INDUSTRY GUIDANCE:

Pre-Harvest Agricultural Water

Prepared by:
IFPA Food Safety Council
Agricultural Water Working Group

INTERNATIONAL FRESH PRODUCE ASSOCIATION℠

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Photo credit:
Bob Nolan, Deer Run Farms

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Introduction

The International Fresh Produce Association (IFPA) convened a small group of volunteers from members of the 140+ IFPA Food Safety Council. Volunteers were tasked with preparation of guidance materials targeted to audiences seeking to comply with the United States of America's Food and Drug Administration (FDA) Produce Safety Rule (PSR) requirements for agricultural water, promulgated as part of the Food Safety Modernization Act (FSMA). While the sections of the rule relating to pre-harvest agricultural water (Subpart E) were under revision by the FDA during the preparation of this guidance document, the resulting briefs and other communications rely on scientific evidence that are applicable to many different cropping systems, recognizing that the rule applies to virtually all produce that is likely to be consumed raw, regardless of where or how it was grown. The goal was to address the most common points of confusion and to provide additional resources for the produce industry. As a living document, additions and revisions will continuously occur to improve upon the support materials offered herein. Most importantly, the final provisions within Subpart E of the PSR for pre-harvest agricultural water have not been finalized, so this document is subject to updates pending final regulation release.

How to Use this Document

This document was prepared as a series of short topic-specific scenarios and briefs for ease of use and distribution. Not all topics that are included in the proposed revisions to PSR requirements for pre-harvest agricultural water are addressed in this document. Topics that have historically generated more questions from stakeholders were selected for focused guidance and case studies. It is recommended that you navigate this document using the Table of Contents and cross-links to sections within the document.

In addition to briefs, a series of four scenarios was developed by the working group and presented according to general order of complexity. Each scenario was evaluated in the context of the proposed revisions to Subpart E, in order to portray how the briefs can be used as an aid for covered farms as they prepare to meet requirements associated with the proposed agricultural water assessment. IFPA and the Agricultural Water Working Group recognize that some commodities benefit from existing industry-specific guidance regarding the management of agricultural water. The IFPA-created guidance in this document is intended to complement, and not replace, existing commodity-specific resources.

Briefs

As part of the proposed rule for pre-harvest water, an agricultural water assessment (AgWA) is required for water that is used to grow produce covered by the PSR. The AgWA is to be conducted at least annually to identify potential conditions which may increase the likelihood of human pathogens being in pre-harvest water. The proposed agricultural water assessment components are individually described in a series of briefs within this document. For any given scenario, a few or many of the briefs may be relevant. Each is intended to contain useful information in stand-alone form, so that they can be used 'a la carte' to build a unique agricultural water assessment for the unique risk landscape present at each covered farm.

The briefs are broken down into two sections:

- Those related to developing a risk profile for the water source, in context of how the water is intended to be used and,
- Those related to determining actions that may be useful to mitigate risk.

To support the briefs, the work group has developed a series of four scenarios (Pre-Harvest Agricultural Water Scenarios) which were used to demonstrate how these briefs could be used by a covered farm to build their agricultural water assessment if the final requirements are similar to the proposed revision. The proposed agricultural water assessment also includes recordkeeping requirements, discussed separately (Required Records).

Scenarios

The scenarios in this document were developed to represent a range of farming practices and a continuum of complexity that may be encountered when evaluating the likelihood of hazard introduction and resulting risk to consumers, as relates to pre-harvest agricultural water and produce covered by the PSR. Each scenario describes the source of the water, potential sources and pathways of pathogen contamination of the water, and how the water is used with covered produce during growing activities (i.e., the pre-harvest water use period). Many scenarios also describe information such as microbiological test results that aid in understanding of, or developing expectations of, overall water quality.

Each scenario is followed by an "unpacking" exercise, in which the proposed requirements related to developing an agricultural water assessment are applied to the information from the scenario. The information briefs, related to specific components of the proposed requirements, are cited in these exercises to demonstrate how the briefs can be applied by a farm when doing an agricultural water assessment (as currently proposed). In each scenario described, the farm is covered by the PSR, and not eligible for the exemptions that are 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).

Disclaimer

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Background Information: Hazard and Risk

Throughout this guidance, several terms are used. Fundamental to successfully managing a pre-harvest agricultural water system, and food safety overall, is understanding the concepts of **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 (FDA Preventive Controls for Human Foods Rule).
  - The Produce Safety Rule focuses on biological hazards only (although produce must always be safe for consumption, and most GAP audits include chemical and physical hazards).
  - Examples of biological hazards include the pathogenic microorganisms listed. (Microbiological Hazards)
- **Risk** is the **probability** of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. To break down the 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?
    - How much of the organism (dose) does it take to make someone sick?
  - **Probability** (i.e., likelihood, or frequency of occurrence) can be assessed by asking some questions:
    - Has this hazard been found before? How often? Under what conditions? At what levels?
    - Have other growers, under similar conditions, found that the hazard is likely present in their agricultural water?
    - Does the testing data show the presence of the hazard?
    - Are there certain conditions (e.g., rain, season) that might increase the chance that the hazard would enter the water system?

Probability can be impacted through the implementation of controls. Some of the controls are outside the control of the grower (e.g., not having rain, slope of land). Other controls are within a grower's control and may be implemented as a result of the evaluation discussed below. For example:

- Are there measures in place that would reduce the likelihood of contamination occurring (e.g., distance, slope, physical barriers such as 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 the 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** are two terms used to express how someone combines the elements of probability and severity of a hazard in order to determine how to manage risk. Some people assign numbers or scores to probability and severity. Some add them together, others multiply them. The math is less important than recognizing that risk is a continuum. Some things 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 agricultural water assessments will document the factors that increase or decrease risk, and responsible growers will be alert to changes in conditions that impact risk. It is possible to identify a hazard and conclude that it is not reasonably likely to cause illness. This should be evaluated based on the probability aspect of risk. When risk increases, growers should consider the tools available to decrease risk, generally through decreasing one of the following:

- Decrease the probability that water will become contaminated,
- Reduce levels of contamination in water if it is contaminated (e.g., water treatment),
- Decrease the probability that 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 has been reproduced from a July 2021 United Fresh Produce Association (now IFPA) article available online 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 that the organisms of concern may be "known and reasonably foreseeable hazards." This is a term that does appear in the Produce Safety Rule but is likely more familiar to those with a background in HACCP (Hazard Analysis Critical Control Point) and individuals who have conducted hazard analyses in accordance with the Preventive Controls Rule for Human Foods (PCHF).

What is a "reasonably foreseeable hazard" in the context of a growing environment? And what is the implication to others in the supply chain? A subgroup of the United Fresh food safety council was able to have a conversation with FDA on this topic, and the synopsis below reflects interpretation of the discussion.

- The term signals 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 that the detection "**may** constitute a known or reasonably foreseeable hazard". In the *E. coli* report, FDA states that the strain "**appears to be**" a known or reasonably foreseeable hazard. This means that the designation is not absolute, and the assessment should be done on a case by case, ranch by ranch 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 farms 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 purchasing produce from growers where this term has been used should consider how of this may impact their hazard analysis. Consider this proclamation a trigger to reevaluate the food safety plan, especially when it comes to supply chain controls.

It is clear that no matter what role individuals hold within the produce supply chain, the term "reasonably foreseeable hazard" is likely to stay and indicates repeated concerns of FDA relative to the produce industry. FDA is increasingly publishing outbreak investigation reports, and there is an expectation that this term could be used to continue to encourage heightened attention to hazards so that their risk can be evaluated and managed.

A Systems Approach to Pre-Harvest Water Risk Management

Because there is no kill step for fresh produce, food safety must be managed throughout the production process and the supply chain. Given the variables associated with agricultural production: the degree of mechanization, water sources, water treatments, growing styles, harvesting approaches, etc., a food safety professional working in the produce industry should carefully assess risks associated with each step. It is only after this analysis has been conducted that the operation can identify the most logical risk 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 very 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.

Fundamental to this assessment is a clear understanding of the difference between hazards and risks. Hazards are agents that have the potential to cause harm (e.g., bacterial pathogens, pesticides, heavy metals, glass). Risk is the likelihood that they actually 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. They should then evaluate the likelihood of each hazard to occur in their specific production system. The prioritization of risks should guide the selection and implementation of mitigation steps. 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. This is especially true of managing pre-harvest agricultural water safety since the body of knowledge and science is continually evolving to inform best practices.

Figure 1: A systems-based approach to food safety risk management may involve 'stacking' multiple interventions appropriate to the hazards identified and likelihood and severity that they will occur. The figure below highlights how different combinations of mitigations can be used to achieve an acceptable level of risk with pre-harvest agricultural water. No pre-harvest agricultural water system will present the same 'stack' of priorities to meet the end goal.

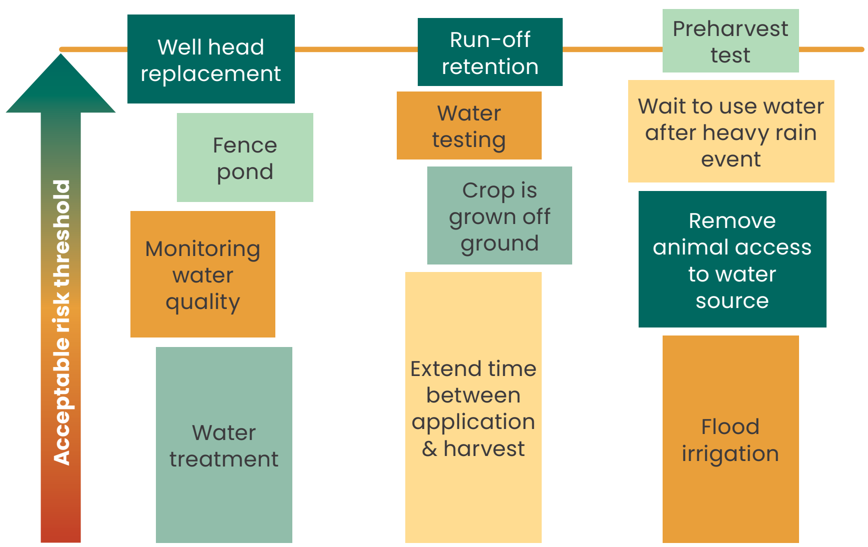


Figure adapted from Dr. Channah Rock, University of Arizona

Comparison: Agricultural Water System Inspection and Proposed Agricultural Water Assessment

In the 2015 PSR, FDA established the requirement to perform an agricultural water system inspection (§ 112.42) on all agricultural water systems, which includes water used for pre-harvest activities (e.g., irrigation, pesticide application) and harvest/postharvest activities (e.g., washing, cooling). There are several key definitions for this section: agricultural water, agricultural water system, and agricultural water assessment. (Relevant Definitions)

The ***agricultural water system inspection*** in 2015 PSR § 112.42 must include the entire water system, to the extent that is under the grower's control. These water system components include the source of agricultural water, the water distribution system, any building or structure 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 is required to be conducted at the beginning of a growing season, at least annually, but more often as appropriate. The end goal is for the agricultural water system to be maintained to reduce the potential for pathogens in the water.

The ***agricultural water assessment*** proposed in § 112.43 is intended to supplement the requirements of the agricultural water system inspection currently required in § 112.42 of the PSR. In contrast to the agricultural water system inspection, the proposed agricultural water assessment focuses on pre-harvest water, which is water that meets the definition of agricultural water and is used during growing activities for covered produce (other than sprouts). The proposed agricultural water assessment would require covered farms to conduct a more comprehensive assessment of possible sources and routes of contamination, including those outside of a farm's control. Details of the individual components within the proposed agricultural water assessment can be found throughout this document.

Understanding Compliance Dates

The best source of current information about compliance dates regarding FSMA is to go directly to the FDA's website. It is important to note that some of the compliance dates have already passed, meaning that farms covered under the PSR must already be in compliance for the vast majority of requirements.

Some PSR requirements related to agricultural water elements are undergoing revision and the FDA is exercising enforcement discretion for those requirements. Additionally, the FDA has modified their current thinking about certain topics, including about the status of specific crops as covered produce. To better understand what enforcement discretion means, please visit the FDA website.

Note that starting January 26, 2023, the FDA ended enforcement discretion for the postharvest requirements of Subpart E for businesses that do not quality as small or very small. This means that compliance with Subpart E is required for postharvest and harvest water applications starting 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 compliance dates for pre-harvest agricultural water have not been finalized as of the original publish date of this guidance.

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; growing fields are formed into beds covered with black plastic mulch, separated by furrows. On this farm, cucumber vines are not trellised, whereas trellising is used for tomato production.

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.
- ***Potential sources of contamination:*** Animal activity (prints, feces, crop damage, and other indications) sometimes is observed in the growing area. Animals that may access 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 that they have been in compliance with total coliform-based testing requirements and standards in the U.S. EPA Safe Drinking Water Act (SDWA).

Unpacking the Vegetable Farm Scenario: *Is an Agricultural Water Assessment Needed?*

An agricultural water assessment probably would not be required in this scenario if the revisions to agricultural water requirements are adopted as proposed.

- ***Irrigation water:*** Irrigation of the 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 agricultural water assessment is not required for water that is not defined by FDA as agricultural water.

- ***Foliar spray water:*** Water is used to mix PPP and applied to the crops before harvest. This use likely constitutes agricultural water. Foliar spray water comes from a public water system that meets the requirements of the SDWA and is, therefore, exempt from the agricultural water assessment requirement.
  - **Note:** Proposed § 112.43(b)(2) provides an exemption from the need to perform an agricultural water assessment 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 proposed agricultural water assessment requirement. The proposed requirement applies only to pre-harvest water (see proposed § 112.43).
- ***Other relevant requirements:***
  - As described in 2015 PSR § 112.42(d) as well as in proposed § 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 flooding1. In this guidance, exposure of the edible portion of the crop to natural flood water is considered an adulteration event. The FDA guidance 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 (proposed § 112.43(b)(2)), a certificate of compliance from the public water system or other documentation would be beneficial. This documentation is not specifically required under proposed § 112.50(b)(6) as currently written.

Proposed § 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 you can demonstrate that the water:

(1) … {relates to no detectable *E. coli* standard}

(2) Meets the requirements in § 112.44(c) for water from a Public Water System or public water supply …

Proposed § 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 and 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.

Scenario 2: Blackberry Farm Using Spring Water and River Water

A blackberry farm produces at two orchards that are 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.
  - Water is piped for the first 5 miles from the spring to the berry 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 and 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 in 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 plant protection products (PPP) for foliar application (Note: this practice may not be appropriate; see the "unpacking" section below).
- ***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, which 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 (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 that are 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.
- ***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: *Is an Agricultural Water Assessment Needed?*

An agricultural water assessment likely would not be required in the blackberry farm scenario if the revisions to agricultural water requirements are adopted as proposed.

- ***Irrigation water:***
  - For both Farm 1 and Farm 2, the combination of production practices and method of application means that the use likely does not meet the definition of agricultural water (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 against adulteration still apply, the requirements of the PSR likely do not apply to this use of the water.
    - If the drip tape leaks, resulting in contact with berries, became a chronic rather than occasional issue, the farm should consider whether the water use does meet the definition of agricultural water. If the use of the water meets the definition of agricultural water, an agricultural water assessment would be required in this scenario.
- ***Foliar spray water:***
  - For both Farm 1 and Farm 2, foliar spray water 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 proposed § 112.46 (Brief 10: Treatment of Agricultural Water) because treated water is exempt from the agricultural water assessment requirement of proposed § 112.43 (see exemption in proposed § 112.43(b)(3)).
  - In particular, pay attention to whether the label for any PPP that is a controlled chemical allows mixing with the water treatment chemical (Brief 11: Treatment of Water – The Label is the Law).

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 …"

- ***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, and higher measurements have been recorded.
  - 100,000 MPN/100 mL is high in relation to U.S. EPA recreational water standards.
    - U.S. 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)

Furthermore, the river catchment area has animal activity, dead animals, and trash especially at high flow conditions when the *E. coli* concentrations are higher. The farm should consider whether any product that comes into contact with this water is adulterated as described in the FD&C Act (Relevant Definitions).

This consideration is important regardless of whether the contact is direct (e.g., foliar application) or incidental (e.g., spraying from a damaged drip line, or secondary contact through tools or clothing that came into contact with the water). The farm should pay attention to areas where river water may be at the surface anywhere on the property, or other ways the river water may be transferred (e.g., with machinery or boots) and be a potential source of pathogens to the crop or food-contact surfaces.

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 requirements.

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 PSR § 112.11 and not allow adulterated food into commerce under the FD&C Act.

Supporting Resources and References

(1) U.S. Food and Drug Administration. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water. {Proposed Revision to Subpart E} 2021. Available at: https://www.govinfo.gov/content/pkg/FR-2021-12-06/pdf/2021-26127.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 inched 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. Harvested product moves along conveyors to the packinghouse, which is chilled. Product remains in bins until 6 a.m. when the packing crew arrives.

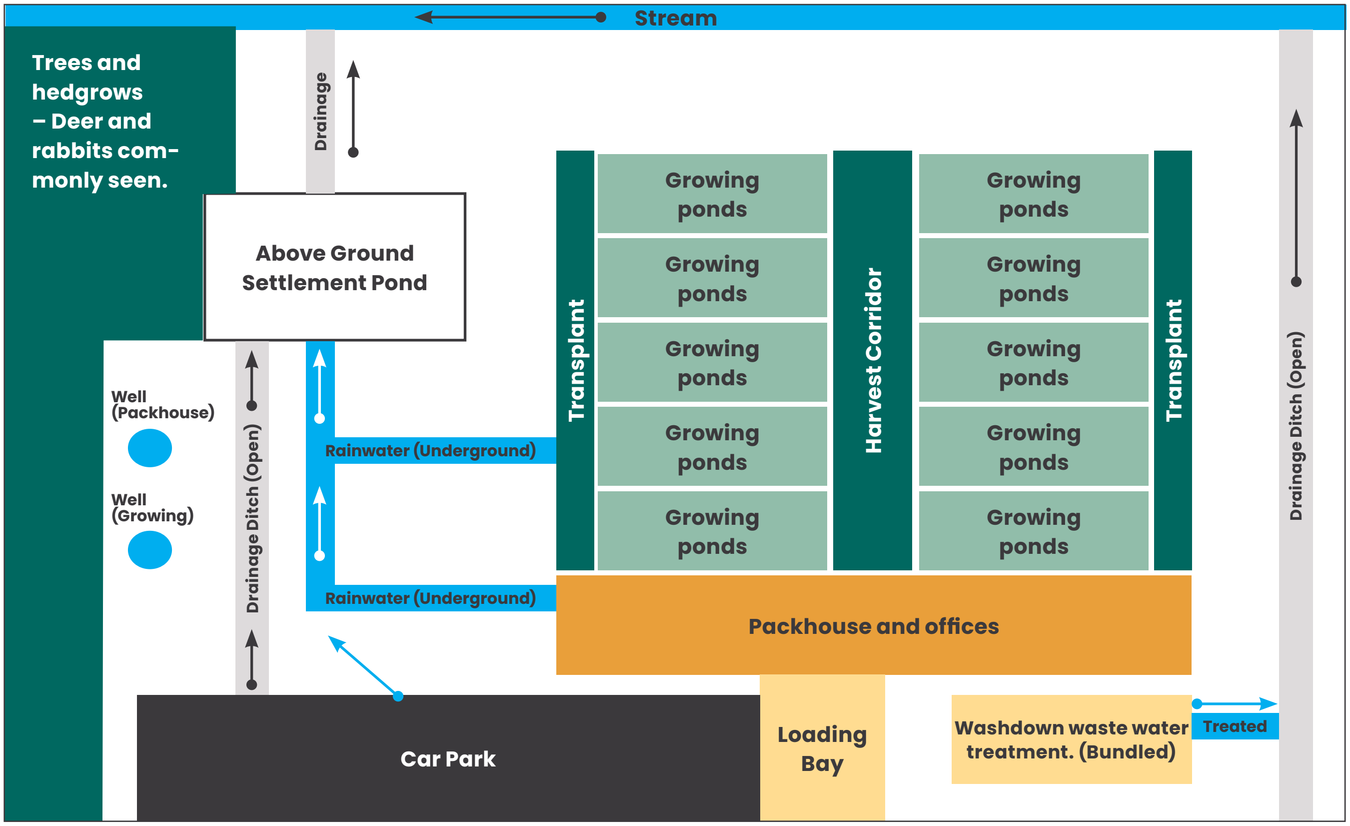
- ***Water source:***
  Water for this operation comes from two wells.
  - Each well is approximately 100 feet from the green-house.
  - Well 1 is used to supply the indoor float ponds used for growing and is slightly elevated. Well 1 is about 200 feet deep, with a 1-foot concrete pad over the grouted 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 is lower and situated about 50 feet from a vehicle parking lot. Well 2 is otherwise 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 of 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.
- ***Potential sources of contamination:***
  - Rainwater run-off 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.
  - Vehicles in the parking lot may be a source of chemical hazards.

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 purpose." (see 2015 PSR § 112.43(a)(1)). In-line sieves and filters that are used to achieve coarse filtration and remove particulates may also remove a limited amount of pathogens. However, generally they are not effective to achieve the intent of § 112.43(a)(1).

- ***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 always no detect (<1 CFU/ 100 mL). Total coliform results tend to be less than 100 CFU/100 mL but concentrations have historically been higher, especially when sampled immediately after rain.

Diagram of the Hydroponic Operation



Unpacking the Hydroponic Operation Scenario:

Is an Agricultural Water Assessment Needed?

- ***Irrigation water*:**
  – The water in the indoor float tanks is used for irrigation, has nutrients added, and does not touch the harvestable crop which is located above the raft. Water splash is unlikely to occur since workers have been trained to manage the removal of rafts to minimize this occurrence.
- ***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 has no nutrients added. It 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 of water from roots or the raft with the harvested crop or food-contact surfaces (e.g., the conveyor belt).

In summary, an agricultural water assessment probably would be required in this scenario if the revisions to agricultural water requirements are adopted as proposed. In particular, the water used to mist product is in direct contact with the baby leaf lettuce and is untreated. The other uses of water likely would not be considered agricultural water.

Even if the irrigation water contacts the harvested leaves or the conveyor belt, water used during or after harvest is not subject to an agricultural water assessment. Any concern about pathogens contacting harvested crop would be addressed by other parts of the 2015 Produce Safety Rule; e.g., § 112.41 and portions of § 112.44 (a), § 112.45(a), and § 112.46 that are related to harvest and postharvest uses of agricultural water.

What Would Be in the Agricultural Water Assessment?

If an agricultural water assessment were required, such for the agricultural water used to mist crop during production, the written assessment might include some components relevant to this scenario such as:

- ***Nature of the water source and degree of protection:***
  - Does the increase in total coliform concentration after rain indicate that surface water infiltrates the well or the reservoir? (Brief 2: Location and Nature of Each Water Source)
  - If water runs from the surface into the borehole (e.g., compromised well pad or grouting), are animals excluded from the area around the well head and is run-off water diverted away from the well pad? (Brief 4: Degree of Protection of Each Agricultural Water System)
- ***Agricultural water practices:***
  - What is the timing of last application (via spray) compared to harvest?
  - Does the crop contact agricultural water in any other way (e.g., do leaves hang over the raft into the water)? (Brief 6: Crop Characteristics)
- ***Crop characteristics:***
  - Are the leafy greens damaged in any way such that pathogens (if in the mist water) could be internalized? (Brief 6: Crop Characteristics)
- ***Environmental conditions:***
  - Is the environment in the growing area consistent with conditions where pathogens tend to die-off over time? Warm temperatures, humidity, lack of UV, and nutrient-rich leaf exudates might reduce potential for die-off. (In-field Die-off for a Minimum of 4 Days)
  - Were the samples tested, that generated the test results of no detectable generic *E. coli* in 100 mL water, representative of the water being used to mist plants? (Brief 8: Other Relevant Factors)

Outcome: The outcome of the agricultural water assessment 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 (proposed § 112.43(c)). In this Hydroponic Operation Using Well Water scenario, a likely determination based on the agricultural water assessment would be that the potential for contamination is low. However, the operation might decide that mitigation is warranted as a precautionary measure, in keeping with best practices.

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

- Though at least four days between last application of agricultural water (misting) and harvest provides time for pathogen die-off (as currently proposed), consider whether conditions are appropriate to use this an appropriate mitigation measure for this scenario. (Brief 12: Allowances for Die-off and Removal in Field and During Storage)
- Using a UV treatment unit or other treatment that is validated to control pathogens helps minimize the chances that pathogens are in the water used for misting. (Brief 10: Treatment of Agricultural Water)

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

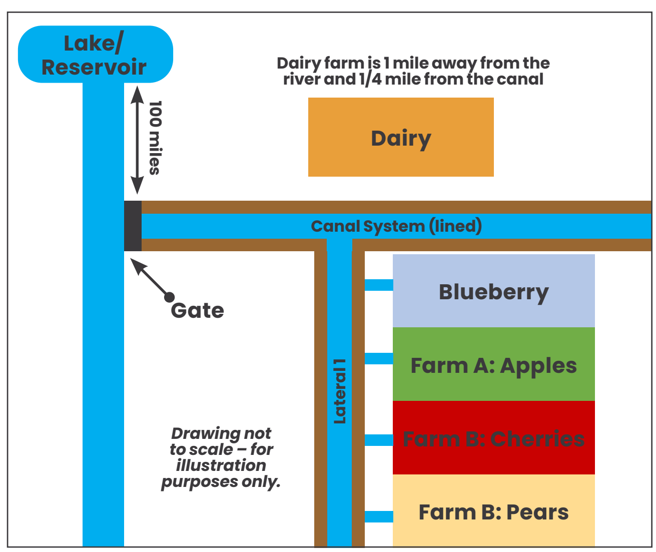
- ***Water source:*** The common water source for all three orchards is a lake/reservoir in a mountainous region about 100 miles from the irrigation district.
  - Water is carried from the reservoir to the orchards by a natural river channel, initially.
  - River water is diverted to a main (lined) canal.
  - 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, 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 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.
  - A blueberry growing operation, immediately upstream from **Grower A**.
    - The blueberry grower's practices include 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 NOP requirements.
    - The blueberry grower has not been through a PSR inspection; however, the blueberry farm is certified annual by a 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 (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 occurs 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 of the 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 about 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.

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

Scenario 4 –
Map of scenario for illustrative purposes



area is further characterized by relative humidity at approximately 50 percent, and a UV index1 of approximately 5 during the late growing season and harvest period for cherries. Temperatures average a high of 74 degrees and a low of 46 degrees (°F).

- ***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 light rainfall (cumulative 0.2 inches precipitation) during the month of August.
    - The area around 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 percent, and a UV index1 of approximately 5 during the late growing season and harvest period for apples and pears.
    - Temperatures average a high of 89 degrees and a low of 57 degrees (°F).

Unpacking the Tree Fruit Farm Scenario: *Is an Agricultural Water Assessment Needed?*

For each grower, an agricultural water assessment would be needed in this scenario if the revisions to agricultural water requirements are adopted as proposed.

- 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 crop and meets the definition of agricultural water.
- The water used for all applications is untreated surface water. No exemptions to the proposed agricultural water assessment requirement apply.

What Would Be in the Agricultural Water Assessment, if Needed?

In this scenario the agricultural water assessment 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 likely will also include **consistent components** relevant to this scenario such as:

- *Nature of the water source and degree of protection*: (Brief 4: Degree of Protection of Each Agricultural Water System)

The importance of known factors:

If a condition that might allow pathogens to be introduced to the water source **<u>is due</u>** to animal activity, BSAAOs, or human waste then a mitigation measure must be implemented **promptly**. Proposed 112.43(c)(2) describes promptly as ‘no later than the same growing season …”

If a condition **<u>is not due</u>** to animal activity, BSAAOs, or human waste then either:

- Mitigation measures must be implemented **as soon as practicable** or
- “Test the water … and take appropriate action”

Proposed 112.43(c)(4)(i) describes the term **as soon as practicable** to be limited to ‘no later than 1 year after …”

– 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'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 after run-off might be a concern, for example, adjacent to the blueberry fields after application of BSAAO.
– Three 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,
  › Recreational water users, and
  › The BSAAO used by the blueberry grower.
– One factor is not directly related to known animal activity, human waste, or BSAAOs. Each assessment should include potential introduction of human pathogens by wildlife feces to the waterway. This access is not known to occur in the scenario but is likely to occur somewhere prior to use at the orchards.

• *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*:
  – None of the crops has historically been associated with an outbreak where preharvest water was implicated as a factor.
  – Each crop grows above ground in a tree, meaning there is lower 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].

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 about 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].

- *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 agricultural water assessment for each grower might include results of testing for generic *E. coli*. Since each grower does their own testing, their results could lead to different determinations.

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.
- *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 that human pathogens, if on the crop, are more likely to die or be physically removed.

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 standalone 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.

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.

- *Crop characteristics*:
  - Apples and pears (but not cherries) are commonly stored in unmodified atmosphere for long durations (months); some are stored under controlled atmosphere conditions to further 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 since 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.

Outcome: The outcome of the agricultural water assessment 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 (proposed § 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 to the proposed revisions, FDA suggests that the U.S. EPA recreational water criterion of 126 CFU/100 mL (geometric mean) may be a meaningful benchmark for agricultural water 11.
- In the proposed requirements, monitoring data are called out as valuable information when a potential source of human pathogens in water is not because of known animal activity, BSAAO, or human waste (proposed § 112.43(a)(5)).
- **Note:** Utilizing 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 the assessment by Grower A likely would likely lead to a determination that measures to mitigate the potential for pathogens on the apples due to water use **are not necessary.**

- 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:
  (1) Knowledge that BSAAO used by the blueberry farmer are treated and,
  (2) The permitting system (with monitoring) for the dairy support a determination that potential for pathogen introduction from those operations is low.
- Test results for generic *E. coli* are relatively low (less than 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. This type of condition falls into the category of those that are not known to be related to animal activity, BSAAO use, or human waste.
- Grower A could also draw on research indicating that typical wash conditions for the apples result in nearly 1-log additional removal of generic *E. coli*, and findings that storage can further reduce the level of generic *E. coli* 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 talked with the blueberry grower, so Grower B does not know that the BSAAO applied by the blueberry grower is treated. Depending on local conditions, Grower A may have a concern that practices at the blueberry operation may result in pathogen introduction to 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.

Considering these factors, **Grower B** may determine that no mitigation measures are needed during years when water does not come into contact with produce within four days of harvest. If Grower B must use irrigation water to apply sprays within four days of harvest, they may decide to test their water close to harvest to ensure that water quality has not changed. Alternatively, the grower may wish to use water from another source that is either potable-quality or where a water quality assessment has been conducted that identifies no conditions in need of mitigation.

Systems approach:

Traditional audit schemes tend to utilize check lists and evaluate each consideration independently.

The PSR, including the proposed 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.

Grower C: Pear Orchard Outcome:

Various factors likely would lead to a determination 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 water 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. (Brief 5: Agricultural Water Practices)
- Use an alternative water source (e.g., untreated ground water with water test results, or municipal water) to mix PPP applied as foliar sprays. (Brief 5: Agricultural Water Practices)
- 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. (Brief 12: Allowances for Die-off and Removal in Field and During Storage)
  - In-field die-off between water application and harvest under ambient environmental conditions.
  - 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.

Supporting Resources and References

(1) UV index scale: U.S. EPA https://www.epa.gov/sunsafety/uv-index-scale-0

(2) World Health Organization and United Nations Environmental Programs. WHO Guidelines for the Safe Use of Wastewater, Excreta, and Greywater, Vol II: Wastewater Use in Agriculture. Page 78. Geneva, Switzerland, 2006.

(3) Presser, K.A. et al. Modelling the Growth Limits (Growth/No Growth Interface) of Escherichia coli as a Function of Temperature, pH, Lactic Acid Concentration, and Water Activity. Applied and Environmental Microbiology 64(5): 1773-1779. 1998

(4) Koutsoumanis, K. et al. Modeling the Boundaries of Growth of Salmonella Typhimurium in Broth as a Function of Temperature, Water Activity, and pH. Journal of Food Protection 67(1):53-59. 2004.

(5) U.S. Food and Drug Administration. Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry (draft). 2017.

(6) Clemson University. pH Values of Common Foods and Ingredients. Undated tabulation.

(7) Rodrigues, C. et al. Factors Impacting the Prevalence of Foodborne Pathogens in Agricultural Water Sources in the Southeastern United States. Water 12(1), 51. 2020.

(8) Rezaie, A. et al. Ultraviolet A light effectively reduces bacteria and viruses including coronavirus. PLOS One. 16 July 2020

(9) Zhu, M. et al. Assessment of overhead cooling practices for apple food safety. Washington Tree Fruit Research Commission. 2016.

(10) Brandl, M.T. et al. Weather stressors correlate with Escherichia coli and Salmonella enterica persister formation rates in the phyllosphere: a mathematical modeling study. ISME Communications 2:91. 2022

(11) U.S. Food and Drug Administration. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water (Proposed Revision to Subpart E). Federal Register 86(231): 69120. See Page 69142. 2021

(12) Killinger, K. et al. Assessment of Apple Packing for Listeria Risk. Washington Tree Fruit Research Commission. 2015.

Pre-Harvest Agricultural Water Briefs

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

Brief description:

Following the annual inspection and routine monitoring and maintenance of the agricultural water system (as required in proposed § 112.42), growers must conduct and document an agricultural water assessment (at least once annually) for water applied using a direct application method to covered produce during pre-harvest (in other words, when the water is used as agricultural water in the growing area).

How does this requirement reduce risk?

The agricultural water assessment includes a description of the agricultural water system. Several factors that affect vulnerability to introduction of hazards include:

(1) Whether the water source is groundwater or surface water,

(2) Whether the water distribution system is an open or closed conveyance; and

(3) Other characteristics of the system such as

  a. Condition of storage areas used for irrigation equipment.

  b. Location of water and equipment relative to human waste 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 can be used to accompany the written part of the assessment. Maps might include permanent fixtures such as gates, reservoirs, returns, and other permanent above-ground components of the irrigation system.

Proposed § 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 …"

Once the system is described, evaluate components to better understand whether the quality of agricultural water is adequate for the intended use. Some factors to consider are summarized here and also the subject of more extensive briefs in this document:

- Comparison against microbial criteria established for the use. (Brief 9: Testing of Agricultural Water)
- Context of adjacent and upstream land uses that may impact agricultural water quality and safety. If possible, measures should be taken to protect the water source from potential for hazards introduction by adjacent land uses. (Brief 4: Degree of Protection of Each Agricultural Water System)

While developing the agricultural water assessment, potential for hazard introduction can be affected by the following factors:

- Water Source: Is the agricultural water from public or municipal sources, wells, untreated surface water, treated water, or recycled water? (Brief 2: Location and Nature of Each Water Source)
- Distribution system: Is the agricultural water from closed (e.g., pipes) or open delivery systems (e.g., canals)? (Brief 3: Type of Water Distribution System)
- Protections and conditions observed: Is water testing or treatment conducted? What has been observed and recorded during pre-season and pre-harvest assessments? Is there any animal intrusion or adjacent land activities of concern? Were there any weather events that caused damage to edible parts of the crop? (Brief 4: Degree of Protection of Each Agricultural Water System)
- 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). (Brief 6: Crop Characteristics)

In addition, risk from hazards that have been introduced to the water despite all efforts to avoid 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? (Brief 12: Allowances for Die-off and Removal in Field and During Storage)
  - Is the water treated prior to use? (Brief 5: Agricultural Water Practices)
  - Is the water used without direct contact such as ground chemigation, drip irrigation, furrow irrigation, dust abatement, cleaning non-food contact farm equipment? (Brief 5: Agricultural Water Practices)
  - Water that is not used in direct contact with covered produce or food contact surfaces is not agricultural water (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 instance, one day before a scheduled irrigation event and close to harvest, a grower might observe animal movement at an adjacent Concentrated Animal Feeding Operation and strong winds that blow the dust in the direction of the water source and unharvested fields. In this case, they may wish to consider mitigation measures such as testing and/or treating the water, adjusting the scheduled harvest day, or testing the unharvested crops.

Photo credit: Trevor Suslow, Trevor Suslow Consulting, LLC

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

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 proposed § 112.43(a)(1).

How does this requirement reduce risk?

The type (nature) of the source water 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 with collecting valuable information about each type of water source.

Public water supplies, especially those regulated under the U.S. EPA Clean 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 run-off (e.g., from animal operations) into the well during flooding or by way of potential subsurface flow.

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 water body. Assess the likelihood that water could be contaminated from origin to point of entry to the farm water distribution system, considering observations such as:

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

Proposed § 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 ….

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 might 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.

***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 intrusion (e.g., land slope prevents pooling)
  - Human and animal activity in the vicinity of the well is minimized
- Understanding whether wells drawing from the same aquifer may affect aquifer water quality
  - Human and animal activity in the recharge area, especially around 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 strong precipitation on the quality of the water during production, especially close to 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, to name a few.

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 (Brief 4: Degree of Protection of Each Agricultural Water System). For example, if the well were 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 were 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 Resources and 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 support understanding of 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 support understanding of surface water contamination pathways.

- Leaman SM, Salas S, Mandrell RE, Suslow TV, Jay-Russell MT, Davis DA. 2022. Environmental risk factors in the human pathogen transmission pathways between animal operations and produce crops. Food Protection Trends. 42(5):362-376.
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- 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.
- Taylor EV, Nguyen TA, Machesky KD, Koch E, Sotir MJ, Bohm SR, Folster JP, Bokanyi R, Kupper A, Bidol SA, Emanuel A, Arends KD, Johnson SA, Dunn J, Stroika S, Patel MK, 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.
- Navarro-Gonzalez N, Wright S, Aminabadi P, Gwinn A, Suslow TV, Jay-Russell MT.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.

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

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, run-off, 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 contaminating reverse-flow.

Proposed § 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…

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. (Brief 4: Degree of Protection of Each Agricultural Water System)

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, run-off 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 run-off.

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 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 wall pads and housing, leading to run-off into well

Supporting Resources and References

- Leaman SM, Salas S, Mandrell RE, Suslow TV, Jay-Russell MT, Davis DA. 2022. Environmental risk factors in the human pathogen transmission pathways between animal operations and produce crops. Food Protection Trends. 42(5):362-376.
- Olds HT, Corsi SR, Dila DK, Halmo KM, Bootsma MJ, McLellan SL. 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.
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Brief 4: Degree of Protection of Each Agricultural Water System (Proposed § 112.43(a)(1))

Brief description:

This issue brief describes assessment of the extent to which the agricultural water system is protected from potential sources of contamination (microbial hazards, like pathogens) as required in proposed § 112.43(a)(1).

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 proposed requirement, 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):

- ***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.

Proposed § 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..., the type of water distribution system..., and **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).**

- ***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 especially close to harvest may be an important factor to consider.
- ***Adjacent and nearby land uses:*** In the proposed 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 run-off, 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 about potential contamination sources allows growers to assess the degree to which the agricultural water system is protected against the introduction of pathogens. Describe how potential for pathogen introduction to the agricultural water is controlled, minimized, prevented, reduced, or mitigated. Degree of protection includes both the likelihood of introduction and the load of pathogens that could be introduced into the water system.

- ***Topography:*** is the hazard uphill or downhill from the canal, and 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 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 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 run-off and filters large particles
- Land slope is gentle from pen to the water source

Liklihood of Introduction

Animal Numbers (Sources)	Pathogen Movement: Low	Pathogen Movement: Medium	Pathogen Movement: High
High			High
Med		Medium	
Low	Low		

Lower Liklihood		Higher Liklihood
More	**Distance**	Less
Less	**Slope**	More
Wider	**Buffer**	Thinner
Exclusion	**Fencing**	Absent
Low	**Precip**	High

In this scenario, the water source is protected against direct access of animals to the water by the fence. Cows have never escaped the enclosure. However, the water source may be incompletely protected against movement of potential pathogens from the pen to the water with run-off.

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

Other factors may afford protection against pathogens carried by run-off including:

- 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 run-off inducing rainfall during the timeframe the farm uses the water

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


Photo credit: Trevor Suslow, Trevor Suslow Consulting, LLC

Brief 5: Agricultural Water Practices (Proposed § 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 agricultural water assessment, as proposed in § 112.43(a)(2).

Proposed § 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 agricultural water assessment explicitly includes two specific agricultural water practices: type of application method and the time interval between the last direct water application and harvest.

- 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. (Brief 12: Allowances for Die-off and Removal in Field and During Storage)

What does compliance look like?

The proposed Subpart E requirements regulate agricultural water, defined in the FSMA Produce Safety Rule as water intended or likely to contact covered produce or food contact surfaces (Relevant Definitions).

- 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, 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 lead to adhesion or internalization within the crop: (Brief 6: Crop Characteristics).

   - For drip irrigation, remember to consider the potential for direct contact with crops grown at or below ground level.
   - While not defined as agricultural water by the proposed 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 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-off in the field environment, reducing risk from agricultural water.
- For more information about environmental factors that may impact pathogen die-off: (Brief 12: Allowances for Die-off and Removal in Field and During Storage).
   - 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).

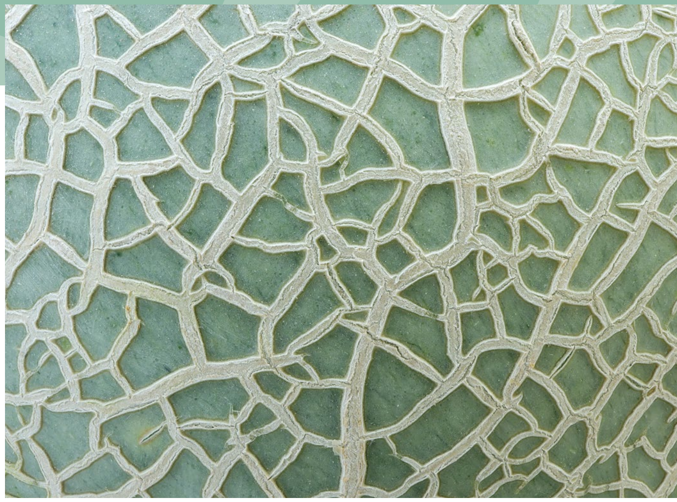
Both method of application and timing of application appear in two contexts in the proposed revision to Subpart E: 1) factors evaluated within the agricultural water assessment (proposed § 112.43) as well as 2) mitigation measures that can be implemented to reduce risks (proposed § 112.45(b)).

- 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 a minimum of 4 days to allow time for pathogens to die-off in the field environment.
   - Growers should consider consulting extension agents 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 agricultural water assessment.
   - 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 agricultural water assessment. 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 (Brief 10: Treatment of Agricultural Water)
– 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, especially 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 the last year's agricultural water assessment, the farm determined that the water is not sufficiently protected from animal intrusion upstream from the dam, on neighboring properties. Based on last year's evaluation, the farm might decide to use the pond water only to irrigate by the drip method under plastic mulch. In this way, the water is not used as agricultural water (not in contact with harvestable produce). The farm may also choose to use other water sources, such as a protected well, to mix any plant protective products applied as spray.



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

Brief description:

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

How does this requirement reduce risk?

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

As part of the agricultural water assessment, crop characteristics such as susceptibility to surface adhesion or internalization affect risk by holding (adhesion) or protecting (internalization) pathogens. 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.

Proposed § 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.

What does compliance look like?

- Protective crop characteristics, supported by data showing that internalization and/or surface adhesion are unlikely, may influence a determination that relatively lesser mitigation measures are necessary.
- Crop characteristics that enhance adhesion or persistence of pathogens on the produce, such as surface texture or structures that allow pathogens to “hide” so that UV rays are less effective or entirely blocked, may influence a determination that relatively stronger mitigation measures are necessary.
    - Stronger mitigation measures might include:
    - Treatment (Brief 10: Treatment of Agricultural Water)
    - Consideration of testing results that provide further information about water quality, when appropriate (Brief 9: Testing of Agricultural Water)
    - Changing to a different water source (if available)

When evaluating known crop characteristics in an agricultural water assessment, harvest and packing processes can affect whether crop characteristics will provide protection as opposed to increasing risk of pathogen adherence and internalization (and resulting persistence).

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. Account for these additional factors when describing crop characteristics, by providing context related to processes at the operation.

Limited research literature exists to demonstrate the susceptibility of specific commodities to internalization of pathogens during growing. The overall public health risk from real-world internalization rates is not easily evaluated; however, general expectations about internalization can help growers determine the outcome of the agricultural water assessment.

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 of *E. coli*, Salmonella, and Listeria depends, in part, on pH. Keep in mind that the pH of the surface will be very different than the pH of the interior/flesh.
- ***Growth characteristics of the crop:*** How a crop grows (i.e., is it 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).
- ***History of outbreaks:*** Summary information about a crop's vulnerability to water as a pathway of contamination can be gleaned from historical outbreak investigations, particularly those where water was considered the route to contamination.

Example Scenario: An agricultural water assessment 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 for 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 a 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
- IFPA commodity-specific resources

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

Brief description:

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

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 split 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. The relationships are not simple. No single factor is likely to drive presence or survival of human pathogens in most situations. Comprehensively assessing environmental conditions may pose a challenge because agricultural water systems are affected by numerous combinations of environmental factors.

- Many scientific reports describe factors that are associated with presence of pathogens (see Supporting Resources and References, this section). However, aligning environmental conditions with microbial contamination can be challenging, especially when numerous combinations of environmental factors can affect and 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) (Brief 12: Allowances for Die-off and Removal in Field and During Storage)

Proposed § 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

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

- Rain and other precipitation can result in run-off from nearby lands to the agricultural water source.

- The flow path of the run-off can affect the likelihood of pathogens being carried to the water source. (Brief 4: Degree of Protection of Each Agricultural Water System)
- Flow from an animal operation or across a grazed pasture may be more likely to carry pathogens compared to run-off 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. (Brief 4: Degree of Protection of Each Agricultural Water System)
  - Dust has not yet been demonstrated to introduce pathogen into water sources, but windborne dust has been shown to introduce foodborne pathogens onto produce.

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

• Ultraviolet light (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 from spore-form bacteria, and viruses and protozoan pathogens have their own characteristics.
    › It is difficult to set 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 that can be expected.
  - For closed water source 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.

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 agricultural water assessment 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 agricultural water assessment 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 be used as input to decision-making such as:

- Preparing procedures to address potential agricultural water system contamination during periods of vulnerability caused by specific weather conditions and events. (Brief 4: Degree of Protection of Each Agricultural Water System)
- 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 known for strong winds and when growing operations may be close to animal operations.

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 (Brief 2: Location and Nature of Each Water Source) (Brief 3: Type of Water Distribution System).

- 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 run-off and windborne dust unless for example, it is protected by a berm or is lined (Brief 4: Degree of Protection of Each Agricultural Water System).

Example Scenario: A farm in the Central Valley of California, which is 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 utilized as one of several considerations to characterize the risk level of a potential hazard upstream from the farm.

Supporting Resources and References

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Brief 8: Other Relevant Factors (Proposed § 112.43(a)(5))

Brief description:

This issue brief discusses a variety of other factors that may address potential for pathogens being introduced into the agricultural water sources, as described in proposed § 112.43(a)(5). Testing, which is referenced as part of this requirement, is described at length in a companion brief (Brief 9: Testing of Agricultural Water).

How does this requirement reduce risk?

Companion briefs that describe the requirements of proposed § 112.43(a)(1) through (a)(4) introduced several elements that must be considered as part of the agricultural water assessment to identify conditions that may introduce pathogens to agricultural water. Under proposed §112.43(a)(5), covered farms would consider any other relevant factors, including testing, that do not fall under the different categories that were previously described.

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."
- Inclusion of flexibility for the grower helps to address diversity of water sources at different geographical regions of the world.
- The responsibility of the grower is to consider varied and unique challenges, that are not explicitly addressed in the regulations, which may nevertheless contribute to the introduction of pathogens into agricultural water if not appropriately managed.

Proposed § 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}

What does compliance look like?

In preparation of a brief on this topic, the authors asked food safety professionals around the Americas about potential sources of contamination that have encountered in their regions. The following are a few examples that may help the reader to think about "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 such as 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 (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 planned for. Some actions taken to reduce risk in these situations include 1) treating the water before use (Brief 10: Treatment of Agricultural Water), or 2) paying particular attention to availability of hygienic facilities and monitoring for hygienic practices, among others.

Growers might encounter other factors that occur unexpectedly throughout the year and consider whether the event might introduce pathogens. The event may be cause for an updated agricultural water assessment. The farm may plan ahead by considering whether the environment in which they grow produce is prone to these types of 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 not sufficient environmental controls.
  - Adjacent and nearby farm operations may trim field edges and leave residues in diches and other water ways.
- Flood water could be pumped into the water source (canals, rivers, etc.) to reduce flood damage.
  - Flood water can carry pathogens from wastewater or from run-off, 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 may be encountered as part of the agricultural water system inspection (2015 PSR § 112.42 and proposed § 112.42). These relate to both pre-harvest water (input to the proposed agricultural water assessment) and water used during and after harvest (covered by provisions in Subpart E of the Produce Safety Rule, which are currently in effect for some farms). Cross-connections in the plumbing system and areas where the distribution system does not have adequate backflow prevention devices to protect the source or distribution system.

- Dead-end or unused water lines connected to the plumbing system.
  - These may be the result of line abandonment or they may have been installed in anticipation of future projects.
- 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 introduction of pathogens into the water system.
- Responses to these findings are often addressed by doing 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 agricultural water assessment, and determining if mitigation measures are necessary.

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

Brief description:

This brief discusses testing as a factor that may be considered in the agricultural water assessment, under proposed § 112.43(a)(5); Specifically, testing is identified as a consideration that may be included in the agricultural water assessment when all three of these conditions are present:

(1) A condition that may result in introduction of pathogens to the water is identified,

(2) The water is not unsafe or not of adequate quality for its intended use, (requirements of 2015 PSR § 112.43(c)(1) would apply instead) and

(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 proposed § 112.43(c)(4)(ii).

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

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 contains fecal material.

- Presence of generic *E. coli* is one indicator that water contains fecal contamination.
- 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 (2015 PSR § 112.44(a))
- For water used before harvest, testing is not required under the proposed rule. Testing is an option that growers can utilize to assess the sanitary quality of the water.
- One benchmark for water, to evaluate whether it contains 'too much' fecal contamination for use in growing activities on covered produce, is a microbial water quality profile (MWQP) with standards described in 2015 PSR § 112.44(b).

Proposed § 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).

Photo credit: Rob Way, Cornell University

- Though not written into the codified language of the proposed revision to Subpart E, FDA depicts the MWQP system as the best available science in the preamble.
- A MWQP consists of 20 or more samples collected over 2 to 4 years, and 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).
- Alternatives to the MWQP system, including frequency of sampling, number of samples, numerical standards, and target indicator of fecal contamination may also be acceptable; growers would have to explain and document why they are acceptable.

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

- Collecting the water sample in an appropriate manner (aseptic technique)
- Taking samples at appropriate time intervals, or targeted sampling when an event occurs that may impact the microbial quality.
- Reviewing the results of the analysis to determine if action must be taken.

It is important that growers understand how to interpret the results of the analysis. Help may 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 agricultural water assessment depends, in part, on the intended use of the water. Specific considerations that may help decide on a sampling strategy:

- 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 may be eligible for an exemption from the agricultural water assessment requirement (see proposed § 112.43(b)(2)). If growers use this type of water as their source, they might choose not to test the water at all.
  - For detailed information, (Brief 2: Location and Nature of Each Water Source)
  - 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 agricultural water assessment.
  - For detailed information about fecal contamination sources, (Brief 2: Location and Nature of Each Water Source)
  - For detailed information about protection from contamination, (Brief 4: Degree of Protection of Each Agricultural Water System)
  - The proposed requirements offer space for growers to establish a sampling strategy that is appropriate to their operation.

  - Because scientific evidence and historical sampling results in the industry indicates generally higher likelihood of pathogens, sampling of untreated surface water should be more intensive (higher frequency) compared with ground water (e.g., wells).
- Untreated ground water also has vulnerabilities to introduction of pathogens.
  - For detailed information about protection from contamination review the Degree of Protection Brief (Brief 4: Degree of Protection of Each Agricultural Water System).
  - Ground water sampling strategies should allow confirmation that the quality of the water is consistent throughout the year.
  - Ground water sampling may be beneficial after an environmental event (e.g., flood that overtops the well head) that would impact the 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 appoint someone to complete the tasks.
- 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 results that are not accurate.
- Laboratories often supply sterile sample containers and instructions for growers.
- If the situation requires a grower to hold samples for more than a few hours before delivery or shipment for sampling, contact the laboratory for specific instructions on how to maintain the integrity of the sample.
- The proposed revisions to subpart E, like the 2015 PSR, requires that all samples be analyzed using scientifically valid methods.

Example Scenario: A farm uses untreated river water as their overhead irrigation water source. While doing the agricultural water assessment, the farm did not find 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.

The farm might choose to 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 the geometric mean (42 CFU/100 mL) and statistical threshold value (216 CFU/100 mL). Since these values are less than the benchmarks suggested by FDA, the farm might use the analysis along with other findings of the agricultural water assessment to determine that no mitigation measures are needed.

Agricultural Water Risk Mitigation Measures

The briefs in this section represent actions that a farm may take in response to findings of the (proposed) agricultural water assessment for pre-harvest uses. These requirements may also be relevant to uses during harvest and postharvest.

The briefs relating to mitigation measures are meant to be used in conjunction with the briefs described in the prior section, related to developing a risk profile for the water source (the section called Briefs: Agricultural Water Assessment for Pre-Harvest Uses)

In a previous section, (Pre-Harvest Agricultural Water Scenarios) were used to demonstrate how these briefs could be applied by a covered farm to build their agricultural water assessment. The scenario breakdowns and briefs that describe components of the proposed agricultural water assessment will be most useful if the final requirements, once published, are similar to the proposed revision.

The proposed agricultural water assessment carries recordkeeping requirements, discussed separately in this document (Brief 13: Records Requirements).

Brief 10: Treatment of Agricultural Water (Proposed § 112.46)

Brief description:

This issue brief discusses treatment of agricultural water as a way to provide water that is safe and of adequate sanitary quality for use (2015 PSR § 112.41). The regulatory requirements described in proposed § 112.46 are essentially the same as 2015 PSR § 112.43. Treatment can result in exemption from various requirements, including the pre-harvest agricultural water assessment requirement (proposed § 112.43(b)(3)) and harvest/postharvest agricultural water testing requirement (proposed § 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 (Brief 11: Treatment of Water – The Label is the Law).

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 agricultural water assessment. Properly selected and applied, in most cases treatment will reduce levels of pathogens in water before the pathogens have a chance to attach to a crop.

Some conditions that might lead to the decision to treat water are:

- Due to adjacent land uses, pathogens are likely to be introduced to the water.
- Protection from the introduction of pathogens is limited.
- There are limited opportunities to reduce the level of pathogens once introduced to produce (e.g., commercial washing, or in-field die-off).

Proposed 21 CFR 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, 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; 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.

What does compliance look like?

Agricultural water may be treated:

- As a corrective measure in response to an assessment that the water does not meet the requirement of § 112.41 and is not safe, or not of adequate sanitary quality for its intended use (proposed § 112.45(a)(2)).
- As a mitigation measure in response to an assessment that conditions for pathogen introduction are known or reasonably foreseeable for an agricultural water source (proposed § 112.45(b)(1)(v)).
- As an alternative for regular testing of an agricultural water source for harvesting, packing, or holding covered produce (proposed § 112.44(c)(3)).

- As an alternative to doing the agricultural water assessment for the water system used for growing covered produce (proposed § 112.43(b)(3)).
  - – Treatment products are regulated by U.S. EPA, and growers may not be able to find a product that is labeled for the use (Brief 11: Treatment of Water – The Label is the Law). As new products for water treatment are developed, this practice may increase in popularity in the industry.
  - – Treating water may not fully eliminate pathogens, and associated risk.

Water treatment requirements (from proposed § 112.46):

- Treatment methods must be registered through the Environmental Protection Agency (EPA) and chemical labels followed for the specific use.
- Treatment delivery ensures water is consistently safe and of adequate sanitary quality for its intended use(s) and, when applicable, meets microbial quality criteria (e.g., for harvest and post-harvest uses of no detectable generic *E. coli* in 100 mL)
  - – The proposed revisions do not establish set microbial quality criteria for pre-harvest use, although many growers might continue to test water as one of piece of information for their agricultural water assessment. (Brief 9: Testing of Agricultural Water)
- Treatment is monitored using an adequate method and frequency (e.g., the treatment remains within control parameters).
- Treatment may be conducted by the grower or by a person or entity acting on their behalf.

Common antimicrobial agricultural water treatment methods *(from Rock, 2021)*

Chemical	• Peroxyacetic acid (Activated Peroxygen, PAA) • Chlorine/Chlorine Dioxide • Sodium or Calcium Hypochlorite • Cooper/Silver ionization • Ozone • Bromine • Electrolyzed Water
Physical	• Heat Sterilization • Ultraviolet Light (UV) • Sand/Membrane Filtration
Biological	• Slow Sand Filtration • Tertiary treatments (e.g., wetlands)

Characteristics of some physical and chemical treatments

Physical treatments	
UV	UV damages and breaks down organic molecules including DNA and RNA. Filtration required prior to treatment.
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 not as sensitive to pH
Chlorine dioxide	Oxidizer. Not as sensitive to organic load and not sensitive to pH
Ozone	Oxidizer. Very sensitive to organic load and 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 agricultural water assessment, the operation recognizes that the aquifer is unconfined and likely mixes with surface water especially after precipitation. This condition might allow introduction of pathogens into the water source.

The operation realizes that testing alone may not accurately reflect risk, which will vary based on weather. They are aware of research showing that rain events may increase risk. Therefore, the operation uses portable ozone generation equipment (appropriately labeled as an antimicrobial device by U.S. EPA) to treat the water prior to use as agricultural water to grow covered produce. Treatment, in this scenario, is a mitigation measure. The treatment must be monitored to ensure the ozone is being generated according to treatment specifications.

- The U.S. EPA label for some products may contain an efficacy statement, which states 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 the treatment is enough to manage the pathogen(s) of concern, at the levels they may be found in the water.

The results of monitoring are recorded and kept in the farm record. If the water is effectively treated prior to use, the farm does not have to conduct an agricultural water assessment in the future. The farm still must do an agricultural water system inspection at least annually (proposed § 112.42)

Supporting Resources and References

PAA & Chlorine

- 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)
- 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

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

Miscellaneous

- https://www.centerforproducesafety.org/amass/documents/researchproject/357/CPS%20Final%20Report%20_Buchanan_January%202016.pdf (Buchanan, 2015)
- CPS Agricultural water treatment webinar – https://www.centerforproducesafety.org/webinars.php#CPS_Agricultural_Water_Treatment_Webinar
- 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.
- 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.
- Buchanan, J. (2015). Evaluation of multiple disinfection methods to mitigate the risk of produce contamination by irrigation water. Center for Produce Safety.
- 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.
- Rock, C. (2019). CPS Rapid Response - Yuma Valley. Yuma, AZ: Center for Produce Safety.
- Rock, C. (2021). Agriculture water treatment - Southwest region. Maricopa, AZ: Center for Produce Safety

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

Brief description:

Beginning January 26, 2023, farms must comply with the agricultural water requirements for harvest and post-harvest water contained in Subpart E of the Produce Safety Rule.

This section will focus on the legalities of treating agricultural water, which applies to pre-harvest, harvest, and postharvest 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 commentary will focus on pre-harvest considerations.

It is critical for growers to consider the implications of decisions related to treatment of water, and to consider unintended consequences that may occur. For example, discontinuing use of a particular sanitizer may put the operation at increased likelihood of crop contamination if the hazard has not been managed through another mechanism (e.g., filtration, UV treatment). This brief will discuss the current (2023) legalities of water treatment (i.e., sanitizer) labeling, however, it should be noted that progress is being made within the industry to expand the collection of products that are approved for use in the field and labeled for human pathogens.

2015 PSR § 112.43 *What requirements apply to treating agricultural water?*

a. When agricultural water is treated in accordance with § 112.45:

(1) 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 and/or meet the relevant microbial quality criteria in § 112.44, as applicable.

As noted above, EPA is the regulatory authority with jurisdiction over the use of chemical water treatments. 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. In the PSA tool, expand the "Label Info", and sort the "Labeled for Use in Irrigation Water" column. This will allow growers to access the associated EPA label.

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

The example below provides sample label information, and IFPA's assessment of whether the use by the grower 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 Produce Safety Rule.

***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 agricultural water risk assessment and determined that the risk of pathogens such as E. coli O157:H7 and Salmonella need 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 have collaborated to develop a testing protocol so that chemical providers can gather the 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.

In the meantime, growers should be wary of the off-label use of a treatment regulated by EPA intended to control risks associated with human pathogen presence in agricultural water. Because FDA does not have regulatory authority over the use of these chemicals, FDA cannot exercise enforcement discretion. The label is the law.

Supporting Resources and References

Produce Safety Alliance. Labeled Sanitizers for Produce – Excel Tool. 2023. Available at: https://cals.cornell.edu/produce-safety-alliance/resources

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

Brief 12: Allowances for Die-off and Removal in Field and During Storage (2015 PSR § 112.45(b)(1))

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 proposed § 112.44(b)(1)(ii) and (iii).

How does this requirement reduce risk?

FDA lists several mitigation options that may be taken. It is up to the grower to determine through an agricultural water assessment what 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 is to account for environmental and ecological factors that often result in die-off of pathogens, or commercial washing processes that physically remove or inactivate pathogens that may be on the produce.

- **In-field die-off:** conditions on the surface of the crop (e.g., sunlight, temperature, moisture level, or interactions with normally resident microorganisms) often result in reduced population of human pathogens over time.
- **Storage die-off:** depending on storage conditions, human pathogens that may be on the surface of the commodity may die-off over time.
- **Removal during commercial washing:** the effects of physical washing and surfactant (if used) may result in physical removal of pathogens from the surface of produce. The use of antimicrobial treatments 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 surface of produce.
- Keep in mind that removal during commercial washing is highly dependent on process and commodity and generally does not result in more than 1-log removal (i.e., 10% survival).

Proposed 21 CFR 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 (with a minimum interval of 4 days between application and harvest, except as supported by test results conducted under § 112.43(d), or other scientifically valid data or information in accordance with § 112.12);
- (iii) Increasing the time interval between harvest and the end of storage using an appropriate microbial die-off rate, and/or conducting other activities, such as commercial washing, to reduce pathogens using appropriate microbial removal rates, provided you have scientifically valid supporting data and information.

What does compliance look like?

Use of In-Field Die-Off as a Mitigation Measure (§ 112.44(b)(1)(ii))

The proposed revision to Subpart E provides two explicit options for an in-field die-off interval:

(1) A minimum of four days between application of agricultural water and harvest; or

(2) An alternative interval less than four days that is supported by scientifically valid data or information (as described by proposed § 112.12 about alternatives) or test results conducted under proposed §112.43(d) (Brief 9: Testing of Agricultural Water)

Minimum of four days: In practice, a four-day interval between the last direct application of agricultural water and harvest is an acceptable mitigation measure without the need for supporting data or additional actions.

- Growers should carefully consider information in the associated call out box as they 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 that up to 1% of the original hazard load may still be present.
- Growers are still subject to the U.S. Food, Drug, and Cosmetic Act (FD&C Act) to ensure that food is produced and handled under sanitary conditions.

Alternative interval: For a die-off interval that is less than four days, the grower will need to obtain scientifically valid data or information that the alternative interval provides the same level of public health protection (proposed § 112.45(b)(ii) referencing § 112.12).

- FDA guidance indicates that if a grower wishes to use the microbial die-off rate of 0.5 log per day reduction of generic *E. coli* for less than four days, then they would also need test re-

In-field Die-off for a Minimum of 4 Days

As part of the proposed agricultural water assessment, growers must consider what mitigation measures identified in the Produce Safety Rule, 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 rates can vary depending on a number of factors. A grower who is utilizing a four-day (or other) die-off option as their only mitigation measure, without supporting data or additional actions, should consider:

- Which specific hazards might be present. Various pathogens can have very different die-off characteristics (Microbiological Hazards).
- The quality of the water they are using (e.g., based on testing their water before harvest). Unusually high test results might indicate that supplemental mitigation measure(s) might be 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.

sults to indicate that the reduction would be sufficient to mitigate risk from the hazard (Brief 9: Testing of Agricultural Water).

- 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 mean that more that 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.

Alternative die-off rate and interval: The grower may provide an alternative die-off rate based on "additional information on in-field die-off that is applicable to their unique circumstances," that is different from the FDA-provided 0.5 log/day based on scientifically valid data or information that the alternative interval provides the same level of public health protection (proposed § 112.45(b)(ii) referencing § 112.12). FDA guidance indicates that:

- An example of when more rapid die-off rate could be expected is when there is "little or no precipitation, coupled with high ultraviolet radiation, high temperature exposures, or low humidity."
- Scientific data and information used to support an alternative pre-harvest die-off interval must be relevant to the crop, region, and environment of the covered farm.
- Since microbial die-off tends to have an initial 'fast' phase and a later 'slow' phase, the data should also allow evaluation of how long the 'fast' phase lasts so the alternative die-off rate can be applied appropriately (e.g., for a maximum number of hours or days).
- Crop/field characteristics that can affect microbial die-off rates include pH, the presence of competing microbes, and a suitable plant substrate.

Other insights and suggestions: For growers 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.
  - 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.
  - Consider worst-case scenarios if developing scientific data to support a die-off rate of more than a 0.5 log reduction and/or less than four days duration.
  - For example, the strongest support might be based on research that measures die-off rates during the night as a worst-case scenario where:
    - UV rates are lowest
    - Humidity levels are highest
    - Temperatures are coolest
    - The study was done on the crop in question, in the region in question, or where environmental conditions are comparable.
- Deviation from average environmental conditions, such as a rainstorm or 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.

- Demonstration of same level of public health protection requires a benchmark for comparison. FDA guidance in the proposed revision to Subpart E identifies the 2015 PSR microbial water quality profile strategy and associated numeric standards as a benchmark (Brief 9: Testing of Agricultural Water).
  – An FDA-provided or alternative die-off rate calculation could be compared against this benchmark.
  – Other indicators of fecal contamination and standards can be applied if they can be demonstrated to achieve the same level of public health protection (proposed § 112.43(d)(3) which references proposed 112.45, leading to § 112.12).

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

Additional mitigation measures can be used should the grower determine, through an agricultural water assessment, that measures are reasonably necessary to manage produce safety risk due to the potential for pathogens in agricultural water. As of now, FDA guidance does not include any time interval or a die-off rate for growers to utilize when modeling either of these 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 commercial washing.

Growers wanting to apply these mitigation measure 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 using the same crop and storage practices as the growers' operation.
- The outcome must be that the water meets the "safe and of adequate sanitary quality for its intended use" expectation and 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 5 times per year close to harvest and calculate from the data that the 4-year rolling geometric mean is about 1,000 CFU/100 mL generic *E. coli*. The grower has no alternative water source available for this use. The grower includes test results as an indication of water quality as part of their agricultural water assessment. As a result, the grower determines that it would not be appropriate to use the water as agricultural water to grow covered produce without a mitigation measure in place.

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 done with the statistical threshold value.

The grower is only able to employ a 24-hour pre-harvest interval between water application and harvest without damaging the produce. One day of in-field die-off at 0.5 log/day would result in an adjusted geometric mean around 316 CFU/100 mL. The grower has additional data that shows the commercial washing step that is utilized during packing provides a 1-log reduction. The validation of this commercial washing process was done using the same crop, antimicrobial treatment, and other parameters including active ingredient and water characteristics. When taken together, the modeled in-field interval and removal achieved during commercial washing may be sufficient mitigation measures to meet regulatory requirements as currently proposed. The combined reduction of 1.5 log (0.5 log from in-field die-off and 1 log from commercial washing) would result in a calculated geometric mean of about 32 CFU/100 mL.

When selecting these mitigation measures, the grower should consider that both the FSMA Produce Safety Rule (§ 112.11) and the federal Food, Drug and Cosmetic 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 and References

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

For an example of data that could be used 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:

- 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.
- 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.
- 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.
- 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 (Proposed § 112.50 and 112.161)

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

- Like most documentation required by the FSMA Produce Safety Rule, 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 someone responsible for the creation and maintenance of the records, who may be a supervisor or worker with specified job duties.

Proposed 21 CFR 112.161

(b) Records required under §§ 112.7(b), 112.30(b), 112.50(b)(2), (5), (7), and (10), 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.

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.

- These records must be signed and dated at the time of review.
- This portion of the requirements is likely to be updated to reflect the proposed numbering system and specific proposed requirements in the proposed revision to Subpart E.
- The full text of the proposed revisions is provided in the associated call-out box.

All required records must be kept for a minimum of two years unless otherwise specified in the Produce Safety Rule. See the following page for a table describing of required records.

The proposed 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, as well as 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
Proposed § 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. Notes 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
Proposed § 112.50(b)(2) Agricultural Water Assessment (Brief 1: Elements of an Agricultural Water Assessment)	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 commence 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
Proposed § 112.50(b)(3) Scientific support for any indicator other than generic *E. coli* as the indicator of water quality (Brief 9: Testing of Agricultural Water)	The information 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 used for covered produce.	Covered farms that opt to use water testing with an indicator other than generic *E. coli* as part of the agricultural water assessment.	Not required
Proposed § 112.50(b)(4) Scientific support for any the frequency of testing or microbial criterion (Brief 9: Testing of Agricultural Water)	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 agricultural water assessment. 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 Produce Safety Rule. Note: There is no allowance for alternative frequency or criterion for the no-detect requirement.	Covered farms that opt to use testing as part of the agricultural water assessment.	Not required

Provision number and record topic	Record description	Required for	Supervisory review and signature
Proposed § 112.50(b)(5) Analytical test results (Brief 9: Testing of Agricultural Water)	Test results should be obtained from the laboratory which 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, reach out the laboratory for support. Most laboratories have staff who are very willing to 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 agricultural water assessment. Also applies to uses of agricultural water during and after harvest.	Required
Proposed § 112.50(b)(6) Certificates of compliance or other documentation from a public water supply (Brief 2: Location and Nature of Each Water Source)	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. As currently written, this record is not required to support exemption from the agricultural water assessment when using water from a public water supply.	Not required
Proposed § 112.50(b)(7) Related to log die-off or log removal during commercial washing (Brief 12: Allowances for Die-off and Removal in Field and During Storage)	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 (such as 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.	Required
Proposed § 112.50(b) (8) Scientific support for pre-harvest water alternative log die-off or log removal expectations (Brief 12: Allowances for Die-off and Removal in Field and During Storage)	When used as a mitigation measure, information should support the use of the die-off rate or log removal rate, as well as the time interval or conditions under which the rate is applicable. In guidance associated with the Produce Safety Rule, FDA provides an in-field die-off rate assumption of 0.5 log per day, which can be used to calculate in-field die-off for no more than 4 days (Memo FDA-2011-N-0921-0992).	Covered farms that opt to provide their own estimates of die-off or removal rates as part of the mitigation measure which is an outcome of the agricultural water assessment.	Not required

Provision number and record topic	Record description	Required for	Supervisory review and signature
Proposed § 112.50(b)(9) Scientific support for adequacy of treatment methods (Brief 10: Treatment of Agricultural Water)	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 agricultural water assessment requirement. Also applies to uses of agricultural water during and after harvest.	Required
Proposed § 112.50(b)(10) Results of water treatment monitoring (Brief 10: Treatment of Agricultural Water)	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 the briefs created for this document.

Relevant Definitions

The sources of the following definitions are identified by superscripts. Please note that many of these terms have regulatory meaning. These are the way the terms are used for purposes of compliance with the FSMA Produce Safety Rule and other 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 proposed 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
   - i. If it bears or contains any **poisonous or deleterious substance which may render it injurious to health** … {statement about quantity}; or
   - ii. … {addresses pesticide chemical residues, food additives, and animal drugs}; or
   - iii. if it consists in whole or in part of any **filthy, putrid, or decomposed substance, or if it is otherwise unfit for food**; or
   - iv. 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
   - v. … {considerations related to diseased animals}; or
   - vi. … {considerations related to container}; or
   - vii. … {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 Water1: 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 Produce Safety Rule, 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 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 open 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.

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

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. {Proposed Revision to Subpart E} 2021. Available at: https://www.govinfo.gov/content/pkg/FR-2021-12-06/pdf/2021-26127.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

Microbiological Hazards

The Produce Safety Rule 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 is intended to provide an overview of some key microorganisms associated with agricultural water, common reservoirs for them, 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 and therefore 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 of the pathogens in the table below may not be relevant to each grower's environment, and there may be pathogens that are 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 such as 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 variety of chemicals (chlorine, peroxyacetic acid, et cetera) depending on parameters of use	Can persist (even if not growing) for long durations in the environment (especially in soil, sediment etc.)
Salmonella spp.	Vegetative bacteria	Poultry/avian (e.g., pellets, feathers), and reptiles, but can be found elsewhere	Same as above	Susceptible to variety of chemicals (chlorine, PAA etc. depending on parameters of use)	Resistant to desiccation (drying) and 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 chemical antimicrobials, and varies based on parasite	Does not grow on produce (only in hosts)
Hepatitis A, Norovirus	Virus	Human (feces)	Due to small size (less than 50 nm diameter), filtration is unlikely to be effective		Does not grow on produce; viruses Require a host. Host range limited to humans