Module 5: Agricultural Water

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This section has two parts since identification of risks and management of microbial water quality are different during production and postharvest activities.

The FSMA Produce Safety Rule requirements for agricultural water are outlined in Subpart E, § 112.41–112.50.

Water requirements for growing sprouts are included in Subpart E § 112.44(a) and Subpart M of the Produce Safety Rule but are not covered in detail in this module. However, the Sprout Safety Alliance has developed educational materials and a curriculum specifically for sprout producers.

Production water refers to water that meets the definition of agricultural water and is used during growing activities for covered produce, other than sprouts, for the purposes of the Produce Safety Rule (§ 112.44(b)).

Postharvest water encompasses water that meets the definition of agricultural water and is used during and after harvest which can include agricultural water used in the field during harvest as well as during packing or holding activities.
A general requirement of subpart E of the FSMA Produce Safety Rule is that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). This requirement applies to agricultural water that is intended or likely to contact covered produce or food contact surfaces and includes agricultural water used during growing activities for covered produce using a direct water application method (covered in Part I of this module), and water used for certain activities during and after harvest (covered in Part II of this module) and for sprout irrigation.
Pathogens can be introduced into water and are easily spread through water, therefore, understanding risks associated with water is important to reducing risks.

Without water there would be no fresh produce, so knowing how to manage water quality and its proper use on the farm is critical to reducing produce safety risks during the production of fruits and vegetables. The specific water monitoring requirements under the FSMA Produce Safety Rule are discussed later in this module and in Module 5 Part II: Postharvest Water.

Several things impact production water risks including the source of the water used (e.g., surface, well, municipal), how it is applied (e.g., overhead, drip, furrow) and when it is applied (e.g., at planting, during production, right before harvest). These topics are discussed in Module 5 Part I: Production Water, while harvest and postharvest water uses are discussed in Module 5 Part II: Postharvest Water.

Additional Resource:
Any water that is applied directly to produce can transfer microorganisms, including potential pathogens, if the water is contaminated.

Production water applications can include irrigation, crop sprays, frost protection, cooling water, and water used as mixes applied directly to produce prior to harvest.

Additional Resources:

This is a key introduction slide to production water as it outlines how this module will proceed. These three areas will be covered first in terms of basic GAPs. After foundational information is shared, specifics of the FSMA Produce Safety Rule will be outlined.

Understanding source water quality is a great place to start, because if the source water quality is good (i.e., less microbial risks are present), the risks are lower at the very start.
If there are concerns about source water quality, growers have an opportunity to reduce risks by modifying the application method (e.g., using water in a way that does not contact fresh produce) or by modifying the timing of application (e.g., extending application to harvest intervals).

In the next slides, each of these topics and how they may affect the safety of produce will be discussed.

Production water primarily comes from three sources with different probabilities of contamination by microorganisms associated with feces: public/municipal drinking water supplies, ground water, and surface water.

Public water supplies, such as municipal drinking water, have their water treated and monitored by the water utility. Water that has been tested to verify that it meets drinking water criteria has lower risk.

Ground water (e.g., well water) is generally less likely than surface water to be contaminated with microorganisms associated with feces. As water filters through layers of soil, clay and rock, the microbial load is reduced before it reaches the ground water aquifer. Because ground water sources can vary widely in terms of aquifer water quality and well construction, ground water is placed in the middle of this diagram. A properly constructed well that is regularly tested and shown to meet microbial criteria can be as safe as public water supplies, but ground water that is subject to contamination by the surface environment can have risks more similar to surface waters.

As defined in the FSMA Produce Safety Rule (§ 112.3), ground water means 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.

Surface water includes rivers, streams, lakes, ponds, manmade reservoirs and any other water source that is open to the environment. The quality of water drawn from surface water sources can vary greatly. This is particularly true for surface waters that are subject to contamination events such as water runoff from upstream livestock operations or wastewater discharge. Contamination of surface waters can happen with different frequency: all the time, rarely, or seasonally. Water testing helps growers understand their surface water source and its risks.
As defined in the FSMA Produce Safety Rule (§ 112.3), **surface water** means 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.

- **Reclaimed water** is often used as a source of irrigation water in dry regions, areas subject to drought, and in other agricultural scenarios. Reclaimed water that has been treated and tested, such as at a wastewater treatment plant, may be used for production water but growers need to be sure the water is safe and of adequate sanitary quality for its intended use and meets numerical GM and STV criteria of the Produce Safety Rule, as applicable. More information about acceptable water quality, and related citations to the Produce Safety Rule, begins on the slide *Evaluating Water Quality: Use of Microbial Water Quality Profiles*.

For water sources in general, using municipal drinking water provides the lowest risk of contamination with microorganisms associated with feces. However, this water source might not always be feasible for all production water needs due to cost or location.

- Water from Safe Drinking Water Act—compliant municipal sources should be potable. It is suggested that these sources should still be tested annually as water distribution systems may be vulnerable to contamination.

- Public Water Supply water may become contaminated in the piping between the treatment plant and the farm, or in the water distribution system on the farm. See slide *Inspect Agricultural Water Sources and Water Distribution Systems* for FSMA Produce Safety Rule requirements concerning inspections.

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**Preventing Contamination of Water from Public Water Supplies**

Public water supplies are treated to meet microbial drinking water standards, but distribution systems can introduce risks, therefore:

- Assess your connection to the public water supply and distribution system downstream
- Test the water if you have any concerns about the water source
- Have a back-up plan if you think water in the distribution system may be unsafe

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Notes:

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If wells are not capped and are open to the environment, the water is more vulnerable to contamination.

Shallow, cracked, or improperly constructed wells are also more vulnerable to contamination.

Even if a well is properly constructed and adequately maintained, it is still possible for the aquifer from which it draws to become contaminated. For example, a septic tank and leach field near the well could pose a serious threat to the quality of ground water. A general GAPs recommendation is to locate septic systems at least 100 feet from a wellhead. This helps to prevent contamination of the aquifer water source.

If the well is also used for drinking water, it should be tested for potability.

The practices described on this slide are Good Agricultural Practices (GAPs) which may be useful in meeting requirements associated with § 112.42 of the FSMA Produce Safety Rule that are described in the slide Inspect Agricultural Water Sources and Water Distribution Systems.

### Additional Information

- This slide is optional.
- Surface water sources, because they are open to the environment, are subject to several contamination risks.
- Understanding the surrounding areas, land topography, water source type, water distribution methods, and animal activity (both wild and domesticated) can lead to actions that help reduce the chances that water sources become contaminated.
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- Assess risks and take steps, when possible, to reduce contamination of surface water sources.

- Flowing sources of water such as streams or rivers may travel long distances before being used for crop production, therefore, it is important to identify upstream sources of contamination.

- Prevention of contamination to the water source might include assessing risks beyond direct impacts to the produce crop, such as raw human and animal wastes, sewage water discharges, and other contaminants from adjacent land, wildlife presence, or manure runoff.

- As discussed in Module 4: Wildlife, Domesticated Animals, and Land Use, keeping animals out of water sources is key because both domesticated animals and wildlife can contaminate water sources with their feces.

The practices described on this slide are Good Agricultural Practices which may be useful in meeting requirements associated with § 112.42 of the FSMA Produce Safety Rule that are described in the slide Inspect Agricultural Water Sources and Water Distribution Systems.

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- In addition to the source of agricultural water, the irrigation method impacts the potential for contamination of produce. The method of irrigation can provide another opportunity to reduce contamination risks by avoiding contact between the water and the produce.

- Overhead (sprinkler) - Higher risk: A direct water application method resulting in contact with produce

- Flood (surface, furrow) - May avoid direct contact with produce - Consider risk of contact with contaminated soil during harvest or from splash

- Drip (trickle, subsurface, micro, under canopy) - Lower risk: Produce generally not in direct contact (except root crops), reduces foliar diseases, improves water use efficiency

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There are various methods for irrigation which can be utilized depending on the environment, water source, availability, type of crop, and cost. Many farms use a combination of irrigation methods.

- **Overhead irrigation**, also referred to as sprinkler irrigation, uses a relatively high volume of water which in effect, simulates rainfall. Plants, including harvestable portions above the soil surface, may be directly contacted with water either through direct irrigation or through splash. Water quality is critical for overhead irrigation because it directly contacts produce that develops either above ground or below ground.

- **Surface, flood, or furrow irrigation** can be an effective and safe method for irrigation, because direct contact with produce above the soil may occur less frequently than with overhead irrigation. However, if contamination is present in the water it may become widely distributed across the soil and splash or soil could then contaminate the produce. The water also could contaminate any produce it contacts.

- **Trickle or drip irrigation** delivers water to growing plants through the surface or subsurface of the soil. In addition to being a more efficient and sustainable method of water delivery, drip irrigation minimizes the risk of unintentional direct water contact with the produce growing above the soil, reducing the chance for contamination. Root crops and some crops growing on or above the ground may be directly contacted if these methods of application are used.

In general, direct water application methods to produce will result in the highest risk for contamination. For some crops even drip irrigation could result in direct contact (e.g., root crops) so assessments of risks needs to consider both crop and application method.

Application methods that are not normally direct application methods can have hidden risks. For example, if flood type irrigation is utilized, water could splash and touch the crop. Additionally, if drip emitters are broken or not functioning properly, they can apply water similar to overhead irrigation and potentially contaminated water can contact the crop.

- Remember, water can serve as both a direct source of contamination and as a vehicle to spread contamination.

**Additional Resource:**

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- If the water does not contact the harvestable portion of the crop, the risk is lower.
- If the water is only applied at the time of seeding or germination, before the harvestable part of the crop has been established, the risk is lower because application at that time does not contact the produce itself.
- If the water contacts the produce, the quality of the water and the timing of application (days before harvest) become more important in terms of options that growers have to reduce risks. For instance, higher quality water (i.e., less fecal contamination) has lower risks when applied directly to crops. Extending the time from water application to harvest is another option growers have for reducing risks.

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- Once growers have assessed the quality of their water source(s) and their methods of application, they should assess risks related to the timing of water applications.
- In general, more time between application and harvest reduces produce safety risks posed by the water application.

Additional Resources:

Notes:

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This slide is the beginning of a series of slides that provide more details about Good Agricultural Practices (GAPs) and the regulatory requirements for water quality, water testing, and timing of application.

Knowing how the water moves on the farm can help assess potential food safety risks. Growers should create a map that describes their water distribution systems before doing the annual inspection.

§ 112.41 specifies that all agricultural water must be safe and of adequate sanitary quality for its intended use. If at any time agricultural water is determined not to be safe or of adequate sanitary quality for its intended use those subject to the rule must immediately discontinue use of that water according to § 112.45(a).

§ 112.42 provides specific requirements for inspection of agricultural water sources and water distribution systems.

§§ 112.42(a)(1) through (5) require that at the beginning of a growing season, as appropriate but at least once annually, growers must inspect all of a farm’s agricultural water systems to the extent they are under the farm’s control to identify produce safety hazards, including:

- The nature of each agricultural water source (e.g., ground, surface water).
- The extent of the farm’s control over each water source.
- The degree of protection of each water source.
- Use of adjacent and nearby land.
- The likelihood of introduction of food safety hazards to agricultural water by another user before it reaches the farm.

Notes:
§ 112.42(c) requires that all agricultural water sources must be adequately maintained to the extent that it is under the farm’s control, including regularly inspecting each source. Hazards that must be identified and corrected include maintenance issues (e.g., piping tanks and treatment equipment, and control of cross-connections) and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination, to the extent practicable.

- Reviewing and inspecting water distribution systems, including backflow devices, hoses, pipes, sprinkler heads, and other distribution equipment will help identify any problems and target areas for cleaning and maintenance. Repairing damaged equipment is important. For example, broken water emitters can turn a drip system into an unintended overhead system, resulting in direct contact between the water and covered produce.

- Open irrigation systems are also considered part of the water system, including ditches and canals that are used for water movement on the farm.

**Image Note:** This is an example of a bad dead-leg with potential for soil intrusion and pooled water intrusion that would pose a contamination risk even if the water source started out uncontaminated.

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**Requirements related to the microbial water quality profile, corrective measures, and numerical GM and STV criteria are discussed in the upcoming slides. The geometric mean (GM) is a log-scale average, the “typical” value. The statistical threshold value (STV) is a measure of variability, the estimated “high range” value (approximated 90th percentile). Both of these are discussed in the slide Geometric Means and Statistical Threshold Values.**

- The microbial water quality profile (MWQP) is a long-term management strategy, and for production water, it is not meant to be used for day-to-day management and decision making about whether the water is suitable for a use at that particular time.

- § 112.46(b)(1) requires that growers subject to the rule must establish an initial microbial water quality profile for untreated water sources (surface or ground water) that are applied using a direct water application method during growing.
It is important to understand that surface water quality can change quickly over time and throughout the season. Water testing only provides an indication of the water quality at the time of sampling and may provide information on long-term sources of fecal contamination that impact the water source.

Generic E. coli is an indicator of fecal contamination. Generic E. coli has historically been used as an indicator of fecal contamination for several types of water. However, presence of generic E. coli does not always mean that pathogens are present. Similarly, absence does not always mean that pathogens are absent.

Monitoring for generic E. coli can assess the potential for agricultural water to contain fecal contamination. This is important since feces can carry human pathogens.

- Pathogens often found in feces include pathogenic E. coli, Salmonella enterica serotype Typhimurium, Cryptosporidium parvum, hepatitis A, and norovirus.

Detection of generic E. coli indicates possible fecal contamination, and the amount of fecal contamination that is detected provides information to growers on how to best manage water that could present a risk to covered produce. Fecal contamination is a risk factor for the presence of pathogens.

- § 112.44 requires that generic E. coli be used as the indicator of water quality.

Key Information about the graphic on this slide

- Generic E. coli are a type of coliform. Coliforms are bacteria that are found in the environment, soil, and intestines of warm-blooded animals. Total coliforms are sometimes used as indicators in other settings (e.g., drinking water).

- Generic E. coli are also fecal coliforms. Fecal coliforms are a type of coliform that are more likely to be associated with human or animal fecal material and are a more accurate indication of the presence of feces than total coliforms. Fecal coliforms are sometimes used as indicators in other settings (e.g., recreational water and livestock water sources).
• Generic *E. coli* is considered to be the most likely species within the fecal and total coliforms to indicate that the water may contain fecal contamination.

### Additional Resources:

- United States Environmental Protection Agency (EPA) 2012 Recreational Water Quality Criteria.

### § 112.44(b) specifies criteria for untreated agricultural water (both surface water and ground water) that is applied with a direct water application method to covered produce during growing activities.

The numerical GM and STV criteria are used to evaluate the microbial water quality profile (MWQP).

- These criteria capture two different pieces of information about the distribution of generic *E. coli* levels in a water source. The geometric mean (GM) is essentially the average amount of generic *E. coli* in a water source. The STV reflects the amount of variation in the *E. coli* levels. Collectively, both pieces of information provide a more complete description of your water quality than either one alone.

- Some terms, as defined in § 112.3(c), are critical to understanding the scope of what is covered under these criteria.
  - **Agricultural water** means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces.
  - **Direct water application method** means 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.
**Covered produce** means produce that is subject to the FSMA Produce Safety Rule. The term “covered produce” refers to the harvestable or harvested part of the crop.

Production water that does not meet the definition of agricultural water (see above) is not covered by the GM and STV criteria in the FSMA Produce Safety Rule. For example, water used for drip or furrow irrigation in apple orchards would not be considered agricultural water as long as the water does not contact the apples. That same water would be considered agricultural water if it were used to mix protective sprays that were then applied directly to the apples.

**Additional Resources:**
- FD&C Act Chapter IV: Food, Section 342 Adulterated Food.
- United States Environmental Protection Agency (EPA) 2012 Recreational Water Quality Criteria.
- For information about how the numerical GM and STV water quality criteria were developed:
- For a historical context of water quality standards:

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The GM and STV criteria are used to determine compliance and appropriate uses of water, and to manage uses with appropriate corrective measures if necessary, under the FSMA Produce Safety Rule.

The graph on the slide shows 21 generic *E. coli* results collected over four years (an initial survey). The values were analyzed to calculate the geometric mean (black line) and the statistical threshold value (blue line). The criteria are included on the plot (dotted

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lines). One thing to point out is that there is a high value in the data set (about 650 CFU/100 mL, in year 4). A data set with some values higher than the criteria can still have a GM or STV less than the criteria. See the slide Visualizing Water Quality Trends for information about how tracking down and addressing the reason for that high value can help the grower protect produce safety.

- Tools are available to assist in calculating the GM and STV. It is important to understand that depending on business size and relevant compliance dates, and the specific water provision, growers will have between January 2018 to January 2022 to come into compliance with the agricultural water requirements.

- Some growers are required to begin building an initial microbial water quality profile by 2018, but the provisions covering the numerical GM and STV criteria and corrective measures do not go into effect until 2020 to 2022 for any grower covered by the Produce Safety Rule.

**Additional Resource:**


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- §§ 112.46(a)(1) and (a)(2) state that if water is sourced from a public water supply (such as municipal drinking water), growers subject to the rule do not need to test the water source as long as they have Public Water System results or a current water supply certificate of compliance that the water meets requirements of the Safe Drinking Water Act, or that it is free of detectable generic *E. coli* in 100 mL of water.

- If municipal drinking water is held in containments open to the environment prior to using it as agricultural water, it is considered equivalent to untreated surface water and then it would need to be surveyed as surface water (see the slide Microbial Water Quality Profile: Survey of Surface Water Sources).

- Though not required, it is a good idea to sample and test at the point of use to ensure that there are no impacts from the water distribution system.

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Notes:
Ground water sources of production water, such as wells, must be tested during an initial year and annually thereafter for calculation of the microbial water quality profile.

- Initial year: 4 times throughout the growing season, or over the period of a year (§ 112.46(b)(1)(i)(B)).
- Subsequent years: 1 time during the growing season or over the period of a year (§ 112.46(b)(2)(i)(B)).
- § 112.46(b)(2)(iii) requires that the microbial water quality profile must be updated with annual survey results. Revised GM and STV values must be calculated using the current annual survey data combined with the most recent initial or annual survey data from within the previous four years to make up a rolling data set of at least four samples for untreated ground water sources.

For surface water sources:

- The survey for surface water sources is more sample-intensive because the quality of surface water is more variable than ground water or public water supplies.
- § 112.46(b)(1)(ii) requires an initial survey to develop a microbial water quality profile to determine whether a water source meets the microbial quality criteria established in § 112.44(b) for the intended use (See slide Water Quality Criteria for Water Used During Growing Activities).
- § 112.46(b)(1)(i)(A) requires that the initial profile use a minimum of 20 samples taken over at least two years but not more than four years.
• § 112.46(b)(1)(ii) requires that the water samples must be representative of the farm’s use and must be collected as close in time as practicable to, but prior to, harvest.

• § 112.46(b)(2)(i)(A) requires that after establishing the initial microbial water quality profile, 5 or more new samples must be analyzed each year to update the microbial water quality profile, resulting in a rolling data set from within the previous four years that always includes 20 or more samples.

For surface and ground water sources:

• § 112.46(b) requires that growers subject to the regulation who use multiple water sources for agricultural water must test each water source to establish the initial profile and collect annual samples to update the profile for each source.

• The FSMA Produce Safety Rule requirements stated above are minimum requirements. Collecting staggered samples as additional tests throughout the season may help the grower to get a more detailed representation of the microbial water quality throughout the season and over time to help identify water quality issues. Any additional samples may or may not be suitable for inclusion in the microbial water quality profile data set, depending on whether the sample is representative of use and collected near harvest.

• Growers who are not subject to the rule should consider testing their water sources as described above because testing may help them identify produce safety risks that may exist with their water source(s).

Selection of sample location is a complex issue. For more information, see response to comment 237 in the FSMA Produce Safety Rule preamble.

• § 112.46(b)(2)(ii) requires that samples of agricultural water must be representative of the use of the water used during growing activities.

• The following examples reflect ways to collect samples:

• When taking a river or pond water sample, for example, one sampling location might be as close to the point of intake as possible.
The person collecting water samples should sample well water at the tap used to draw production water. For example, the person collecting water samples should not sample from the house tap if the house tap water has a chlorinator in the line and the production water, as used, is not chlorinated.

For municipal drinking water or other public water supplies, water testing is not as critical because the water has been treated by the public water authority (see slide Requirements for Public Water Sources for details). It might be a good idea to sample and test at the point of use to ensure that there are no impacts from the water distribution system.

Additional Resource:

The person collecting water samples should follow all sampling instructions from the laboratory, if provided.

§ 112.47(b) requires that samples must be collected using aseptic technique. This means the person collecting water samples must use a sterile bottle to collect samples and not contaminate the bottle when removing the lid (e.g., do not put fingers on the lip or on the inside of the bottle).

Here are some recommendations for sampling water:
- The person collecting water samples should not rinse sterile bottles before collecting samples. Residual chemicals such as chlorine in municipal drinking water supplies may kill any bacteria in the sample and some bottles have a protective chemical inside that should not be rinsed out.
- A sampling aid (e.g., water sampling stick with a sterile bottle) can be used.
- In a distribution system, the person collecting water samples should let the water run before sampling in order to collect a representative sample. The length of time the water should run may vary from a few minutes to hours, depending on the distribution system.
• Water collected from the end of a pipe or distribution system should reflect typical conditions during water application, including typical temperature at application.

• In general, piped water systems should be flushed for 3 to 6 minutes, or until the temperature stabilizes, before sampling.

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- The lab used to analyze water tests should be accredited. Some audits require water analysis be done by a GLP certified lab but environmental monitoring is more often done by State or third-party accredited labs (e.g., ISO, A2LA, NELAP).

- Quantified generic *E. coli* tests generally cost between $30–50 and many laboratories offer the test.

- Acceptable Methods: § 112.151 requires that the laboratory must test using (a) U.S. EPA Method 1603 (membrane filtration using modified mTEC) or (b)(1), a method that is at least equivalent to Method 1603 in accuracy, precision, and sensitivity or (b)(2) a scientifically valid method for an alternative indicator

- Submit questions about method suitability to the FSMA Technical Assistance Network.

- Growers seeking water quality data (whether covered by the regulation, not covered, or exempt) should be sure the lab can perform the test that is needed. Some labs only do presence/absence tests on potable or drinking water, so growers must be sure that the lab can analyze surface water and other agricultural water sources using acceptable methods.

- Dilutions: Dilution may be needed to get a value to calculate the GM and STV of the water source. The GM and STV cannot be calculated using “greater than” results.

- Transport and Delivery: Be sure the lab provides instructions regarding the type of sampling container, how to take the sample, acceptable hold times (i.e., the time between when the sample is taken and when the sample is analyzed), storing, and transportation expectations.

  • U.S. EPA Method 1603 requires that the sample be stored on wet ice, but not frozen.

  • Method 1603 also requires delivery of the sample to the laboratory within 6 hours.

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• Exceeding the sample hold time could make the test invalid. Growers may need to communicate with their analysis laboratory, inspectors, and FDA regarding concerns about sample hold time.

• If you are having trouble finding a lab, contact your local extension office or grower organization to help you identify appropriate laboratories.

Additional Resources:


Corrective measures specify requirements outlined in the FSMA Produce Safety Rule when specific numerical criteria are not met.

§ 112.45(b) requires that if the source microbial water quality profile (MWQP) does not meet numerical GM and STV criteria (see the slide Water Quality Criteria for Water Used During Growing Activities for details), growers subject to the rule must discontinue use of the water as soon as practicable and no later than the following year unless a corrective measure is implemented. Options for corrective measures include the following:

1. § 112.45(b)(1) allows growers to achieve the water quality criteria by applying a time interval for die-off, or a reduction by removal processes.
   i. Apply a time interval between last application and harvest as described in Corrective Measure: Water Application and Timing. § 112.45(b)(1)(i)(A) includes a die-off rate of 0.5 log per day, for up to four consecutive days. § 112.45(b)(1)(i)(B) allows use of alternative microbial die-off rates and accompanying maximum time intervals, if scientifically valid.
ii. Apply a time interval between harvest and end of storage. § 112.45(b)(1)(ii) allows application of a time interval between harvest and end of storage using a scientifically valid die-off rate. The provision also allows use of appropriate microbial removal rates during activities such as commercial washing.

2. § 112.45(b)(2) allows growers to re-inspect the entire affected agricultural water system to the extent it is under the farm’s control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective and adequately ensure that agricultural water meets the applicable microbial quality criteria.

3. § 112.45(b)(3) allows growers to treat the water in accordance with § 112.43. See Corrective Measure: Treating Production Water for more information.

- As a guide, a 1 log removal or die-off is 90% reduction (10% remaining). A 0.5 log removal or die-off can be approximated as 68% reduction (32% remaining).

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- More days between last water application and harvest reduces risk. If water is applied close to harvest and contacts the crop, there may not be sufficient time for microbial die-off through UV (sun exposure) or desiccation (drying).

- One option for a corrective measure is to use a time interval between last application of water using a direct water application method and harvest.

- § 112.45(b)(1)(i)(A) allows a 0.5 log calculated reduction in generic E. coli for each day (up to four consecutive days) between last application of water and harvest to achieve calculated values that meet the GM and STV water quality criteria.

- As an example, if the microbial water quality profile shows a GM of 1000 CFU generic E. coli per 100 mL of water:
  - A time interval of one day with a 0.5 log per day reduction would result in a GM of 316 CFU/100 mL.

Notes:
A time interval of two days would result in a GM value of the water source of 100 CFU/100 mL and the water would meet the GM criterion of 126 CFU/100 mL required in § 112.44(b)(1).

- Note: Water that requires greater than the maximum 4-day time interval means that 99% die off alone will not resolve certain water quality issues.

- The 0.5 log per day die-off rate is intended to account for variability in microbial characteristics, production practices, environmental conditions (such as high UV, dry climates), and specific commodity types.

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- § 112.45(b)(2) describes one of the three corrective measures in the FSMA Produce Safety Rule: re-inspect the entire affected agricultural water system and make changes to address any “known or reasonably foreseeable hazards” that are under the farm’s control (refer to slide Corrective Measures).

- Many topics covered in other modules of this training could represent “known or reasonably foreseeable hazards,” including wildlife and manure runoff (§ 112.134(a)), septic tank overflows (§ 112.131), or other wastewater overflows that could result in contaminated water coming into contact with production water in absence of control (§ 112.133).

- Corrective actions might include building berms to reduce or redirection of run-off or taking measures to deter wildlife.

- One way to confirm that any changes were effective is to re-test the water.

- § 112.50(b)(6) requires that growers subject to the rule must document all actions taken in accordance with § 112.45. These could include changes to water treatment processes, wildlife and domesticated animal exclusion, or other actions meant to control sources of contamination.

Notes:
If the treatment option is used (see the slide Corrective Measures for details), any chemicals used to treat water must be EPA-registered for that use and targeted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) before they can be lawfully used.

Non-chemical options such as filtration and/or UV may be used, but growers must be sure they are adequate in terms of the volume of water that needs treatment and the resulting microbial risk reduction is sufficient to meet regulatory requirements (as indicated by the text of § 112.43(a)(1)).

- Simple sand filters may remove large particles from the water, but are less effective at removing bacteria such as generic *E. coli*.

Treating any sources of agricultural water requires a careful review of the potential environmental impacts. Chemically treating water sources, especially if they are open to the environment, can be detrimental to wildlife habitat.

Growers subject to the rule are required to use treatment methods that are effective (§112.43(a)(1)). The FSMA Produce Safety Rule does not require growers to test treated water to determine generic *E. coli* levels after treatment. However, growers are encouraged to verify that the treatment they applied was effective under the conditions on their farm by testing one or more samples of treated water for generic *E. coli* levels.
The term *corrective action* as used in this module is a general term. It is intended to convey actions that are based on Good Agricultural Practices, that are not explicitly required in the FSMA Produce Safety Rule, but that can be used to support and comply with various provisions that are in the Produce Safety Rule.

Produce can be contacted by water due to many unforeseen events such as broken emitters, human mistakes, and natural disasters (flood events).

Each of these events are examples that should trigger an assessment of risks.

**Broken Irrigation Equipment and Other Water Application Issues**

- Broken emitters or hoses may result in unintended water contact with the edible portion of the crop. Inspecting the water distribution system at the beginning of the season and throughout its use will help ensure that all equipment is functioning properly.

**Human Mistakes**

- They happen! Be sure to train workers how to mix tanks for crop/pesticide sprays, how to manage irrigation systems to properly deliver water to the crop, and what to do if there is a problem that might compromise the safety of the produce (i.e., report the issue, document, implement corrective actions). Training can go a long way in reducing human errors and an even longer way in ensuring a safe crop is produced and harvested.

**Flooding**

- If flood waters (e.g., breached or overflowing streams, lakes, other water sources) contact the harvestable portion of a crop, it is considered adulterated by the FDA and cannot be sold or used as human food.

**Flood type irrigation**

- Flood type irrigation is not the same as natural flooding. With intentional flooding of a field for irrigation purposes, the quality of water should be known through testing and the water should not run off into other fields or contain other contaminating agents such as chemicals as with unintentional flooding.

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**Notes:**

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• In-field flooding, such as flooding resulting from forgetting to turn off a water pump, is viewed differently from natural flooding because the water is only in the field and less likely to contain chemical and biological contaminants that would be present in typical flood waters.
• In some cases, flood type irrigation water quality could be covered under § 112.44(b), if it directly contacts covered produce.
  • 112.42(d) requires implementing measures to reduce the potential for produce contamination as a result of contact with pooled water.

Additional Resource:

Additional Information
• This slide is optional.
• The microbial water quality profile allows growers to assess the microbial quality of their production water source over time, and make any necessary management decisions to address suitability for intended uses.
• The following references to the FSMA Produce Safety Rule are sometimes repetitive with information presented earlier in this module, but they offer a comprehensive overview of the statutory framework developed over the prior slides in this module. The trainer can use this as an effective summary slide covering this aspect of the Produce Safety Rule.

START:
• § 112.46(b)(1)(i)(A) requires that the surface microbial water quality profile is first created over 2 to 4 years by analyzing at least 20 samples. The GM and STV are calculated for that water source using the initial microbial water quality survey samples.

ANNUALLY AFTER START:
• §§ 112.46(b)(1)(iii) and (b)(2)(i)(A) require that after the profile is developed, at least 5 samples must be taken annually to update the profile. The rolling profile consists of at least 20 samples from within the previous four years.
Additionally, under § 112.46(b)(2)(ii) samples must continue to be representative of your use of the water and collected as close in time as practicable to, but before, harvest.

§§ 112.46(b)(2)(iii) and (iv) require that the microbial water quality profile is maintained by recalculating the GM and STV annually, and that the revised values be used to modify your water use, as appropriate, by application of corrective measures described below.

**IF YOUR WATER CHANGES:**

§ 112.46(b)(3) requires that if the grower has reason to believe that the microbial water quality profile no longer represents the quality of water (such as changed land use on adjacent land likely to impact water quality) those subject to the rule must create a new microbial water quality profile with at least 20 samples representing the quality of the water with the changed condition.

**IF YOUR PROFILE DOES NOT MEET CRITERIA:**

§ 112.45(b) requires that if a water source exceeds the water quality criteria (§ 112.44(b)) growers must discontinue use as soon as practicable and no later than the following year unless corrective measures are used.

**ALLOWED CORRECTIVE MEASURES:**

Several corrective measures can allow use of agricultural water that does not meet the GM and STV criteria for production use.

1. § 112.45(b)(1) Achieve the water quality criteria by:
   i. Applying a time interval between application and harvest as described in Corrective Measure: Water Application and Timing. § 112.45(b)(1)(i)(A) includes a 0.5 log die-off per day assumption for up to four consecutive days while § 112.45(b)(1)(i)(B) and §§ 112.12(b) and (c) allow use of alternative microbial die-off rates and accompanying maximum time intervals, if scientifically valid.
   ii. Applying a time interval between harvest and end of storage. § 112.45(b)(1)(ii) allows application of a time interval between harvest and end of storage using a scientifically valid die-off rate. The provision also allows use of appropriate microbial removal rates during activities such as commercial washing.

2. § 112.45(b)(2) Re-inspect the entire affected agricultural water system to the extent it is under the farm’s control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective and adequately ensure that agricultural water meets the microbial quality criteria. Inspection was described in the slide Inspect Agricultural Water Sources and Water Distributions Systems.

Notes:
3. § 112.45(b)(3) Treat the water in accordance with § 112.43. This option was described in the slide Corrective Measure: Treating Production Water.

35 Additional Information
- This slide is optional.
- This slide is identical to the Surface Microbial Water Quality Profile version, other than the text in green. Some of the relevant provision numbers are different.

36 Additional Information
- This slide is optional.
- Testing water does not end when the sample is sent to the lab. The results should be reviewed and used to make decisions that enhance produce safety.
- If the water quality results are high growers should stop and consider whether it is safe to use the water for production until they know more.
- Remember that the microbial water quality profile requirements in the FSMA Produce Safety Rule are minimum requirements, and they cannot by themselves guarantee produce safety is achieved.
- Some practices that reduce risk could include:
  - Making necessary repairs to system or equipment, or better protecting the water source from access by domesticated animals.

Reviewing Test Results
- If your water test results are higher than expected, take action as soon as possible!
  - Investigate water sources for possible causes
    - Manure application and run-off
    - Fecal contamination from wildlife, migratory birds
    - Incorrect/inadvertent cross connections
    - Wellhead impacts
- Implement practices to reduce risks
• Changing the application method (use drip instead of overhead irrigation).
• Changing the water source (use well water instead of surface water for frost protection).

37 Additional Information

- This slide is optional.
- Keeping records and developing a graph of water test results can help visualize trends and identify problems, whether acute or persistent.
- Testing multiple times throughout the season can help the grower understand changes in water quality. Understanding variability in water quality of a source is important when making decisions about uses. Having water quality data over time is especially helpful when looking for the sources of water quality issues.
- Upon first using a water source, a grower may want to test more frequently to understand the variations over time.
- In this example, the high test result in July might indicate a contamination event. The key message of this slide is that if test results are unusually high, growers should take action to identify any potential hazards through a water source and distribution system inspection.
- When appropriate, the grower must follow up with corrective actions and corrective measures as specified in the FSMA Produce Safety Rule under Subpart E, such as in § 112.45(a).
- Note to trainers: This would be a good opportunity to discuss potential reasons why the spike in the water testing data occurred.

Visualizing Water Quality Trends

Looking for data trends in your water test results can help you identify possible risks in your water source.

Note:

This slide is optional.

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Additional Information

- This is an optional slide meant to help guide evaluation of risks.

- Here is one example to discuss. Ask participants: Do you think this scenario represents high or low risk and why?
  
  - It is a surface water source, open to the environment, and therefore more susceptible to contamination.
  
  - Water is applied by overhead irrigation (a direct water application method for this crop).
  
  - It is applied near harvest so there is little time for microorganisms to die off due to UV rays from the sun or desiccation (drying out).

- As the three bullets describe, this example includes several practices that represent higher risk.

Additional Information

- This is an optional slide meant to help guide evaluation of risks.

- Here is another example to discuss. Ask participants: Do you think this scenario represents high or low risk and why?

- This example illustrates a lower risk practice, even though a higher risk source (surface water) is used. Water is applied through a method that is not as likely to contact the harvestable portion of the crop (in this case, tomatoes).
Records for all analytical water tests must be kept, as well as any corrective measures that are taken to identify and reduce risks that may be present in the water or the water delivery system.

Template logs are provided to assist growers with this recordkeeping process. Be sure the grower knows to tailor the logs to fit their operation and production practices.

§§ 112.50(b)(1) through (9) requires that the following records must be established and kept, if applicable:

- The findings of agricultural water system inspection as required by § 112.42(a).
- Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance (such as E. coli test results).
- Scientific data or information the farm relies upon to support the adequacy of the methods used to satisfy §§ 112.43(a)(1) and (2) (for water treatment).
- Documentation of the results of water treatment monitoring as required by § 112.43(b).
- Scientific data or information relied upon to support the microbial die-off or removal rate(s) that were used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic Escherichia coli (E. coli), in accordance with § 112.45(b)(1)(ii).
- Documentation of actions taken in accordance with § 112.45. § 112.45 describes measures to take if agricultural water does not meet the safe and of adequate sanitary quality for intended use requirement in § 112.41 or the numerical criteria in § 112.44.

- With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation must include:
  - the specific time interval or log reduction applied,
  - how the time interval or log reduction was determined, and
  - the dates of corresponding activities such as the dates of last irrigation and harvest,
  - the dates of harvest and end of storage, and/or
  - the dates of activities such as commercial washing.
• Annual documentation of the results or certificates of compliance from a public water supply as required in §§ 112.46(a)(1) or (2), as applicable.

• Scientific data or information relied upon to support any alternative established and used in accordance with § 112.49.
  • Alternative microbial quality criteria using an appropriate indicator of fecal contamination.
  • Alternative microbial die-off rate and accompanying maximum time interval.
  • Alternative minimum number of samples in the initial survey.
  • Alternative minimum number of samples in the annual survey.
  • Additional information on alternatives can be found in § 112.12

• Any analytical methods used in lieu of the method that is incorporated by reference in § 112.151(a) (U.S. EPA Method 1603; modified mTEC).

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• Surface water can be used in the production of fresh produce, but growers should be aware of the microbial quality and the risks that may exist.

  • Water use decisions are made by 1) long-term testing for generic E. coli and calculating a microbial water quality profile and 2) water system inspection. Manage water on a long-term ongoing basis to reduce risk associated with various water sources.

  • Risks are lower if the water does not contact the harvestable portion of the crop.

  • To assess risks, evaluate the water source, water quality, method of delivery, and timing of application.

  • Specific corrective measures can be taken to address production water sources that do not meet quality requirements: application of a time interval for die-off or removal, re-inspection and taking corrective actions to address hazards, and treatment of the water.

  • As always, document all test results and actions taken for managing your water sources, as necessary.

Summary

• Contaminated agricultural water has been implicated in some foodborne outbreaks associated with fresh produce
• Knowing the water quality through long-term testing will help establish management practices for appropriate use of the water
• If the water IS NOT applied by a direct application method to the harvestable portion of the crop, the risks are lower
• Extend time between last application of water and harvest to reduce risks, if water quality is a concern
• Treating water is an option to reduce risks
• Keep copies of all water test results
• Document all water management practices

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