with sewage specific bacterial indicators. *PLoS Med.* 15(7):e1002614.

Brief 4: Degree of Protection of Each Agricultural Water System (§ 112.43(a)(1)(iii))

Brief description:
This issue brief describes assessing the extent the agricultural water system is protected from potential sources of contamination (microbial hazards, like pathogens) as required in § 112.43(a)(1)(iii).

How does this requirement reduce risk?

Degree of protection of the agricultural water system is another way of saying, "How could the pathogen possibly get into the water supply?" The degree of protection describes the potential for the pathogen to enter the system. If the water system is well protected, then the likelihood of contamination is low. If the water system is not well protected and vulnerable to the hazard, then the contamination risk is higher.

When evaluating the degree of protection, it is helpful to understand what potential sources of pathogens are of concern. In the revised provisions of Subpart E, FDA calls out three specific hazards to address when considering the extent to which agricultural water system is protected (note that these three areas may overlap):

> **§ 112.43(a)(1)**
>
> *Elements of an agricultural water assessment. …The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce…or food contact surfaces, based on an evaluation of the following factors:*
>
> (1) Each agricultural water system you use for growing activities for the covered produce, including (i) the location and nature of the water source…, (ii) the type of water distribution system…, and (iii) ***the degree of protection from possible sources of contamination (including by other water users; animal impacts; and adjacent and nearby land uses related to animal activity (for example, grazing or commercial animal feeding operations of any size), application of biological soil amendment(s) of animal origin, or presence of untreated or improperly treated human waste).***

- **Other users:** Upstream or other users of water in the agricultural water system can contaminate the water in many ways.
  - Growers might learn about other uses by scouting activities upstream, outside of the property, and in the area surrounding the water system.
  - Pay attention to potential sources of fecal contamination such as releases of sewage into the stream from which irrigation water is drawn.
  - Recreational uses can also affect water quality so pay attention to whether, for example, children or adults are allowed to play or recreate in the water system.
  - Sometimes waste flow is intermittent or unintentional, such as when another grower cleans equipment in the water that will eventually become part of the water system.
- **Animals:** If animals have, or may potentially have, access to the agricultural water system, this access can be documented and used as part of the degree of protection assessment.
  - Consider domesticated animals, wildlife, and birds that are resident in the area or migrating through the area.
  - The likelihood of access (and contamination) of water may depend on fencing or other protections, as well as migratory patterns or access to alternate water sources.
  - For seasonal migratory animals, the timing of access relative to timing of the water use, particularly close to harvest may be an important factor to consider.
- **Adjacent and nearby land uses:** In the updated revisions to Subpart E: Agricultural Water, FDA comments that animal grazing, concentrated animal feeding operations (CAFOs), the application of improperly treated biological soil amendments of animal origin, or the presence of untreated or improperly treated human waste (e.g., sewage) as potential contamination sources on land adjacent to or near to the agricultural water system. Pay attention to things like runoff, leakage, traffic patterns,

wind, and flooding that could carry pathogens from adjacent and nearby land into the agricultural water source or distribution system.

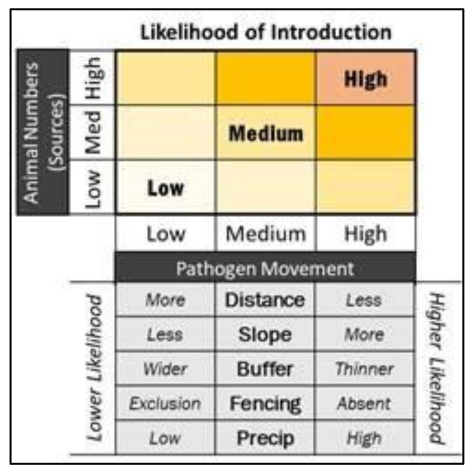
What does compliance look like?

Knowledge of potential contamination sources enables growers to assess how well their agricultural water system is protected against the introduction of pathogens. It is important to describe the measures taken to control, minimize, prevent, reduce, or mitigate the potential for pathogen introduction into the agricultural water system. The degree of protection should encompass both the likelihood of pathogen introduction and the potential pathogen load that could be introduced into the system.

- *Topography*: Is the hazard uphill or downhill from the canal? Can the slope potentially introduce pathogens into the water based on its location and steepness?
- *Fencing, windbreaks, berms, and vegetative strips*: Are they present? Are they effective in minimizing the potential for pathogens to be carried to the water?
- *Other factors*: Depending on the circumstances, other factors (such as impervious lining in a canal channel or grouting and casing of a well borehole) may be notable factors related to protection.

Example Scenario:

An example of how the degree of protection from a hazard adjacent to an agricultural water system may be assessed is to consider potential sources of pathogens and factors affecting movement. In this example, less protection means a higher likelihood of introduction.



Potential source: A large dairy herd
Factors affecting movement:

- Dairy pen is 50 yards from the water supplying the system.
- Pen fencing is sturdy and well-maintained, prevents direct access to the water source.
- Vegetation along the bank of the water source slows runoff and filters large particles.
- Land slopes gently from pen to the water source.

In this scenario, the water source is protected against direct access by animals due to the presence of a fence, and cows have never escaped the enclosure. However, the water source may not be fully protected against the movement of potential pathogens from the pen to the water through runoff.

- Relatively short distance (50 yards)
- Slope of the land (in direction of water source)

Other factors that may provide protection against pathogens carried by runoff include:
- The slope from the pen to the water source is gentle, not steep.
- The buffer strip likely reduces the number of pathogens that can get to the water source.
- There may not be runoff inducing rainfall during the timeframe the farm uses the water.

In addition, if the produce farm operator talks with the dairy farm owner, they may find that the dairy farm already has taken additional measures to reduce runoff to the water source, particularly if required to do so by Federal, State, or local regulations.

Brief 5: Agricultural Water Practices (§ 112.43(a)(2))

Brief description:
This issue brief discusses agricultural water practices associated with agricultural systems, specifically the type of application and time interval between application and harvest. These factors are necessary to consider when conducting an AgWA, as described in § 112.43(a)(2).

> **§ 112.43(a)(2)**
> *Elements of an agricultural water assessment. …* The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce … or food contact surfaces, based on an evaluation of the following factors:
> (2) Agricultural water practices associated with each agricultural water system, including the type of direct application method (such as foliar spray or drip irrigation of covered produce growing underground) and the time interval between the last direct application of agricultural water and harvest of the covered produce.

How does this requirement reduce risk?

The AgWA explicitly includes two specific agricultural water practices: type of application method and the time interval between the last direct water application and harvest. Considerations to address:

- How the water is applied affects whether it contacts the harvestable part of the crop. If the water does not contact the crop, then pathogens that might be in the water will not contact the produce directly.
- Timing of water application affects the time interval over which potential pathogens might die-off naturally in the field because of environmental conditions. {Link to Allowances for Die-off and Removal Brief}

What does compliance look like?

Subpart E requirements regulate agricultural water, defined in the FSMA PSR as water intended or likely to contact covered produce or food-contact surfaces {Link to Relevant Definitions}. The agricultural water requirements (including AgWA) only apply to water that meets the definition of agricultural water.

- Consider how pre-harvest agricultural water is applied to the crop.
  - Think about all water uses including, but not limited to, irrigation, fertigation, pesticide application, frost protection, and dust abatement.
  - Evaluate whether the water directly contacts the harvestable portion of the crop.
- For most crops, the likelihood of pathogen transfer during direct contact (e.g., overhead irrigation, foliar application of pesticides) is higher than with indirect application (e.g., drip irrigation).
  - For more information about crop characteristics that can affect potential for adhesion or internalization within the crop: Link to Crop Characteristics Brief}.
  - For drip irrigation, remember to consider the potential for direct contact with crops grown at or below ground level.
  - While some methods of irrigation may not generally be defined as agricultural water by the rule, it is important for public health and compliance with the FD&C Act to consider the effects of incidental contact due to broken emitters in drip irrigation or splashing during furrow irrigation.

The time interval between the last direct application of agricultural water and harvest of covered produce is the second explicit practice to evaluate. This is because under certain conditions, microorganisms (including human pathogens) can die over time. Some things to consider include:

- How close to harvest is the water being applied to the crop? More time between applying water and harvesting the crop can allow for pathogens to die in the field environment, reducing risk from agricultural water.

- For more information about environmental factors that may impact pathogen die-off: Link to Allowances for Die-Off and Removal Brief}.
    - These factors include UV exposure, temperature, humidity, and presence of competitive organisms in the environment.
    - The effects of these factors may vary with short-term weather, and type of production system (e.g., indoor farms).
    - The rate of die-off may also be dependent on commodity type and geographic location (e.g., climate factors).

Both the method of application and timing of application appear in two contexts in the revision to Subpart E: 1) elements to evaluate within the AgWA (§ 112.43) as well as 2) mitigation measures that can be implemented to reduce risks (§ 112.45(b)).

- Growers may choose to change the water application method, so the water does not directly contact fresh produce, such as by switching from overhead irrigation to drip irrigation.
- The timing between application and harvest may be increased to allow time for pathogens to die-off in the field environment.
    - Growers should consider consulting Extension agents, scientific publications, or other experts to understand if this time interval is sufficient for their commodity, growing style, and area in light of the contamination risks that they identify in their AgWA.
    - There is no acceptable level of human pathogens on fresh produce because some organisms, such as *E. coli* O157:H7, can make people severely ill with extremely low doses.
    - Die-off characteristics of pathogens that are not bacteria, such as *Cyclospora*, generally are less well characterized. Many can persist for long periods of time.

Type of application and time interval between application and harvest are the only factors listed within the agricultural water practices regulatory language, when conducting the AgWA. However, it may be important to consider additional practices within the agricultural water system that may impact water quality and risk. Examples include:

- Whether the water is treated prior to application {Link to Treatment of Agricultural Water Brief}.
- Amendments or probiotics that may be added to the water prior to application, such as for fertigation.
    - Nutrients in the water may promote the growth of bacterial pathogens from insignificant levels to levels that are meaningful.
    - Nutrients, particularly nitrogen, can also affect the efficacy of some chemical treatments.

Example Scenario:

A tomato farm might draw water from a reservoir or pond formed by damming a creek. During last year's AgWAs, the grower determined the water is not sufficiently protected from animal intrusion upstream from the dam, on neighboring properties. Based on last year's assessment, the grower might decide to use the pond water only to irrigate by the drip method under plastic mulch. The farm may also choose to use other water sources, such as a protected well, to mix any PPPs applied as a foliar spray.

Brief 6: Crop Characteristics (§ 112.43(a)(3))

Brief description:
This issue brief describes assessing the extent to which the characteristics of the crop, including susceptibility to surface adhesion or internalization, affects the likelihood of pathogens on the harvestable portion of the crop as required in § 112.43(a)(3).

How does this requirement reduce risk?

> **§ 112.43(a)(3)**
> *Elements of an agricultural water assessment. …* The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce … or food contact surfaces, based on an evaluation of the following factors:
> (3) Crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards.

Unlike the other factors in the risk assessment, crop characteristics do not affect the quality of agricultural water. Instead, crop characteristics are a factor that might affect the potential for pathogens that may be in water to contaminate produce.

Including crop characteristics in an AgWA allows evaluation of how variables like potential for holding (adhesion) or protecting (internalization) pathogens affects the overall risk profile for the growing operation. Crops that do not exhibit adhesion or internalization characteristics may be less susceptible to retaining any potential pathogen in or on the product, or pathogens may not persist as well to the time of harvest and/or consumption – reducing public health risk.

What does compliance look like?

Information about crop characteristics is useful to the AgWA and can be actionable. However, quantitative information is limited in this area. When data regarding crop characteristics are lacking, this factor is a neutral unknown for AgWAs. In other words, absence of data on crop characteristics should not be considered to increase or decrease the risk posed by a potential hazard.

If available, commodity-specific information on the potential for pathogens in water to "successfully" contaminate produce and survive to the point of consumption can be used to assess the risk to consumer health.

- Protective crop characteristics, supported by data indicating that internalization and/or surface adhesion are unlikely, may influence the decision that less stringent mitigation measures are necessary.
- Crop characteristics that enhance adhesion or persistence of pathogens on the produce include surface roughness and surface area, or punctures and bruising that may serve as an entry point through the epidermal layer. Characteristics such as these may influence a determination that relatively stronger mitigation measures are necessary.
    - Stronger mitigation measures might include:
        - Treatment {Links to [Treatment of Agricultural Water](#) Brief}
        - Consideration of testing results that provide further information about water quality, when appropriate {Link to [Testing of Agricultural Water](#) Brief}
        - Changing to a different water source (if available)

When evaluating known crop characteristics in an AgWA, harvest and packing processes can affect how crop characteristics affect pathogen adherence, internalization, and/or survival.

For example, available data show that internalization of pathogens by apples is impacted by whether the fruit is punctured, and how the fruit is treated postharvest. It is important to account for these additional factors when describing crop characteristics, by providing context related to processes at the operation.

Limited scientific literature exists to demonstrate the susceptibility of specific commodities to internalization of pathogens while growing. The overall public health risk from real-world internalization rates is not easily evaluated; however, general expectations about internalization can help growers develop their AgWA.

While data regarding internalization or surface adhesion is limited for many produce commodities, other relevant crop characteristics may be easier to describe. For example:

- *Effects of pH*: Growth potential for bacterial foodborne pathogens like *E. coli*, *Salmonella*, and *Listeria* depends, in part, on pH. Keep in mind that surface pH will be very different than the pH of the interior/flesh.
- *Growth characteristics of the crop*: How a crop grows (i.e., grown in or on the ground, or in the air) can affect shading, moisture, and other factors that affect pathogen survival on the surface. In addition, some commodities change form as they mature (e.g., iceberg and cabbage form tight heads early, whereas romaine heads do not close until later in the growth cycle).
- *Data on Pathogen Survival:* How existing growing, harvest, and postharvest practices (e.g., the length of time between last water application and harvest, commercial washing, and/or storage) may discourage pathogen survival. These factors may only be factored into a risk assessment if supported by scientific data. {Link to Allowances for Die-off and Removal Brief} for more information on factors to consider and scientific data needed to support how these practices positively impact die-off.)

History of outbreaks: Although the FDA stated in the Preamble of the 2024 revision to Subpart E of the rule that the absence of outbreaks should not be considered a factor in an agricultural risk assessment, growers of commodities involved in an outbreak where water was identified as a vector may gain valuable insights from the resulting investigations or subsequent research.

Example Scenario:

An AgWA involved in surface-applied irrigation water is otherwise the same (based on the observations, the water may be expected to infrequently contain some pathogens). The determination of the two commodities could be different based on crop characteristics:

- The determination for a rough-surfaced commodity to which pathogens are known to adhere may be that more substantial mitigation measures are necessary.
- The determination for a commodity with smooth, waxy skin that has been demonstrated to demonstrate minimal or no pathogen adherence may be that lesser mitigation measures are appropriate.

Supporting Resources and References

- pH levels supporting growth of potential pathogens (page 23)
- Infiltration, survival, and growth of pathogens within fruits and vegetables
- UC Davis commodity-specific food safety information

Brief 7: Environmental Conditions (§ 112.43(a)(4))

Brief description:
This brief discusses environmental conditions that might affect the AgWA, including weather and seasonality factors, such as precipitation, wind, UV exposure, and temperature, among other factors as described in § 112.43(a)(4).

> **§ 112.43(a)(4)**
> *Elements of an agricultural water assessment. …* The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce … or food contact surfaces, based on an evaluation of the following factors:
> (4) 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

How does this requirement reduce risk?

Environmental conditions can affect the likelihood that pathogens may have been introduced into any given water source. Their impact on produce safety can be categorized into two general factors:

- The likelihood of water being contaminated before or at point of use.
- The likelihood of pathogen surviving long enough for introduction onto produce via agricultural water.

Pathogen introduction to and survival in water can be affected by environmental conditions. Relationships are not simple. No single factor is likely to drive presence or survival of human pathogens in most situations. Comprehensively assessing environmental conditions can be challenging because agricultural water systems are affected by numerous combinations of environmental factors.

- Many scientific reports describe factors associated with the presence of pathogens (see Supporting Resources and References, this section). However, aligning environmental conditions with microbial contamination can be challenging, particularly when numerous combinations of environmental factors can affect an agricultural water system.
- Different pathogens can behave differently when exposed to various environmental conditions (e.g., different survival rates).
- The likelihood of water contamination is the focus of this brief. For factors that influence pathogen die-off (or growth) on produce {Link to Allowances for Die-off and Removal Brief}

Introduction of pathogens: Foodborne pathogens can be introduced into agricultural water sources via a variety of routes. Weather factors, such as precipitation and wind, can lead to movement of pathogens into water.

- Rain and other precipitation can result in runoff from nearby lands to the agricultural water source. Heavy prolonged rains can cause more runoff, which may carry contamination into surface water. Surface water (e.g., pond, river) levels can also rise and immerse sources of contamination on or near the original bank introducing new sources of contamination, among others.
    - The flow path of the runoff can affect the likelihood of pathogens being carried to the water source. {Link to Degree of Protection Brief}
    - Flow from an animal operation or across a grazed pasture may be more likely to carry pathogens compared to runoff from an unamended produce field.
- Dust and other particulates carried via wind have been shown to carry foodborne pathogens.
    - Wind direction and speed, as well as the presence of barriers, may provide insights into the origin of any dust. {Link to Degree of Protection Brief}
    - While dust has not yet been shown to introduce pathogens into water sources, windborne dust has been demonstrated to carry foodborne pathogens onto produce.

Persistence of pathogens: Growth, die-off, and survival of foodborne pathogens in water have been associated with weather factors, such as ultraviolet (UV) light and temperature.

- UV, including the UV wavelengths of sunlight, cause die-off of some foodborne pathogens.
    - The intensity of sunlight required for sufficient die-off is currently not well characterized.
    - Different organisms can be expected to react differently to the same UV intensity, in particular vegetative bacteria respond differently than do spore-forming bacteria, and viruses and protozoan pathogens have their own characteristics.
        - It is difficult to establish a UV or sunlight expectation where pathogens in agricultural water can be expected to die-off.
    - Turbidity of water impacts the amount of die-off from UV light that can be expected.
    - For closed water sources, such as deep wells, die-off due to UV light is not relevant.
- Research results indicate slower die-off of foodborne pathogens in water at lower temperatures under some conditions.
- Environmental conditions can also affect the survival of pathogens on produce. For instance, heavy rain or hail may physically damage produce and make it more susceptible to colonization by foodborne pathogens following introduction via agricultural water. This should be accounted for in an AgWA.

In summary, much work has been done to describe relationships between temperature, UV light, and foodborne pathogen growth, die-off, and survival.

- Specific temperature and UV exposure levels for sufficient foodborne pathogen die-off in agricultural water have not been identified.
- Interactions among these factors and other factors (e.g., turbidity and nutrient profile in the water) are complex.
- Under most conditions, it may be difficult to support the use of environmental conditions as a governing factor when making determinations based on the AgWA observations.

To better utilize observations about environmental factors to make risk-reduction decisions, development of predictive models has been proposed to indicate conditions when foodborne pathogens are more likely to be present in agricultural water sources. These models show promise as a tool to assess the likelihood of pathogen presence based, in part, on the environmental conditions. This underscores the value of data sharing and data analytics among produce industry stakeholders.

What does compliance look like?

The AgWA will include a section about environmental conditions. It may be useful to collect seasonal information about the growing environment including parameters like:

- Average temperatures
- Days of sunshine (and irradiation)
- Rainfall patterns
- Relative humidity

This information can inform decision-making, such as:

- Preparing procedures to address potential agricultural water system contamination during periods of vulnerability caused by specific weather conditions and events. {Link to Degree of Protection Brief}
- Enhance protections to reduce the potential for windborne dust, including soil from roads adjacent to fields, to water. Consider the use of berms, windbreaks diversions, ditches, and vegetated filter strips.

  - **Note:** This recommendation is most appropriate for regions with strong winds and dry conditions, particularly when growing operations are located near animal facilities.

When considering the effects of precipitation and wind on the likelihood of pathogen introduction into agricultural water, the type of water source and distribution system should be considered {Link to Location and Nature of Each Water Source and Type of Water Distribution System Briefs}.

- A deep well may not be impacted by run-off or wind assuming it is in proper working condition (e.g., no cracks in the well casing).
- An open water source (e.g., a canal or reservoir) may be impacted by runoff and windborne dust unless for example, it is protected by a berm or is lined {Link to Degree of Protection Brief}.

In certain growing regions, typical weather conditions may vary by season. Differences in weather conditions across seasons may alter water use (e.g., irrigation is only performed during dry seasons). This variation should be included in the AgWA. In addition, reassessment of a water source under § 112.43(e) may be necessary following unexpected or extreme weather events that may significantly alter the water quality. For example, reassessment may be necessary following an earthquake that damages a closed water system or following a series of atmospheric rivers that impact an agricultural water system over an extended period of time.

Scenario:

A farm in the Central Valley of California--known for intense sunlight and high temperature during the growing season--may factor these environmental conditions into their assessment. Specifically, the farm may consider that any pathogens potentially introduced into water sourced from the water district canal are more likely to die-off under local environmental conditions, compared to waterways with less sunlight exposure or lower temperatures.

This farm may be challenged to use this assessment alone to support a decision about whether corrective measures are, or are not, necessary in the context of environmental conditions. However, it may be used as one of several considerations to characterize the risk level of a potential hazard upstream from the farm.

Supporting Resources

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2. Belias, A., Brassill, N., Roof, S., Rock, C., Wiedmann, M., and Weller, D. 2021. Cross-validation indicates predictive models may provide an alternative to indicator organism monitoring for evaluating pathogen presence in Southwestern U.S. agricultural water. *Frontiers in Water*. 3:693631.
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Brief 8: Other Relevant Factors (§ 112.43(a)(5))

Brief description:
This issue brief discusses additional factors that may address the potential for pathogens to be introduced into agricultural water sources, as described in § 112.43(a)(5). Testing, which is referenced as part of this requirement, is described at length in a companion brief {Link to Testing of Agricultural Water Brief}.

How does this requirement reduce risk?

Companion briefs that describe the requirements of § 112.43(a)(1) through (a)(4) introduced several elements that must be considered as part of the AgWA to identify conditions that may introduce pathogens to agricultural water. Under § 112.43(a)(5), covered farms should consider any other relevant factors—including testing—that are not addressed by the previously described categories.

> **§ 112.43(a)(5)**
> *Elements of an agricultural water assessment. …*The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce …or food contact surfaces, based on an evaluation of the following factors:
> (5) Other relevant factors, including, if applicable, the results of any testing conducted pursuant to paragraph (d) of this section. {where paragraph (d) is described as *Testing for assessment purposes*}

This provision incorporates flexibility and responsibility for the grower related to factors that must be included.

- In describing their approach to rulemaking, FDA describes *"systems-based agricultural water assessments that are designed to be more feasible to implement across the wide variety of agricultural water systems, uses, and practices, while also being adaptable to future advancements in agricultural water quality science and achieving improved public health protections."*
- The inclusion of flexibility for the grower helps to address diversity of water sources in different geographic regions of the world.
- The grower is responsible for considering diverse and unique challenges—not explicitly addressed in the regulations—that could contribute to the introduction of pathogens into agricultural water if not properly managed.
-

What does compliance look like?

The authors asked food safety professionals across North and South America about potential sources of contamination they have encountered in their regions. The following examples might help the reader consider "other relevant factors" based on real-life scenarios.

- Discharges of sewage from areas where there are endemic diseases (e.g., parasites like *Cyclospora cayatenensis*) or regional prevalence of diseases (e.g., viruses like Hepatitis A).
- Use of rivers and other agricultural water sources for swimming and other recreational purposes, or for basic household and personal hygiene functions, such as bathing, washing dishes, doing laundry, and animal husbandry (i.e., drinking water and/or bathing water for domesticated animals).

Some factors might be observed or characterized, particularly at the start of the season, and can be proactively addressed. Risk-reduction actions in these situations may include: 1) treating the water before use {Link to Treatment of Agricultural Water Brief}, or 2) ensuring the availability of hygienic facilities and closely monitoring hygienic practices, among other measures.

Growers might encounter other factors that occur unexpectedly throughout the year and consider whether the event might introduce pathogens. The event might be cause for an updated AgWA. The farm may plan ahead by assessing whether the growing environment is prone to such events.

- Cars falling into water and other accidental intrusions.
    - It would be difficult to confirm if these events resulted in pathogen introduction.
- Unfortunate and significant levels of sporadic violence and unrest in several large and well-known growing regions.
    - Conditions of concern in these regions include reports and testimonials of human bodies found in irrigation canals.
- Pre- and post-consumer vegetative waste or table waste can be discharged to the water source if there are insufficient environmental controls.
    - Adjacent and nearby farm operations may trim field edges and leave residues in ditches and other water ways.
- Flood water could be pumped into the water source (e.g., canals, rivers) to reduce flood damage.
    - Flood water can carry pathogens from wastewater or from runoff, among other sources.
    - Keep in mind that the FDA considers produce in contact with natural flood water to be adulterated and may not be legally sold in the U.S. as human food or animal feed.

Some responses to these conditions may include 1) temporary suspension of use as agricultural water or 2) treating the water before use. Finally, other factors might be encountered as part of the agricultural water systems inspection (§ 112.42). These relate to both pre-harvest water (input to the AgWA) and water used during and after harvest (covered by provisions in Subpart E of the Produce Safety Rule).

- Cross-connections in the plumbing system and areas lacking adequate backflow prevention devices in the distribution system can pose a risk to the safety of the water source or the integrity of the distribution system.
- Abandoned or inactive wells, which may become contaminated due to lack of maintenance.
    - Some growers consider these boreholes to be “emergency wells.”
    - If not properly capped and maintained, conditions of these wells may allow the introduction of pathogens into the water system.

Responses to these findings are often addressed through maintenance, such as installation or repair of equipment or routine flushing (e.g., of unused lines).

Example Scenario:

The list of factors throughout this brief was based on real scenarios that growers encountered in different growing regions. Many conditions are specific to different regions. Understanding conditions in the region is important to understanding the system, performing an effective AgWA, and determining if mitigation measures are necessary. It is critical to monitor changes in conditions that could affect a grower’s AgWA.

Supporting References

1. U.S. Food and Drug Administration. *Guidance for Industry: Evaluating the Safety of Flood-affected Food Crops for Human Consumption*. October 2011. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-evaluating-safety-flood-affected-food-crops-human-consumption.

Brief 9: Testing of Agricultural Water (§ 112.43(d))

Brief description:
This brief discusses testing as a factor to consider in the AgWA, under § 112.43(a)(5). Testing can be a useful part of any AgWA, particularly to make decisions about whether mitigation measures are reasonably necessary. Under some circumstances, an AgWA process can pause in order to collect test results as input to the AgWA. Factors that define these circumstances are:

1. A condition that may result in the introduction of pathogens to the water is identified.
2. The water does not violate the requirement to be safe and of adequate sanitary quality for its intended use, (requirements of § 112.43(c)(1) would apply instead).
3. The condition is not “related to animal activity, application of a biological soil amendment of animal origin, or the presence of untreated or improperly treated human waste on adjacent or nearby lands” as described in § 112.43(c)(4)(ii).

If testing is considered as part of the AgWA, the testing must meet requirements described in § 112.43(d).

§ 112.43(d)
Testing for assessment purposes. In conducting testing to be used as part of your assessment under paragraph (a)(5) of this section, you must use scientifically valid collection and testing methods and procedures, including:
(1) Any sampling conducted for purposes of paragraph (c)(4)(ii) of this section must be collected aseptically immediately prior to or during the growing season and must be representative of the water you use in growing covered produce (other than sprouts).
(2) The sample(s) must be tested for generic *Escherichia coli* (*E. coli*) as an indicator of fecal contamination (or for another scientifically valid indicator organism, index organism, or other analyte).
(3) The frequency of testing samples and any microbial criteria applied must be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under paragraph (a) of this section, 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 your agricultural water used in growing covered produce (other than sprouts).

How does this requirement reduce risk?

Managing the quality of the agricultural water sometimes requires understanding, to the best of the grower’s ability, whether the water is susceptible to a chronic or acute source of direct or indirect fecal contamination.

- The presence of generic *E. coli* in groundwater sources, such as wells assumed to be pathogen-free, is sufficient to warrant an investigative response and implementation of appropriate corrective measures. Elevated levels of generic *E. coli* (based on individually determined baselines) in surface water indicates potential fecal contamination and may warrant further investigation. For agricultural water used during and after harvest, testing to the standard of no detectable generic *E. coli* in a 100 mL water sample is required (§ 112.44(a)).
- For water used before harvest, testing is not required under the rule. Testing is an option that growers can utilize to establish the sanitary quality of the water or to identify a pre-treatment baseline.
- One way to use *E. coli* test results is an approach called the microbial water quality profile (MWQP) and associated standards described in Comments 38, 95, and 96 of the 2024 revisions to PSR Subpart E. The use of the MWQP approach is conditional on the premise that the water samples are representative of use, and that the criteria are relevant to establish a management strategy based on the hazards identified. The FDA is clear that *E. coli* results alone should not be the only input to making an AgWA determination.
- An MWQP (as described in the Produce Safety Rule, published in 2015) consists of 20 or more samples collected over 2 to 4 years, with the standards based on calculation of geometric mean value (no more than 126 CFU/100 mL water) and statistical threshold value (no more than 410 CFU/100 mL). Other

options to the MWQP system, including frequency of sampling, numerical standards, and target indicator of fecal contamination, may also be acceptable. Importantly, growers must justify and document why they are acceptable.

Microbial testing for water usually requires specialized skills and tools. Most growers rely on laboratories to process samples. The elements of the process the grower must manage include:

- Collecting the water sample in an appropriate manner specific to source and conveyance system, including using an appropriate aseptic technique.
- Taking samples at appropriate time intervals, or targeted sampling when an event occurs that might impact microbial quality.
- Asking for the appropriate analysis (often generic *E. coli*) and confirming that an appropriate analysis method is used (reference FDA Equivalent Testing Methods fact sheet).
- Reviewing the results of the analysis to determine if action must be taken.

Importantly, growers need to understand how to interpret the results of the analysis. Help can be found from Extension educators, websites, or the laboratory staff who processed the samples.

What does compliance look like?

The strategy for sampling of water in support of an AgWA depends, in part, on the intended use of the water. Key considerations for developing a sampling strategy include:

- If the farm uses water from a Public Water System (see Safe Drinking Water Act (SDWA) regulations 40 CFR part 141) that is compliant with the microbial requirements, the grower might be eligible for an exemption from the AgWA requirement (see § 112.43(b)(2)). If growers use this type of water as their source, they might choose not to test the water at all, provided the conveyance and distribution of this water to point of application does not introduce any additional risk. Testing is one practical approach to verify the quality of the Public Water System source has not been compromised within the distribution system.
    - For detailed information, {Link to Location and Nature of Each Water Source Brief}
    - Keep in mind that under circumstances where a natural disaster or contamination event occurs that impacts a Public Water System, growers may want to have the water tested.
- Untreated surface water may be vulnerable to fecal contamination, depending on factors evaluated in the AgWA.
    - For detailed information about fecal contamination sources, {Link to Location and Nature of Each Water Source Brief}
    - For detailed information about protection from contamination {Link to Degree of Protection Brief}
    - The requirements offer space for growers to establish a sampling strategy that is appropriate to their operation.
    - Sampling data from surveys, including scientific publications and industry data, indicate generally higher likelihood of pathogens in untreated surface water. Sampling of these sources should be more intensive (higher frequency) compared with ground water (e.g., wells).
- Untreated ground water also has vulnerabilities to introduce pathogens.
    - For detailed information about protection from contamination review the Degree of Protection Brief.
    - Ground water sampling strategies should allow confirmation that water quality is consistent throughout the year, including specific assessments during periods of substantial storm events

(>2 inches in 24 hours) to ensure the ground water quality is not impacted by processes like seep or the down-hole flow from a rain event.
  - Ground water sampling should be conducted after an environmental event (e.g., flood that overtops the well head or on-farm risers) that would impact water quality.

Sampling must be done effectively to obtain results that are meaningful. A few guidelines on effective water sampling are included in the list below:

- Growers can collect their own water samples, or they can assign someone to complete this task.
- The sample must be collected in an aseptic manner.
- Samples that are mishandled, such as exposed to high temperatures or not processed in a timely fashion, can return inaccurate results.
- Laboratories often supply sterile sample containers and instructions.
- If the situation requires a grower to hold samples for more than a few hours before delivery or shipment of the samples, contact the laboratory for specific instructions on how to maintain the integrity of the sample.
- When generic *E. coli* is used as a fecal indicator, the analysis must be done using a method equivalent to EPA Method 1603 (modified mTEC; see Supporting Resources for a list of equivalent methods). If an indicator other than *E. coli* is used, the methods requirement is less restrictive. Methods for other indicators must be scientifically valid and appropriate to that fecal indicator.

Scenario:

A farm uses untreated river water as their overhead irrigation water source. While completing the AgWA, the farm did not identify any specific conditions (e.g., unmanaged human waste discharges or land uses, such as land application of untreated manure) that might introduce pathogens to the river. However, the farm cannot rule out the likelihood that wildlife in the riparian areas might access the river resulting in fecal contamination.

In this scenario, the grower decides to begin a water sampling program to quantitatively evaluate their water quality. After carefully reviewing the guidance provided in Comments 95 and 96 of the 2024 rule revising Subpart E, they determine that the MWQP sampling frequency and criteria are meaningful for their water source and operation. The grower could sample the river 5 times per year for generic *E. coli* and, upon developing a MWQP of 20 or more samples over 4 years, calculate their MWQP statistics resulting in a geometric mean of 42 CFU/100 mL and a statistical threshold value of 216 CFU/100 mL. The grower might use the MWQP analysis in conjunction with other findings of the AgWA to make their determination about whether measures are reasonably necessary.

Supporting Reference:

U.S. Food and Drug Administration. 2024. FSMA Final Rule on Pre-harvest Agricultural Water: Equivalent Testing Methodology for Agricultural Water Produce Safety Rule (21 CFR 112).

Agricultural Water Assessment Corrective Measures and Mitigation Measures

The FDA has established specific measures that growers may implement based on the results of a pre-harvest AgWA. The type of measure required depends on the severity of the identified risks. These measures fall into two categories: **corrective measures** and **mitigation measures**.

Corrective measures refer to actions that must be implemented if a grower determines their water is not safe, or not of adequate sanitary quality for its intended use. Corrective measures are required when the risk is more severe. Immediately after discovering the water is not safe, or not of adequate sanitary quality, the farm must discontinue the use of water and implement corrective measure(s) before resuming use. Preamble (2024) comment 78 gives several examples of factors that would cause water to not be safe or of adequate sanitary quality, including leaking sewage from a ruptured pipe, a manure lagoon overflowing into the water system, and the presence of dead and decaying animals. The FSMA PSR establishes just two corrective measures in Subpart E (§112.45(a)):

- Re-inspect the entire affected agricultural water system to the extent that it is under your control and, among other steps, make necessary changes and take adequate measures to determine if your changes were effective.
- Treat the water before use.

Mitigation measures are actions a grower must take when conditions on the farm or nearby lands could allow pathogens to compromise produce safety through the water system. Mitigation measures are used when action is reasonably necessary to protect produce safety, but the extent of the risk is not at the level that requires a corrective measure. These risks could be related to animal activity, BSAAO, human waste, or other conditions. Depending on the type of risk and the location of the condition (e.g., on-farm or on adjacent and nearby lands), mitigation measures have more flexibility as to when they need to be implemented. The FSMA PSR lists six mitigation measures in Subpart E (§112.45(b)):

- Make necessary changes (e.g., repairs).
- Increase the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off.
- Increase the time interval between harvest and the end of the storage period and/or conducting other activities during or after harvest to allow for microbial die-off or removal.
- Change the method of water application to reduce the likelihood of produce contamination.
- Treat the agricultural water.
- Take alternative mitigation measures.

FDA's "FSMA Final Rule on Pre-harvest Agricultural Water: Corrective and Mitigation Measures for Pre-harvest Agricultural Water for Non-Sprout Covered Produce" factsheet includes more detail on corrective and mitigation measures.

§112.45(a)

(a) *Discontinue use(s).* If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use(s) in growing, harvesting, packing, or holding covered produce as required under § 112.41, and/or if your agricultural water used as sprout irrigation water or for harvesting, packing, or holding activities does not meet the requirements in § 112.44(a) (including the microbial quality criterion), you must immediately discontinue such use(s). Before you may use the water source and/or distribution system again for the intended use(s), you must either:
(1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective, and as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or
(2) Treat the water in accordance with the requirements of § 112.46.

The briefs on corrective and mitigation measures are intended to be used in conjunction with those described in the previous section, which focus on developing a risk profile for the water source. (the section called Briefs: Agricultural Water Assessment for Pre-Harvest Uses)

As a reminder, scenarios were used in a previous section to demonstrate how these briefs could be applied by a covered farm to build their AgWA.The AgWA includes recordkeeping requirements, which are discussed separately in this document {Link to Records Requirements Brief}.

Supporting References

1. FDA FSMA Final Rule on Pre-harvest Agricultural Water: Corrective and Mitigation Measures for Pre-harvest Agricultural Water for Non-Sprout Covered Produce factsheet: https://www.fda.gov/media/178228/download?attachment

Brief 10: Treatment of Agricultural Water (§ 112.46)

Brief description:
This issue brief discusses the treatment of agricultural water, an allowed option to deliver water that is safe and of adequate sanitary quality for use § 112.41. Treatment may exempt growers from certain requirements, including the pre-harvest agricultural water assessment (§ 112.43(b)(3)) and the harvest/postharvest water testing requirement (§ 112.44(c)(3)). Additional requirements (by U.S. EPA), related to use of treatments that are considered antimicrobial pesticides, are described in a companion brief {Link to Treatment of Water – The Label is the Law Brief}.

§ 112.46
(a) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use(s) and/or meet the microbial quality criterion in § 112.44(a), as applicable;
(b) You must deliver any treatment of agricultural water in a manner 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); and
(c) You must monitor any treatment of agricultural water 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).

How does this requirement reduce risk?

In some cases, the decision to treat water before use will be made based on the results of the AgWA. Properly selected, applied, and verified practical treatment options will reduce levels of some pathogens in water before they can attach to a crop. Conditions that might lead to the decision to treat water:

- Pathogens are likely to be introduced to the water due to adjacent land and nearby land uses.
- Preventing the introduction of pathogens is not feasible without environmental impact.
- Due to adjacent and nearby land uses outside the farm's control, further risk reduction from any attached pathogens by use of in-field die-off, die-off during storage, or physical removal during post-harvest processing is operationally limited or not applied for quality reasons.

What does compliance look like?

Agricultural water may be treated:

- As a corrective measure in response to an assessment that the water may not consistently or reliably meet the requirement of § 112.41 and has been determined not to be safe for its intended use (§ 112.45(a)(2)).
- As a mitigation measure in response to an assessment that chronic or acute conditions for pathogen introduction are known or reasonably foreseeable for an agricultural water source § 112.45(b)(1)(v)).
- As an alternative to conducting the AgWA for the water system used for growing covered produce (§ 112.43(b)(1)(iii).

Consider that treatment products for use in the United States are regulated by U.S. EPA, and growers are responsible for selecting a product that is appropriately labeled for the use when applicable (Refer to Treatment of Water – The Label is the Law Brief for more information).

Water treatment requirements (§ 112.46):

- Treatment methods must ensure that the water is consistently safe and of adequate sanitary quality for its intended use(s).

  - Provision § 112.46 does not establish set treatment targets such as microbial quality criteria for pre-harvest use, although many growers might continue to test water as one piece of information for their AgWA. (Refer to Testing of Agricultural Water Brief for more information).
  - Treating water may not fully eliminate pathogens at practical and non-phytotoxic rates and there may be residual public health risk. Some pathogens of concern will not be reduced by current practical and economically sensible treatment options.
- Treatment must be monitored using an adequate method and frequency (e.g., the treatment remains within scientifically valid process control parameters).
- Treatment may be conducted by the grower or by a person or entity acting on their behalf (§ 112.46(d)).

Common agricultural water treatment methods (from Rock, 2021)

Chemical	• Peroxyacetic acid (Activated Peroxygen, PAA) • Chlorine • Chlorine Dioxide • Sodium or Calcium Hypochlorite • Cooper/Silver Ionization • Ozone
Physical	• Heat Sterilization • Ultraviolet Light
Biological	• Slow Sand Filtration • Tertiary treatments (e.g., wetlands) in combination with exclusion and prevention management plan.

Characteristics of selected physical and chemical treatments

Physical treatments	
UV	UV light damages and breaks down organic molecules including DNA and RNA. Filtration required prior to treatment as soils and organic matter reduce UV transmittance. When used alone, antimicrobial action is not carried through the distribution system. Utilizing an UV treatment system at field level may be challenging due to damage during field-to-field movement and the need to establish a preventive maintenance program (e.g., frequency to replace light bulbs).
Chemical treatments	
Chlorine	Oxidizer -- sensitive to organic load and effectiveness is dependent on water pH levels
PAA	Oxidizer -- not as sensitive to organic load and pH. Phytotoxicity has been reported at realistic effective dose.
Chlorine dioxide	Oxidizer -- not as sensitive to organic load and negligibly affected by pH.
Ozone	Oxidizer -- very sensitive to organic load but not sensitive to pH.

Example Scenario:
A growing operation in Florida uses a system of sand-point wells to obtain irrigation water from a near-surface ground water aquifer in coarse sand. As part of the AgWA, the operation recognizes that the aquifer is unconfined and likely mixes with surface water, particularly after precipitation. This condition might allow the introduction of pathogens into the water source.

The operation recognizes that testing alone may not accurately reflect risk, which will vary based on weather and the potential for surface fecal contamination. The operator is aware of research showing that rain events may increase risk. Therefore, the operation uses portable ozone generation equipment (labeled as an antimicrobial device by EPA) to treat the water prior to use as agricultural water to grow covered produce. Treatment, in this scenario, is a mitigation measure applied pre-emptively (before the growing season begins). The treatment must be monitored to ensure that ozone is generated in accordance with treatment specifications.

- Antimicrobials registered with the EPA may contain an efficacy statement on its label, stating that under the conditions (control parameters) of the label use instructions the product will reduce the level of pathogens by a certain amount.
- The efficacy statement, if available, may allow growers to decide whether that antimicrobial is sufficient to manage the pathogen(s) of concern, at the levels found in the water.

Manufacturer technical data, including control parameters for effective use, and treatment monitoring records are kept in the farm's records. The farm may qualify for an exemption from future AgWA, provided the treatment conditions outlined in the PSR are met (§112.46). However, the farm is still required to conduct an inspection of its agricultural water system at least annually (§ 112.42).

Supporting Resources and References

PAA & Chlorine

1. https://www.centerforproducesafety.org/amass/documents/researchproject/455/CPS%20Final%20Report_Rock%20%28AWT%29%20-%20September%202021.pdf (Rock, Agriculture water treatment - Southwest region, 2021)
2. https://www.centerforproducesafety.org/amass/documents/researchproject/442/CPS%20Final%20Report%20Rapid%20Response_Rock_080719.pdf (Rock, CPS Rapid Response - Yuma Valley, 2019)

Chlorine dioxide

3. https://www.centerforproducesafety.org/amass/documents/researchproject/374/CPS%20Final%20Report_Allende_January%202017.pdf (Allende, 2016)

Miscellaneous

4. https://www.centerforproducesafety.org/amass/documents/researchproject/357/CPS%20Final%20Report%20_Buchanan_January%202016.pdf (Buchanan, 2015)
5. CPS Agricultural water treatment webinar – https://www.centerforproducesafety.org/webinars.php#CPS_Agricultural_Water_Treatment_Webinar
6. Allende, A. (2016). Demonstration of practical, effective and environmentally sustainable agricultural water treatment to achieve compliance with microbiological criteria. Murcia, Spain: Center for Produce Safety.
7. Asma Jamil, S. F. (2017, March 27). Ozone Disinfection Efficiency for Indicator Microorganisms at Different pH Values and Temperatures. Ozone: Science & Engineering. Islamabad, Pakistan: Taylor & Francis.
8. Buchanan, J. (2015). Evaluation of multiple disinfection methods to mitigate the risk of produce contamination by irrigation water. Center for Produce Safety.
9. D. Gombas, Y. L. (2017, January 24). Guidelines to Validate Control of Cross-Contamination during Washing of Fresh-Cut Leafy Vegetables. Journal of Food Protection, 312-330.
10. Rock, C. (2019). CPS Rapid Response - Yuma Valley. Yuma, AZ: Center for Produce Safety.
11. Rock, C. (2021). Agriculture water treatment - Southwest region. Maricopa, AZ: Center for Produce Safety

Brief 11: Treatment of Water – The Label is the Law

> **§ 112.46 *What requirements apply to treating agricultural water?***
> (a) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use(s) and/or meet the microbial quality criterion in § 112.44(a), as applicable;
> (b) You must deliver any treatment of agricultural water in a manner 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); and
> (c) You must monitor any treatment of agricultural water 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).

This brief will focus on the legalities of treating agricultural water, which applies to pre-harvest, harvest, and post-harvest water uses. From the standpoint of permitted uses of antimicrobials, options currently appear to be more limited for water used during pre-harvest, so the following commentary will focus on pre-harvest considerations.

It is critical for growers to consider the implications of decisions related to the treatment of water, and to consider unintended consequences that may occur. For example, discontinuing use of a particular sanitizer may increase the likelihood of crop contamination if the hazard has not been managed through another mechanism (e.g., filtration, UV treatment). This brief will discuss existing chemical water treatment (i.e., sanitizer) labeling practices, however, it should be noted that progress is being made within the industry to expand the collection of antimicrobials that are EPA-registered and labeled for use as a treatment of pre-harvest agricultural water. Some labels are also updating their efficacy statement to include control of human pathogens.

As noted above, EPA is the regulatory authority with jurisdiction over the use of chemical water treatments in the United States. Therefore, EPA (not FDA) is the agency that can approve various uses. The Produce Safety Alliance has compiled a list of antimicrobials approved by EPA for various purposes, including irrigation water, which is referenced at the end of this brief. Note that "approved" for irrigation water does NOT necessarily mean it is intended to treat water for human pathogens. An efficacy statement indicates the target organisms against which the product is effective. In the PSA tool, expand the "Label Info", and sort the "Labeled for Use in Irrigation Water" column. This will allow access to the associated EPA label and, if available, the manufacturer product label.

Note that irrigation is not the only pre-harvest use of agricultural water. Chemical sanitizers may also be labeled for use in foliar sprays applied to fruits and vegetables. This labeled use is relevant to PPPs and can be identified by reviewing the notes column of the Produce Safety Alliance tool.

Each grower should determine if water treatment is appropriate based on their AgWA. Treating water, particularly water used in the field, should not be the default because of the possible impacts to the broader ecosystem. Impacts to the environment are part of EPA's evaluation of the product during the approval process. It is important to note that off-label use, particularly for in-field water treatment, may result in unintended and detrimental environmental impacts.

The example below provides sample label information and assessment of whether grower use is appropriate, both from a scientific standpoint as well as how a regulator may view things. FDA does not have the authority to supersede EPA regulations or approvals. EPA approves antimicrobials for treating irrigation water; FDA enforces the PSR.

Example label scenario:
A grower treats pre-harvest water that will be used for overhead irrigation with peroxyacetic acid.

The label states: “Bacteria, Slime, Odor and Algae Control in: Recirculating Cooling Water and Evaporative Coolers, Reverse Osmosis, Nano and Ultra Filtration, and Agricultural Waters.”

The “**directions for use**” further states “AGRICULTURAL or HORTICULTURAL USES There is a Restricted-Entry-Interval of zero (0) hours after the use of this product. This product must never be mixed or combined with any other pesticide or fertilizer. Upon soil contact, this product decomposes rapidly to oxygen, carbon dioxide and water. This product may be harmful to fish if exposed on a continuous basis at concentrations of 0.5 ppm or more of active peroxyacetic acid. Meter this product into pressurized pipes using a plastic or stainless-steel injection/backflow device installed far enough upstream from the target equipment to ensure thorough mixing. For open flowing bodies of water, apply this product as far upstream as possible to allow adequate mixing prior to the flow entering any larger body of water. If open pouring of this product is required, pour product as close to the surface of the water as possible to reduce odor exposure. **Treatment of Irrigation Water Systems** (sand filters, humidification systems, storage tanks, ponds, reservoirs, canals): *For the control of odor, sulfides, slime and algae* in water systems, apply this product at 2 oz. per 100 gal of water (10 ppm peroxyacetic acid). This feed rate equals 1.5 gal per 10,000 gallons of water. Repeat dose as necessary to maintain control, which will vary with seasonal conditions. For prevention of algae some systems may require continuous low-level dosing during warm sunny periods. Drip Irrigation System Cleaning: To clean slime and algae from drip system tapes and emitters, meter this product upstream from pumps or filters at the rate of 1-2 oz per 50 gallons of water (10-20 ppm peroxyacetic acid). This feed rate equals 1.5-3 gal per 10,000 gallons of dilution water. When required, during normal irrigation cycles, use this product at the recommended dose for a minimum of 30 minutes. After an irrigation cycle do not flush the lines.”

If the grower has conducted an AgWA and determined the risk of the presence of pathogens, such as E. coli O157:H7 and Salmonella needs to be managed, is the use of PAA as detailed in this example acceptable?

Answer 1: Does the science support treatment efficacy to reduce or eliminate human pathogens?

Possible. The grower would need to have conducted or evaluated scientific studies to determine if PAA was effective against the pathogens the grower identified as needing to be controlled. PAA is known to have an antimicrobial effect, but the grower would need to understand the concentrations and contact time needed within their water system to determine that the treatment would in fact be effective. It is possible that, from a scientific perspective, PAA could be used to treat irrigation water to reduce the risk of pathogens in the water.

Answer 2: Is the product used in a way that is compliant with current regulations?

No. Directly under the “Directions for Use”, it states “it is a violation of Federal law to use this product in a manner inconsistent with its labeling.” The labeling indicates that the product, when used for the treatment of irrigation water systems, is used for the “control of odor, sulfides, slime and algae in water systems”. It is not approved, in this application, for the treatment of bacteria of public health concern such as *E. coli* O157:H7 or *Salmonella*.

FDA and EPA collaborated to develop a testing protocol so chemical providers can gather data needed to support registration or amend a current EPA label to include human pathogens. Growers can consider contacting their current antimicrobial suppliers to learn if the company intends to follow the protocol to add treatment for human pathogens to the labeled use. It is important to remember that the product label is legally binding. The label is the law. The PSR does not require that sanitizers used to treat pre-harvest water have an efficacy statement that includes human pathogens.

Supporting Resources

1. Produce Safety Alliance. EPA-Labeled Sanitizers for Produce – Web Tool. 2024. Available at: https://resources.producesafetyalliance.cornell.edu/sanitizer/
2. U.S. EPA and FDA. Efficacy Protocol and U.S. Environmental Protection Agency Protocol Review. 2022. Available at: https://www.fda.gov/media/140640/download
3. U.S. Food and Drug Administration. 2017. Determining Regulatory Authority for Antimicrobial Substances. Available at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/determining-regulatory-authority-antimicrobial-substances

Brief 12: Allowances for Die-off and Removal in Field and During Storage (§ 112.45(b)(1)(ii) and (iii))

Brief description:
This issue brief discusses the use of die-off as a mitigation measure to address circumstances where pathogens may be introduced into agricultural water prior to use. The regulatory requirements associated with die-off as a mitigation measure are described in § 112.44(b)(1)(ii) and (iii).

How does this requirement reduce risk?

> **§112.45(b)**
> *Implement mitigation measures.*
> (1) You must implement any mitigation measures that are reasonably necessary to reduce the potential for contamination … {abridged text describes types of contamination and time frames}. Mitigation measures include:
> (ii) Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided you have scientifically valid supporting data and information;
> (iii) Increasing the time interval between harvest and the end of storage to allow for microbial die-off, and/or conducting other activities during or after harvest to allow for microbial die-off or removal, provided you have scientifically valid supporting data and information;

FDA lists several mitigation options that may be taken. It is up to the grower to determine through an AgWA which mitigation measures are reasonably necessary to manage produce safety risk due to the potential for pathogens in agricultural water.

One class of these mitigation measures involves accounting for environmental and ecological factors that lead to pathogen die-off or activities that physically remove or inactivate pathogens on produce.

- **In-field die-off:** conditions on the produce surface (e.g., sunlight, temperature, moisture level, or interactions with normally resident microorganisms) often result in a reduced population of human pathogens over time.
- **Storage die-off:** depending on storage conditions, human pathogens that may be on the produce surface may die off over time.
- **Removal during harvest or postharvest activities,** such as physical washing with a surfactant (if used) may result in physical removal of pathogens from the produce surface. The use of antimicrobial treatments in the postharvest process water can have several benefits:
    - Reduce the survival of pathogens in water,
    - Reduce the likelihood of cross contamination, and
    - Cause die-off of some pathogens if they are on the produce surface.
- Keep in mind that removal during activities like commercial washing is highly dependent on process and commodity and generally does not result in more than 1-log removal (i.e., 10% survival), so growers should be cautious about relying solely on such activities as a mitigation measure if their water is poor quality.

What does compliance look like?

Use of In-Field Die-Off as a Mitigation Measure (§ 112.45(b)(1)(ii))
The final rule states that an acceptable mitigation measure is to increase the time interval between the last direct application of water and harvest, provided the grower has scientifically valid supporting data and information to support your approach to using die-off as a mitigation measure.

The 2024 preamble provides more information regarding FDA expectations for how in-field die-off would be used as a mitigation measure. In response to comment 114, FDA states farms may establish that an interval between the last direct application of agricultural water harvest is appropriate to manage hazards that are identified. FDA further states that if a grower does not test their agricultural water, then an acceptable mitigation measure could be to increase the time interval between the last direct water application and harvest to four days, based on discussion captured in the preamble. If a grower does test their water and it is above the threshold detailed in the PSR, then the grower can adopt a microbial die-off rate of a 0.5 log reduction per day (which may be less than four days to reach that microbial threshold, based on analytical data the grower has). The FDA also emphasized that an adequate die-off rate can be applied if supported by scientifically valid data to achieve a calculated log reduction to meet the criteria the farm establishes in accordance with § 112.43(d)(3). Importantly, the four day die-off option is not universally protective and depends on the crop, region, and environment among other factors.

Minimum of four days: Based on this FDA guidance, a four-day interval between the last direct agricultural water application and harvest is an acceptable mitigation measure without the need to provide supporting data or additional action, and without any water testing information if on-farm conditions are consistent with the FDA summarized studies. However:

- Growers should carefully consider field conditions to evaluate the appropriate use of this mitigation measure option.
- Using the FDA-provided 0.5 log/day die-off assumption, a four-day interval results in 2-log or more die-off (greater than 99% die-off) meaning up to 1% of the original hazard load may still be present.
- Growers are still subject to the FD&C Act to ensure food is produced and handled under sanitary conditions.
- Mathematically, the reduction in *E. coli* concentration would be less than 2-log (<99%) if a 0.5 log/day die-off were applied for fewer than four days. This means more than 1% or more of the original generic *E. coli* load (and any associated biological hazards) may still be present. It is important to recognize that pathogens might die-off at different rates and the 0.5 log/day assumption was drawn from research limited to a subset of pathogens. As stated in the call-out box, die-off rates vary based on environmental conditions, characteristics of pathogens and characteristics of the crop. Therefore, growers should be cautious about using this as a stand-alone mitigation measure if water quality is poor.

In-field Die-off as a Mitigation Measure

As part of the AgWA, growers must consider what mitigation measures identified in the PSR, if any, are appropriate to reduce the risk associated with hazards identified through the assessment. Growers should recognize that in addition to regulatory compliance, they are also responsible for producing food that is not injurious to consumers (i.e., compliance with the FD&C Act).

Pre-harvest die-off can vary depending on a number of factors. A grower who is using a die-off option as their only mitigation measure should consider:

- Which specific hazards might be present. Various pathogens can have very different die-off characteristics {Link to Microbial Hazards table}.
- The quality of the water used (e.g., based on testing their water before harvest). Unusually high test results might indicate supplemental mitigation measure(s) are advisable to address any elevated potential for hazards (pathogens).
- Environmental conditions in the growing region and commodity characteristics. Use of supplemental mitigation measure(s) may be appropriate during conditions that favor survival over die-off, particularly during the time period leading up to harvest, or if the commodity in question has been shown to have slower die-off rates under specific environmental conditions.

Other insights and suggestions: For farms that choose to use in-field microbial die-off as a mitigation measure, consideration of the following factors (with documentation) may be beneficial.

- Environmental factors that affect die-off rates include sunlight (UV) intensity, moisture level, and temperature.
    - Pre-harvest die-off can be supported by documenting average conditions within their region during the time of year when water is being used close to harvest.

- For example, the strongest support might be based on research that measures die-off rates during the night as a conservative scenario where:
  - UV rates lowest.
  - Humidity levels highest.
  - Temperatures coolest.
  - The study was done on the produce commodity in question, in the region in question, or where environmental conditions are comparable.
- Deviation from typical environmental conditions, such as a rainstorm, unseasonable cold, or cloudy conditions during the period before harvest, may slow down the die-off rate.
  - Document the deviation.
  - Consider using the FDA-provided 0.5 log/day microbial die-off rate, if appropriate.

Use of Microbial Die-off in Storage or Removal through Postharvest Practices as a Mitigation Measure (§ 112.44(b)(1)(iii)):

Additional mitigation measures may be implemented if the grower determines—through an AgWA—that such actions are reasonably necessary to manage produce safety risks related to potential pathogen presence in agricultural water. Currently, FDA guidance does not specify a recommended in-storage time interval or die-off rate for growers to use when modeling these mitigation options.

- Apply a microbial die-off interval between harvest and the end of storage for covered produce.
- Apply microbial die-off or removal associated with activities during or after harvest.

Growers wanting to apply these mitigation measures must establish scientific support for the die-off rate or log-removal rate, and time interval (when applicable).

- Supporting data or other information must describe how the rate was determined and how long it was applied.
- The rate should be determined by using the same crop and storage practices as the growers' operation.
- The outcome must be that potentially present pathogens are adequately managed. The expectation is that no pathogens are present on produce when it reaches consumers.
- If another entity within the supply chain (e.g., a packer or processor) stores or washes the produce, then the grower will need to obtain the information regarding storage and/or washing practices from that entity if they want to use postharvest die-off or removal during commercial washing as mitigation measures.

Example Scenario:

A grower may routinely test their direct-contact irrigation water more than five times per year near harvest and determine from the data that the 4-year rolling geometric mean is approximately 1,000 CFU/100 mL of generic *E. coli*. With no alternative water source available, the grower includes these test results as part of their AgWA to evaluate water quality. Based on this assessment, the grower concludes that it would be inappropriate to use the water for growing covered produce without implementing a mitigation measure.

If the commodity, region, and pathogens of concern are consistent with the studies reported by FDA (see Comment 114 of the 2024 preamble), the grower could choose to assume an 0.5 log/day reduction rate based on FDA guidance and calculate that after two days the adjusted geometric mean value would be about 100 CFU/100 mL. The adjusted value is less than the benchmark of 126 CFU/100 mL that FDA supports. A similar calculation with similar outcome is performed using the statistical threshold value.

The grower can only implement a 24-hour pre-harvest interval between water application and harvest without causing damage to the produce. One day of in-field die-off at a rate of 0.5 log/day would reduce the geometric mean to approximately 316 CFU/100 mL. Additional data indicate the commercial washing step used during packing achieves a 1-log reduction. This washing process has been validated using the same crop, antimicrobial treatment, and relevant parameters, including active ingredient and water quality characteristics. When considered together, the modeled in-field die-off and the validated commercial washing process may provide sufficient mitigation to meet regulatory requirements. The combined 1.5-log reduction (0.5 log from in-field die-off and 1 log from washing) would lower the calculated geometric mean to approximately 32 CFU/100 mL.

When selecting these mitigation measures, the grower should consider both the FSMA PSR (§ 112.11) and the FD&C Act necessitate consideration of whether the farm can provide reasonable assurances that the produce is not adulterated. Food “shall be deemed to be adulterated (a) Poisonous, insanitary, etc. ingredients (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health…”

Supporting Resources

Historic weather conditions can be accessed from: https://www.weather.gov/

For an example of data to support an alternative die-off approach: Zhu, M. et al. *Assessment of overhead cooling practices for apple food safety*. Washington Tree Fruit Research Commission. 2016.

Literature that further describes observations related to die-off:

1. Lopez-Velasco, G.,Tomas-Callejas A., Sbodio A.O., Pham, X., Wei, P., Diribsa, D., Suslow, T.V. 2015. Factors affecting cell Population density during enrichment and subsequent molecular detection of *Salmonella enteria* and *Escherichia coli* O157:H7 on lettuce contaminated during field production. *Food Control* 54: 165-175.
2. Gutierrez-Rodriguez, E., Gunderson A., Sbodio, A., Koike, S., Suslow, T.V. 2019. Evaluation of post-contamination survival and persistance of applied attenuated *E. coli* O157:H7 and naturally-contaminating *E. coli* O157:H7 on spinach under field conditions and following postharvest handling. *Food Microbiology* 77: 173-184.
3. Belias A.M., Sbodio A., Truchado P., Weller D., Pinzon J., Skots M., Allende A., Munther D., Suslow T., Wiedmann M., Ivanek R. 2020. Effect of weather on the die-off of Escherichia coli and attenuated Salmonella enterica serovar Typhimurium on preharvest leafy greens following irrigation with contaminated water. *Applied and Environmental Microbiology*. 86:e00899-20. https://doi.org/10.1128/AEM.00899-20.
4. Snellman, E.A., Fatica, M., Ravaliya, K., Assar, S. Review of microbial decay constants reported in field trials of contaminated produce. U.S. Food and Drug Administration Memorandum to the File. Accessed from https://www.regulations.gov/document/FDA-2011-N-0921-18604.

Required Records

Brief 13: Records Requirements (§ 112.50 and 112.161)

Written records are necessary to comply with the revisions to Subpart E and to make management decisions regarding water use and application.

- Like most documentation required by the PSR, these records need to include the farm name and location, the date and time of the activity, and other requirements in Subpart O.
- This portion of the requirements has not changed since publication of the final version in 2015.
- The full text of the requirements is provided in the associated call-out box.

Specific records must be reviewed by a supervisor or responsible party.

- These records must be signed and dated at the time of review.

All required records must be kept for at least two years unless otherwise specified in the PSR. See the following page for a table describing the required records in revised Subpart E.

2015 PSR 21 CFR 112.161

What general requirements apply to records required under this part?

(a) Except as otherwise specified, all records required under this part must:

(1) Include, as applicable:

(i) The name and location of your farm;

(ii) Actual values and observations obtained during monitoring;

(iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;

(iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

(v) The date and time of the activity documented;

(2) Be created at the time an activity is performed or observed;

(3) Be accurate, legible, and indelible; and

(4) Be dated, and signed or initialed by the person who performed the activity documented.

§ 112.161

(b) Records required under §§ 112.7(b), 112.30(b), 112.50(b)(2), (5), (7), and (11), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6) must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

The revision to Subpart E specifies the types of records required. In the following table, each required record is annotated according to farm decisions or practices that may trigger the record requirement. The table also indicates whether the record must be reviewed and signed by a supervisor or responsible party. Note that this table focuses on records required when using agricultural water to grow covered produce other than sprouts. Record requirements for agricultural water used during or after harvest are indicated but not described in detail.

Provision number and record topic	Record description	Required for	Supervisory review and signature
§ 112.50(b)(1) Agricultural Water System Inspection	Must include the findings of the agricultural water system inspection. Inspection records may include individual or community water systems. Assess for changes to the agricultural water delivery systems, accumulation of debris, and suitability for use in the upcoming season. Note repairs or maintenance needed to manage potential risks.	All covered farms that use agricultural water for any covered activity pre-harvest, during harvest, or postharvest.	Not required
§ 112.50(b)(2) Agricultural Water Assessment {Link to Elements of an Agricultural Water Assessment Brief}	Must include descriptions of factors evaluated and written determinations. For some growers, the assessment of the risks associated with agricultural water may remain similar from year-to-year. For others, the risks may vary based upon changes to leased land, activities of neighboring landowners, and rotation of crops. The assessments may be based upon documentation from prior years but must be updated annually before farming activities begin and whenever changes that could influence water quality occur to the water system.	All covered farms that use agricultural water for pre-harvest uses (growing covered produce).	Required
§ 112.50(b)(3) Scientific support for any indicator other than generic *E. coli* as the indicator of water quality {Link to Testing of Agricultural Water Brief}	The information provided should address why the indicator is scientifically valid. Publications and other information may be available from local extension offices, grower advocacy groups, universities, and commodity commissions. **Note:** There is no allowance for alternatives to generic *E. coli* for the no-detect requirement. This applies to sprout operations as well as harvest and postharvest use of covered produce.	Covered farms that opt to use water testing with an indicator other than generic *E. coli* as part of the AgWA.	Not required
§ 112.50(b)(4) Scientific support for any the frequency of testing or microbial criterion {Link to Testing of Agricultural Water Brief}	The information should address why the frequency of testing and/or the microbial criterion is scientifically valid and appropriate for determining the outcome of the AgWA. Referencing publications and websites by reputable universities and agencies is one approach to complying with this requirement. FDA guidance supports the use of the microbial water quality profile system and criteria published in the 2015 final PSR. **Note:** There is no	Covered farms that opt to use testing as part of the AgWA.	Not required

Provision number and record topic	Record description	Required for	Supervisory review and signature
	allowance for alternative frequency or criterion for the no-detect requirement.		
§ 112.50(b)(5) Analytical test results {Link to Testing of Agricultural Water Brief}	Test results should be obtained from the laboratory that analyzed the water sample and kept in the farm records. The grower should be able to interpret and understand the results of the water analysis. If there is confusion, contact the laboratory for support. Most laboratories have staff who will help growers understand analysis results. Local Extension offices may also have staff to assist.	Covered farms that opt to use water testing as part of the AgWA. Also applies to uses of agricultural water during and after harvest.	Required
§ 112.50(b)(6) Certificates of compliance or other documentation from a public water supply {Link to Location and Nature of Each Water Source Brief}	Some growers rely on public water systems that are managed by local, state, or federal agencies. These agencies often publish annual reports describing of maintenance, water analysis, and inspection of their managed systems as required under the U.S. EPA Safe Drinking Water Act. Some of these agencies operate websites where water analysis data is available throughout the season. If growers rely upon a public water system, contact the administrator of the system to understand whether a certificate of compliance that meets the requirements of this regulation is available.	Applies to uses of agricultural water during and after harvest. This record is required.	Not required
§ 112.50(b)(7) Documentation of actions taken to reduce risk of agricultural water	You must include descriptions of specific actions taken to reduce the potential for contamination should agricultural water be determined to represent a risk. Documentation must address the details of any and all corrective measures or mitigation measures taken as a result of the risks identified during the AgWA.	All covered farms that use agricultural water for any covered activity pre-harvest, during harvest, or postharvest.	Required
§ 112.50(b)(8) Related to log die-off or log removal during commercial washing {Link to Allowances for Die-off and Removal Brief}	Documentation should include the die-off rate or log removal rate used, the duration over which the die-off rate was applied, how a target time interval or log reduction was determined, and the dates of relevant activities (e.g., last agricultural application and harvest, start and end of storage, or when commercial washing occurred).	Covered farms that opt to utilize die-off (in-field or during storage) or removal during commercial washing as a mitigation measure.	Not required
§ 112.50(b)(9) Scientific support for an alternative mitigation measure	When using an alternative mitigation measure, it must be supported with scientific data or information.	Covered farms that opt to use a mitigation measure which is not listed in § 112.45(b)(1)(i-v)	Not required
§ 112.50(b)(10) Scientific support for adequacy of treatment methods	Information should support the expectation that, as used, the treatment will adequately meet requirements for water quality. As noted in other sections of this document, the label is the law. A grower should include the label of treatments in their documentation, as well as any publications addressing	Covered farms that opt to treat their agricultural water, including as a mitigation measure or corrective measure.	Not required

Provision number and record topic	Record description	Required for	Supervisory review and signature
{Link to Treatment of Water – The Label is the Law Brief}	the efficacy of the treatment that may be available. The Produce Safety Alliance maintains a list of EPA-labeled treatments, which simplifies the process of finding label information.	Also applies to uses of agricultural water during and after harvest.	
§ 112.50(b)(11) Results of water treatment monitoring {Link to Treatment of Agricultural Water Brief}	Documentation of treatment monitoring should indicate the control parameters, the measurement made, and any corrective action in response to the measurement. Documentation should be clear and include date and time when monitoring is done. The Produce Safety Alliance maintains a series of required records templates, which simplifies recordkeeping.	Covered farms that choose to treat their agricultural water as a mitigation measure or for exemption from the AgWA requirement. Also applies to uses of agricultural water during and after harvest.	Required
§ 112.50(b)(12) Equivalent analytical methods {Link to Testing of Agricultural Water Brief}	The analytical methods should be described, and the grower should be able to understand how to interpret results. FDA prepared a fact sheet (*Equivalent Testing Methodology for Agricultural Water*) in which a suite of equivalent methods is described.	Covered farms that use a laboratory that provides analysis for generic *E. coli* or an alternative indicator by a method other than Method 1603: Modified mTEC. Also applies to uses of agricultural water during and after harvest.	Not required

Understanding Terminology

Common usage of terminology is key to effective understanding and communication. The following sections address key terminology and how the terms relate to concepts described in this document.

Relevant Definitions

The sources of the following definitions are denoted by a superscript number. Of note, many of these terms have regulatory meaning. These terms are used in this way for the purpose of compliance with the PSR and other regulatory requirements.

Adequate[1]: that which is needed to accomplish the intended purpose in keeping with good public health practice. In some instances, FDA provides guidance in the rule about what is considered adequate, but in other cases the onus is on the grower to make this determination.

Adulterated[2]: A food shall be deemed to be adulterated (a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any **poisonous or deleterious substance which may render it injurious to health** … {statement about quantity}; or

(2) … {addresses pesticide chemical residues, food additives, and animal drugs}; or

(3) if it consists of whole or in part of any **filthy, putrid, or decomposed substance, or if it is otherwise unfit for food**; or

(4) if it has been **prepared, packed, or held under insanitary conditions** whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) … {considerations related to diseased animals}; or

(6) … {considerations related to container}; or

(7) … {considerations related to radiation}

Agricultural Water[1]: water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Agricultural Water Assessment[3]: an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to:

(1) Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces; and

(2) Determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food-contact surfaces with such known or reasonably foreseeable hazards.

Agricultural Water System[2]: a source of agricultural water, the water distribution system, 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.

Direct Water Application Method[1]: using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water.

Ground Water[1]: the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.

Hazard[1]: any biological agent that has the potential to cause illness or injury in the absence of its control.

Log die-off or log removal: Although there is no definition of log die-off or log removal in the PSR, FDA describes "logs" of kill as part of Hazard Analysis Critical Control Points (HACCP) guidance[4]. To paraphrase the statement below, 1 log die-off or removal means 0.1x the original (10%) remains. Higher removals of 2 log (0.01x, or 1% remaining), 3-log (0.001x, or 0.1% remaining, and so on to 6-log (0.000001x, or 0.0001% remaining) are easier to describe with this system.

> [4]Food processing experts evaluate treatments intended to kill or inactivate pathogens in food in terms of "logs" of kill, where the term "log" is a shorthand expression of the mathematical term logarithm. A logarithm is the exponent of the power to which a base number must be raised to equal a given number. In thermobacteriology, the base number is usually 10. As an example, the number 100 = 10^2 where the base number is 10 and the exponent is 2. Because the exponent is 2, the number 100 = log 2. Likewise, the number 1000 = 10^3 = log 3. The important thing to understand is that each "log" of kill is capable of causing a tenfold reduction in the number of microorganisms that the treatment is designed to kill, i.e., the most resistant microorganism of public health significance.

For context on log removal, consider the expected log reduction requirement in the State of California[5] for reuse of municipal wastewater for potable purposes. Note that the *E. coli*-based requirement for potable water is no detectable generic *E. coli* in 100 mL (approximately 7 logs lower than untreated wastewater)[6]. In California, wastewater treatment must achieve a 12-log reduction of viruses and 10-log reduction of the protozoan pathogens *Cryptosporidium* and *Giardia* for the water to be considered suitable for use as potable water.

Surface Water[1]: all water opens to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.

Supporting Resources and References

1. U.S. FDA. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. {Produce Safety Rule} Subpart A: General Provisions. 2015. Available at: https://www.ecfr.gov/current/title-21/section-112.3
2. U.S. Code Title 12. Food and Drugs. Chapter 9. Federal Food, Drug, and Cosmetic Act. Subchapter IV. Food. Section 342. Adulterated food. 2011. Available at: https://www.govinfo.gov/content/pkg/USCODE-2011-title21/html/USCODE-2011-title21-chap9-subchapIV-sec342.htm

3. U.S. Food and Drug Administration. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water. { Revision to Subpart E} 2024. Available at: https://www.govinfo.gov/content/pkg/FR-2024-05-06/pdf/2024-09153.pdf
4. U.S. Food and Drug Administration. Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. No date. Available at: https://www.fda.gov/files/food/published/Draft-Guidance-for-Industry--Hazard-Analysis-and-Risk-Based-Preventive-Controls-for-Human-Food---Preventive-Controls-%28Chapter-4%29-Download.pdf
5. Olivieri, A. et al. California water reuse—Past, present and future perspectives. Advances in Chemical Pollution, Environmental Management and Protection. 2020; 5: 65–111. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7482601/
6. Raboni, M. et al. Assessment of the Fate of *Escherichia coli* in Different Stages of Wastewater Treatment Plants. Water Air and Soil Pollution 2016. 227(12) Available at https://link.springer.com/article/10.1007/s11270-016-3157-8

Acronym Guide

AgWA – agricultural water assessment
CFU – colony forming unit
CAFO – concentrated animal feeding operation
EPA – United States Environmental Protection Agency
FDA – United States Food & Drug Administration
FSMA – Food Safety Modernization Act
HACCP – Hazard Analysis Critical Control Point
MPN – most probable number
PPP – plant protection products
PSR – Produce Safety Rule
PCHF – Preventive Controls Rule for Human Food

Microbiological Hazards

The PSR focuses on managing microbiological (versus chemical or physical) hazards. Growers are not expected to be microbiologists but should recognize that not all microorganisms are equal. The table below provides an overview of key microorganisms associated with agricultural water, reservoir/source, and impact of physical and chemical treatments. **Note:** Although they may be present in the growing environment, pathogens, such as *Listeria monocytogenes,* are more likely to impact harvest equipment, packing, and processing facilities where they can establish niche opportunities for growth so have been omitted from this table. A grower's hazard identification should help identify which pathogens are of relevance for their operation and activities. The table is for informational purposes only and is not necessarily relevant to all growers. Some pathogens in the table below may not be relevant to each farm environment. There may be pathogens not included on the list that the assessment will identify.

Organism Name	Type	Reservoir/Source	Physical Treatment	Chemical Treatment	Notes
STEC (shiga toxin producing *E. coli*) including O157:H7	Vegetative bacteria	Ruminants like cattle are natural hosts (e.g., feces) but can be found in other animals	UV: susceptible Filtration: only effective at pore sizes too small to be practical for natural waters, due to clogging	Susceptible to a variety of chemicals (e.g., chlorine, peroxyacetic acid) depending on parameters of use	Can persist (even if not growing) for long durations in the environment (particularly in soil and sediment)
***Salmonella* spp.**	Vegetative bacteria	Poultry/avian (e.g., pellets, feathers) and reptiles but can be found elsewhere	UV: susceptible Filtration: only effective at pore sizes too small to be practical for natural waters, due to clogging	Susceptible to variety of chemicals (e.g., chlorine, PAA depending on parameters of use)	Resistant to desiccation (drying) More tolerant of acid (low pH) than most bacteria
Cyclospora cayetanensis ***Giardia lamblia*** ***Cryptosporidium parvum***	Parasite	Cc: Human (feces) Gl: mammals (cattle, sheep, goats) Cp: humans, cattle/calves	As larger microbes, filtration may be effective based on CPS research	Early research shows limited effect of antimicrobials and varies based on parasite	Does not grow on produce (requires a host).
Hepatitis A **Norovirus**	Virus	Human (feces)	Due to small size (<50 nm diameter), filtration is unlikely to be effective		Do not grow on produce (requires a human host).