Produce Safety
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Agricultural Water—Part 1

Cornell University

5-1) Agricultural Water
Part 1: Production Water

Learning Objectives
Module 5—Part I: Production Water

Objective 1:
Identify risks that may impact the microbial safety of agricultural water sources.

Objective 2:
Describe practices such as water application methods and timing that can reduce produce safety risks.

Objective 3:
Adopt practices for managing agricultural water that limit impacts to and from the environment, soil, and wildlife habitat.

Objective 4:
Describe the importance of water testing for different water sources (e.g., surface water, ground water, public water supply) used during growing activities as well as the sampling frequencies needed to build microbial water quality profiles.

Objective 5:
Describe FSMA agricultural water quality criteria, and how the microbial water quality profile results are used to assess the microbial quality of a water source and its suitability for intended uses.

Objective 6:
Describe corrective measures and corrective actions that could be taken if a microbial water quality profile or water system inspection indicates that agricultural water is not suitable for its intended use.

Objective 7:
Identify records that must be kept including documentation of agricultural microbial water quality and monitoring of any water treatment (if used).

Critical Concepts

- How to evaluate the quality and minimize contamination of surface water, ground water, and public water sources and distribution systems
- Requirements for agricultural water system inspections
- Requirements for agricultural water sampling frequency and testing
- The geometric mean and statistical threshold value calculations for the microbial water quality profile
- Knowing water quality criteria for untreated agricultural water sources used during growing activities that directly contact produce crops, and how microbial water quality profiles are used to assess if agricultural water is suitable for its intended use
- What corrective measures can be used for water that does not meet the numerical GM and STV criteria.
- Recordkeeping practices that are used to document agricultural water quality

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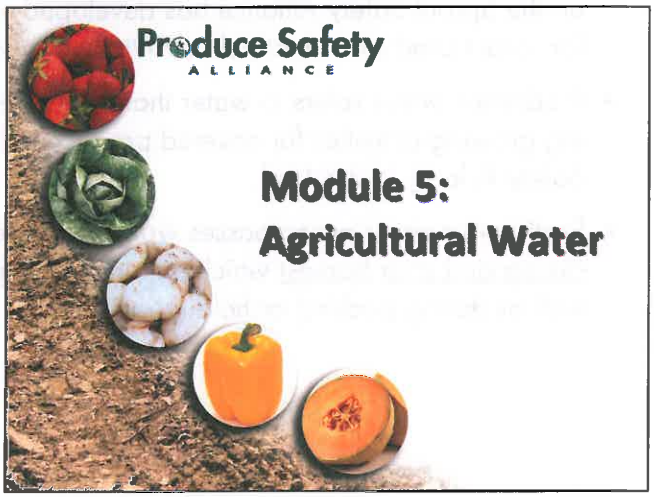
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Module 5:
Agricultural Water

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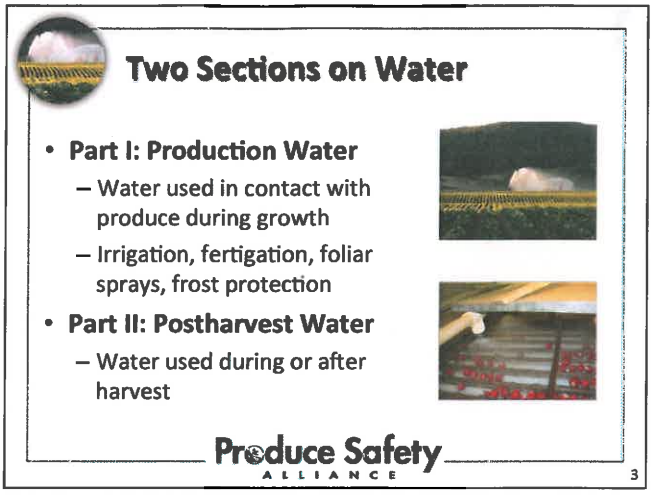

- This section has two parts since identification of risks and management of microbial water quality are different during production and postharvest activities.
- The FSMA Produce Safety Rule requirements for agricultural water are outlined in Subpart E, § 112.41–112.50.
- Water requirements for growing 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 available at: http://www.iit.edu/ifsh/sprout_safety/
- 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.

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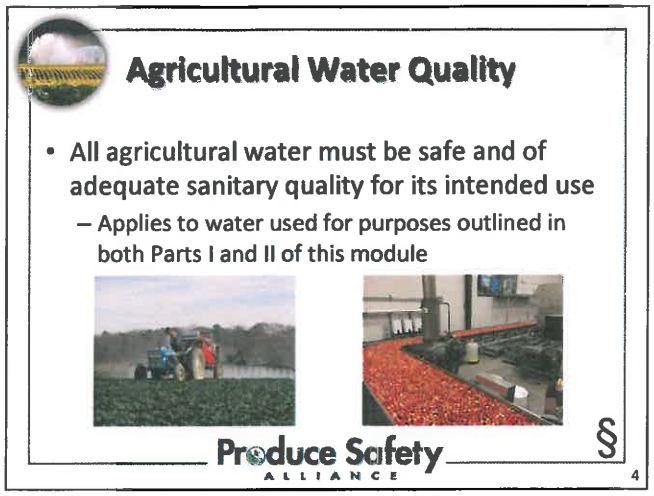

- A general requirement of subpart E of the FSMA Produce Safety Rule is that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). This requirement applies to agricultural water that is intended or likely to contact covered produce or food contact surfaces 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.

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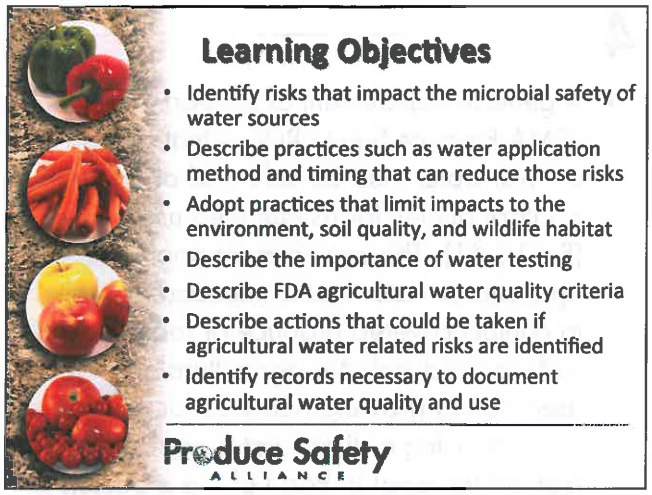

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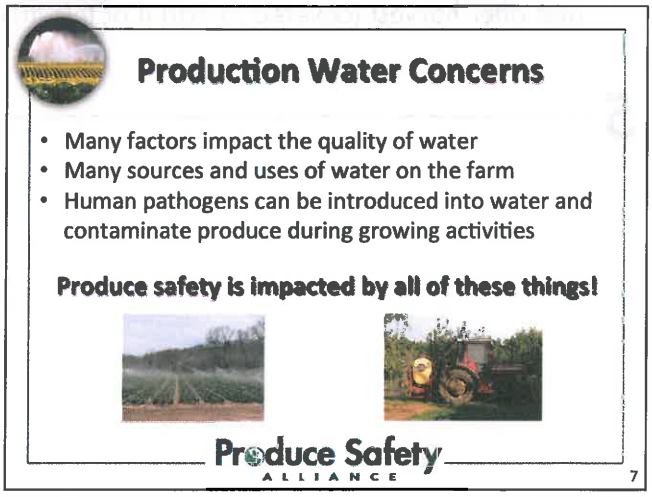

- Pathogens can be introduced into water and are easily spread through water, therefore, understanding risks associated with water is important to reducing risks.
- Without water there would be no fresh produce, so knowing how to manage water quality and its proper use on the farm is critical to reducing 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:

- Beuchat, L.R. (2006). Vectors and conditions for pre-harvest contamination of fruits and vegetables with pathogens capable of causing enteric diseases. *Brit Food J*, 108(1), 38–53.

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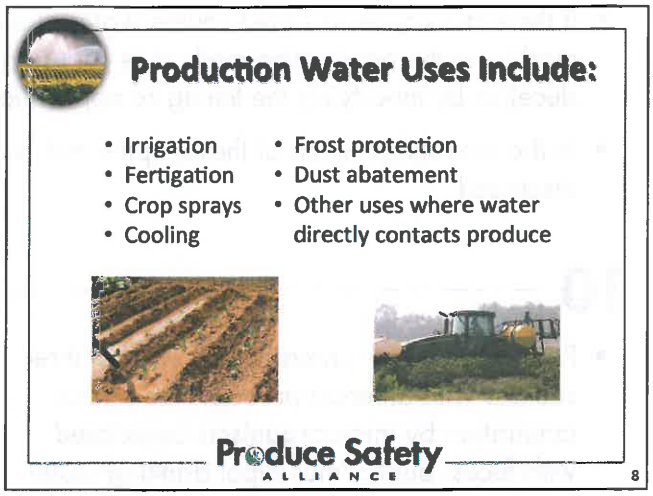

- Any water that is applied directly to produce can transfer microorganisms, including potential pathogens, if the water is contaminated.
- Production water applications can include irrigation, crop sprays, frost protection, cooling water, and water used as mixes applied directly to produce prior to harvest.

Additional Resources:

- Guan, T.Y., Blank, G., Ismond, A., & Van Acker, R. (2001). Fate of foodborne bacterial pathogens in pesticide products. *J Sci Food Agric*, 81(5), 503–512.
- Steele, M., & Odumeru, J. (2004). Irrigation water as source of foodborne pathogens on fruit and vegetables. *J Food Prot*, 67(12), 2839–2849.
- Stine, S.W., Song, I., Choi, C., & Gerba, C.P. (2005). Application of microbial risk assessment to the development of standards for enteric pathogens in water used to irrigate fresh produce. *J Food Prot*, 68(5), 913–918.

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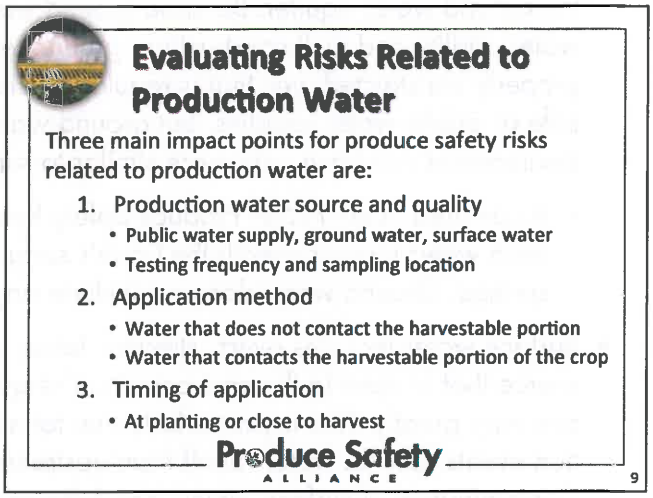

- This is a key introduction slide to production water as it outlines how this module will proceed. These three areas will be covered first in terms of basic GAPs. After foundational information is shared, specifics of the FSMA Produce Safety Rule will be outlined.
- Understanding source water quality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

Notes:

- 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.

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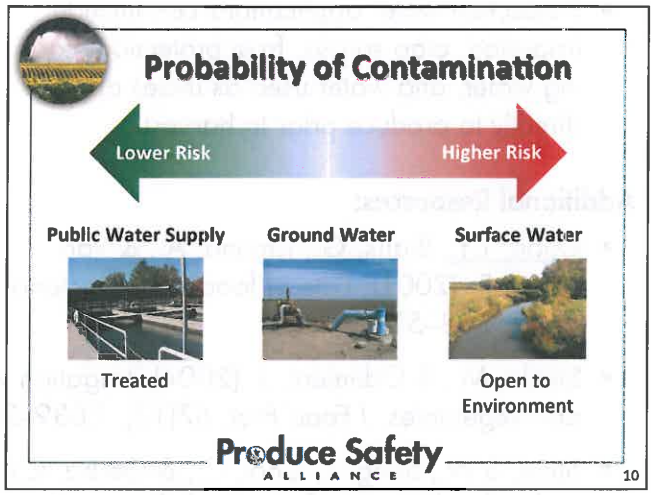

- Production water primarily comes from three sources with different probabilities of contamination by microorganisms associated with feces: public/municipal drinking water supplies, ground water, and surface water.
- Public water supplies, such as municipal drinking water, have their water treated and 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.

Notes:

  - 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.*

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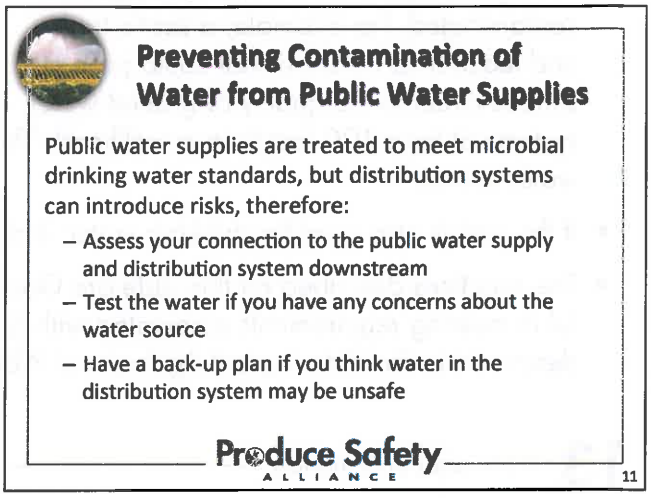

- For water sources in general, using municipal drinking water provides the lowest risk of contamination with microorganisms associated with feces. However, this water source might not always be feasible for all production water needs due to cost or location.
- Water from Safe Drinking Water Act—compliant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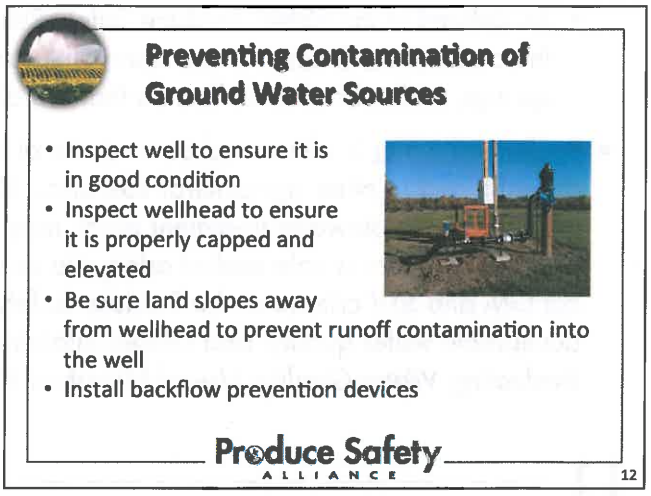
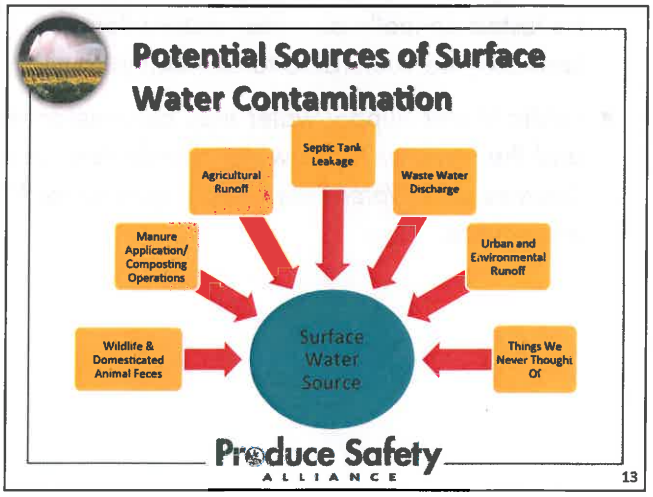


- If wells are not capped and are open to the environment, the water is more vulnerable to contamination.
- Shallow, cracked, or improperly constructed wells are also more vulnerable to contamination.
- Even if a well is properly constructed and adequately maintained, it is still possible for the aquifer 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*.

13 *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.

Notes:

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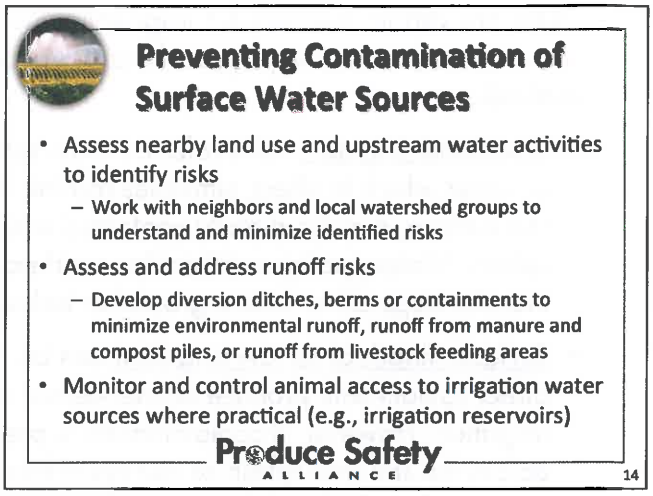

- Assess risks and take steps, when possible, to reduce contamination of surface water sources.
  - Flowing sources of water such as streams or rivers may travel long distances before being used for crop production, therefore, it is important to identify upstream sources of contamination.
  - Prevention 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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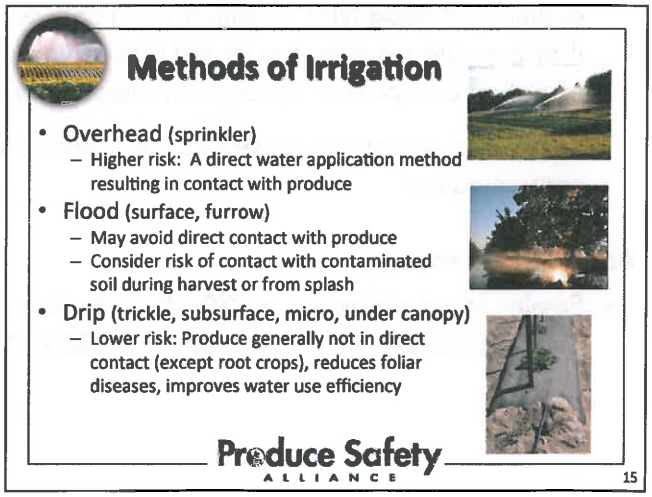

- In addition to the source of agricultural water, the irrigation method impacts the potential for contamination of produce. The method of irrigation can provide another opportunity to reduce contamination risks by avoiding contact between the water and the produce.

Notes:

- 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:

- Steele, M., & Odumeru, J. (2004). Irrigation water as source of foodborne pathogens on fruit and vegetables. *J Food Prot*, 67(12), 2839–2849.

Notes:

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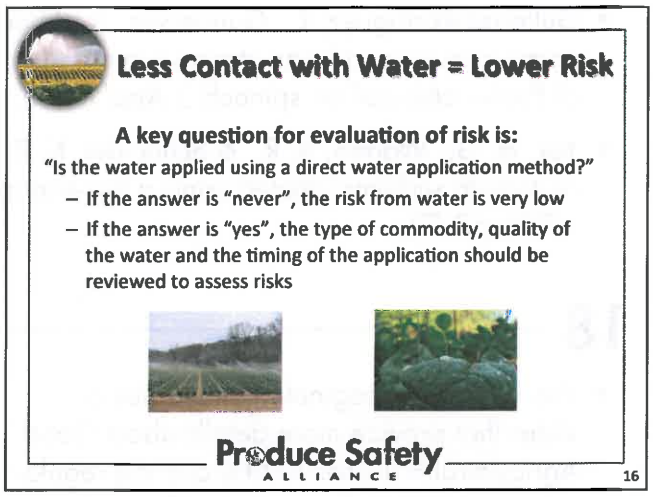

- If the water does not contact the harvestable portion of the crop, the risk is lower.
- If the water is only applied at the time of seeding or germination, before the harvestable part of the crop has been established, the risk is lower because application at that time does not contact the produce itself.
- 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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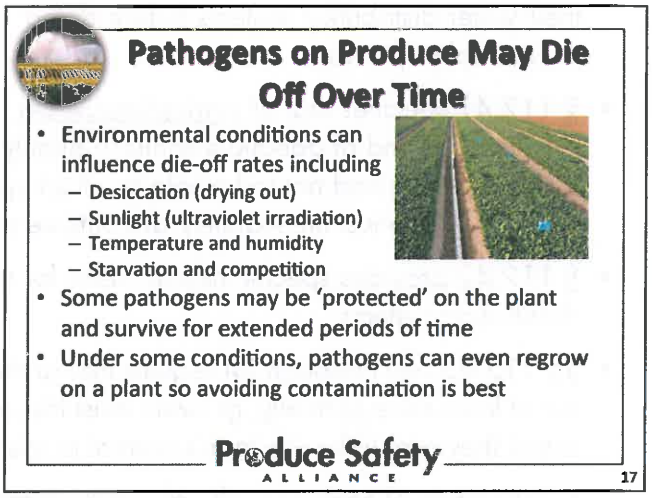

- Once growers have assessed the quality of their water source(s) and their methods of application, they should assess risks related to the timing of water applications.
- In general, more time between application and harvest reduces produce safety risks posed by the water application.

Additional Resources:

- 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 enterica* and *Escherichia coli* O157: H7 on lettuce contaminated during field production. *Food Control, 54*, 165–175.

Notes:

- Gutiérrez-Rodríguez, E., Gundersen, A., Sbodio, A. O., & Suslow, T. V. (2012). Variable agronomic practices, cultivar, strain source and initial contamination dose differentially affect survival of *Escherichia coli* on spinach. *J Appl Micro, 112*(1), 109–118.
- Yuk, H. G., Warren, B. R., & Schneider, K. R. (2007). Infiltration and survival of *Salmonella* spp. on tomato surfaces labeled using a low-energy carbon dioxide laser device. *Hort Technology, 17*(1), 67–71.

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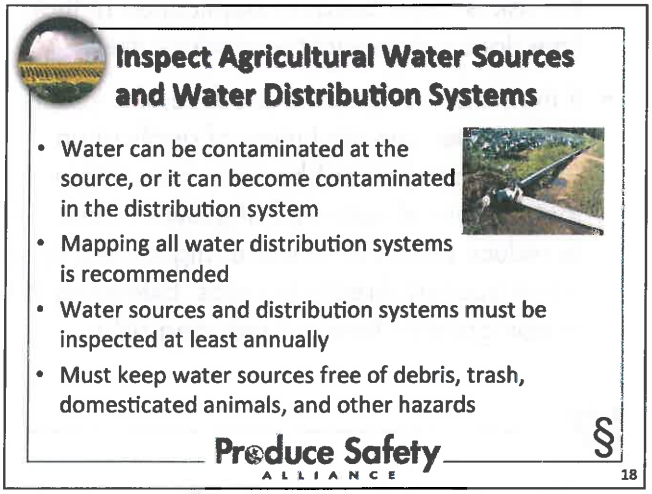

- This slide is the beginning of a series of slides that provide more details about Good Agricultural Practices (GAPs) and the regulatory requirements for water quality, water testing, and timing of application.
- Knowing how the water moves on the farm can help assess potential food safety risks. Growers 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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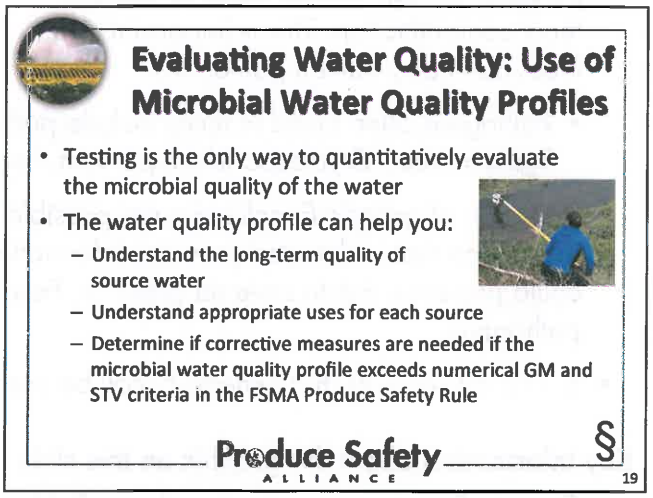

- Requirements related to the microbial water quality profile, corrective measures, and numerical GM and STV criteria are discussed in the upcoming slides. The geometric mean (GM) is a log-scale average, the "typical" value. The statistical threshold value (STV) is a measure of variability, the estimated "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.

Notes:

- 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.

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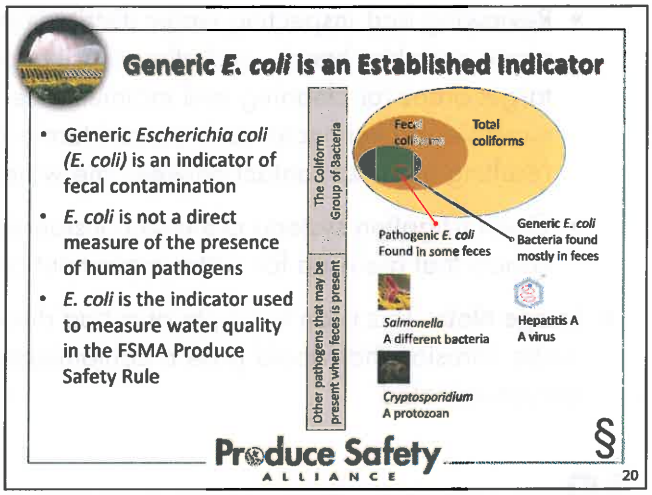

- Generic *E. coli* is an indicator of fecal contamination. Generic *E. coli* has historically been used as an indicator of fecal contamination for several types of water. However, presence of generic *E. coli* does not always mean that pathogens are present. Similarly, absence does not always mean that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

Notes:

- 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:

- Suslow, T. (2002). Eliminate Fecal Coliforms From Your Vegetable and Fruit Safety Vocabulary. http://ucanr.edu/sites/GAP/newsletters/Eliminate_Fecal_Coliforms41373.pdf
- United States Environmental Protection Agency (EPA) 2012 Recreational Water Quality Criteria: http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/upload/RWQC2012.pdf
- Wade, T. J., Pai, N., Eisenberg, J. N., & Colford Jr, J. M. (2003). Do US Environmental Protection Agency water quality guidelines for recreational waters prevent gastrointestinal illness? A systematic review and meta-analysis. *Environmental Health Perspectives*, 111(8), 1102.

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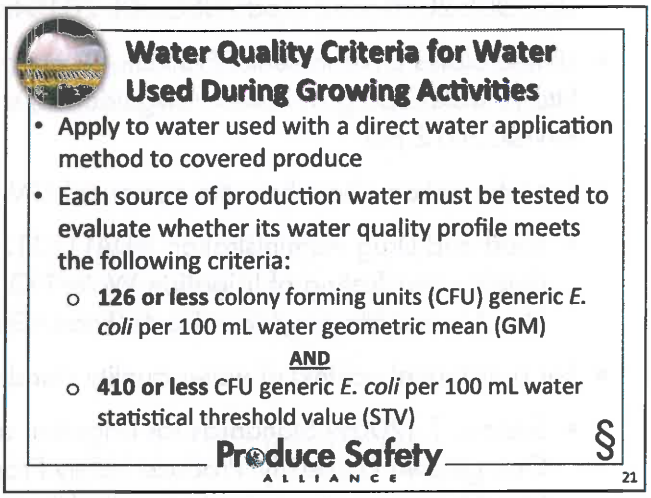

- § 112.44(b) specifies criteria for untreated agricultural water (both surface water and ground water) that is applied with a direct water application method to covered produce during growing activities.
- The numerical GM and STV criteria are used to evaluate the microbial water quality profile (MWQP).
  - 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.

Notes:

  - **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: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIV-sec342.pdf
- United States Environmental Protection Agency (EPA) 2012 Recreational Water Quality Criteria: http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/upload/RWQC2012.pdf
- For information about how the numerical GM and STV water quality criteria were developed
  - Food and Drug Administration (FDA) (2015) How did FDA Establish Requirements for Water Quality and Testing of Irrigation Water? Questions and Answers with Samir Assar: http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM473335.pdf
- For a historical context of water quality standards:
  - Suslow, T. (2009) Standards for Irrigation and Foliar Water Contact. Pew Charitable Trusts at Georgetown University. Produce Safety Project. http://www.pewtrusts.org/~/media/Assets/2009/PSPWaterSuslow1pdf.pdf
  - Dufour, A., & Schaub, S. (2007). The evolution of water quality criteria in the United States. *Statistical Framework for Recreational Water Quality Criteria and Monitoring*, 65, 1.

Notes:

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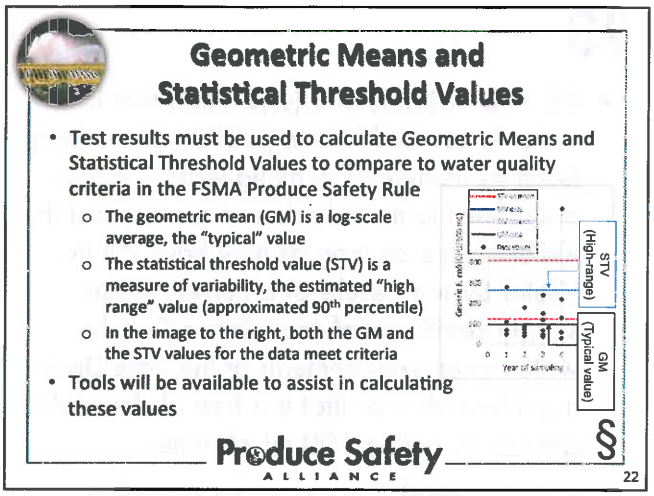

- The GM and STV criteria are used to determine compliance and appropriate uses of water, and to manage uses with appropriate corrective measures if necessary, under the FSMA Produce Safety Rule.
- The graph on the slide shows 21 generic *E. coli* results collected over four years (an initial survey). 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 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.
- There will be tools provided to make calculating the GM and STV easier. 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:

- Western Center for Food Safety. University of California Davis. Excel Tools to Calculate Geometric Means and Statistical Threshold Values: http://wcfs.ucdavis.edu/

Notes:

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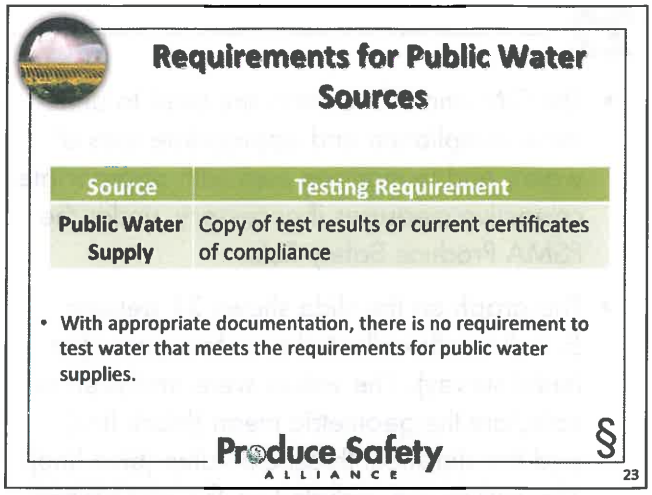

- §§ 112.46(a)(1) and (a)(2) state that if water is sourced from a public water supply (such as municipal drinking water), growers subject to the rule do not need to test the water source as long as they have Public Water System results or a current water supply certificate of compliance that the water 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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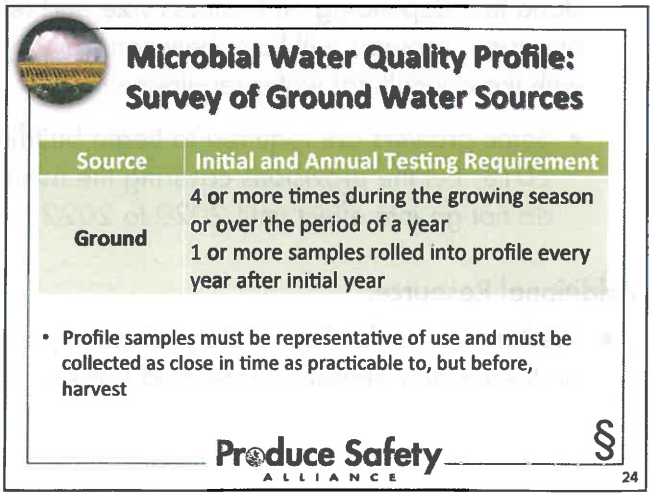

- **Ground water** sources of production water, such as wells, must be tested during an initial year and annually thereafter for calculation of the microbial water quality profile.
  - Initial year: 4 times throughout the growing season, or over the period of a year (§ 112.46(b)(1)(i)(B)).
  - Subsequent 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.

Notes:

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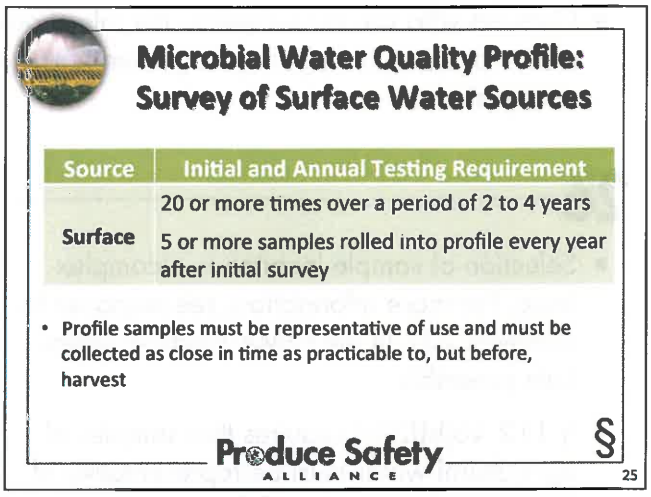

For surface water sources:

- 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.

Notes:

- 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).

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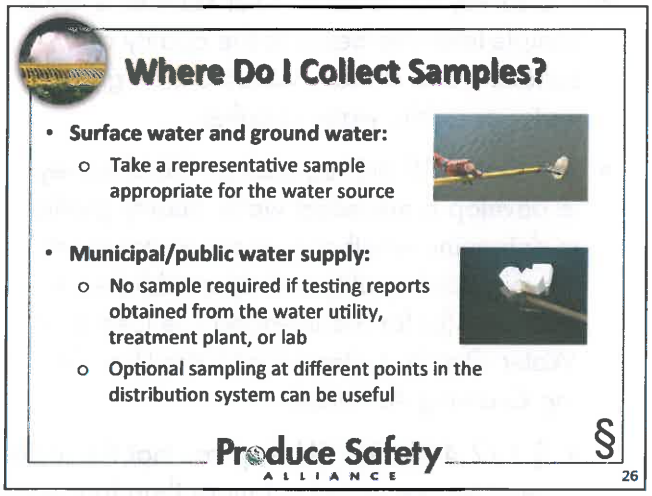

- Selection of sample location is a complex issue. For more information, see response to comment 237 in the FSMA Produce Safety Rule preamble.
- § 112.46(b)(2)(ii) requires that samples of agricultural water must be representative of the use of the water used during growing activities.
- The following 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:

- FSMA, Produce Safety Rule, 21 CFR 112 (2015), Comment/Response 237, pages 74451 to 74452.

Notes:

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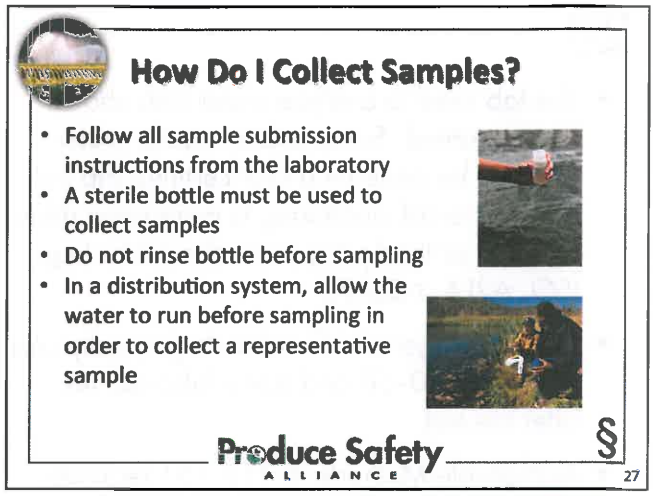
- The person collecting water samples should follow all sampling instructions from the laboratory, if provided.
- § 112.47(b) requires that samples must be collected using aseptic technique. This means the person collecting water samples must use a sterile bottle to collect samples and not contaminate 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.

Notes:

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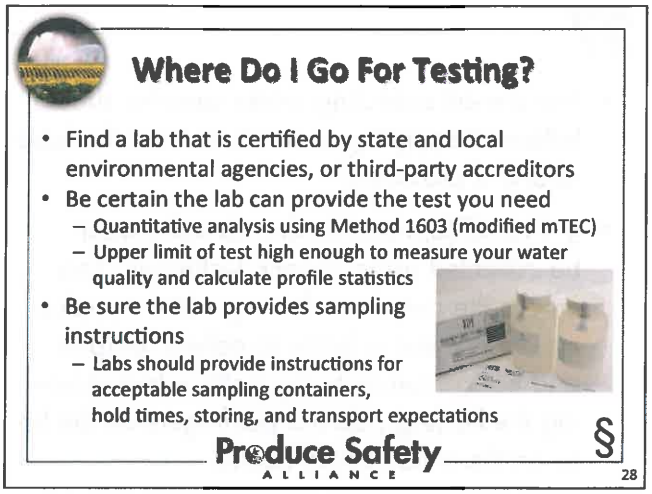

- The lab used to analyze water tests should be accredited. Some audits require water analysis be done by a GLP certified lab but environmental monitoring is more often done by State or third-party accredited labs (e.g., ISO, A2LA, NELAP).
- Quantified generic *E. coli* tests generally cost between $30–50 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 (www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm).
- 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.
  - 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.

Notes:

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

Additional Resources:

- Francy, DS and Darner, RA. (2000). Comparison of methods for determining *Escherichia coli* concentrations in recreational waters. *Water Research*, 34(10): 2770–2778.
- Pope, M. L., Bussen, M., Feige, M. A., Shadix, L., Gonder, S., Rodgers, C., Chambers, Y., Pulz, J., Miller, K., Connell, K., & Standridge, J. (2003). Assessment of the effects of holding time and temperature on *Escherichia coli* densities in surface water samples. *Appl Environ Micro*, 69(10), 6201–6207.
- EPA (2009). Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC).

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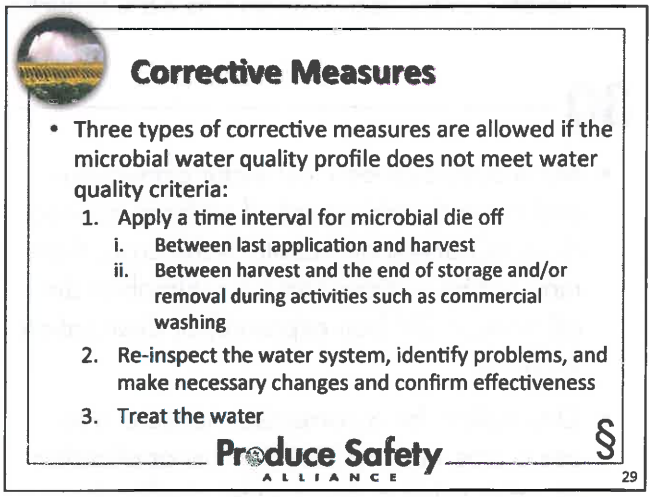

- Corrective measures specify requirements outlined in the FSMA Produce Safety Rule when specific numerical criteria are not met.
- § 112.45(b) requires that if the source microbial water quality profile (MWQP) does not meet numerical GM and STV criteria (see the slide *Water Quality Criteria for Water 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*. Provision 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.

Notes:

ii. Apply a time interval between harvest and end of storage. Provision 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 by approximated as 68% reduction (32% remaining).

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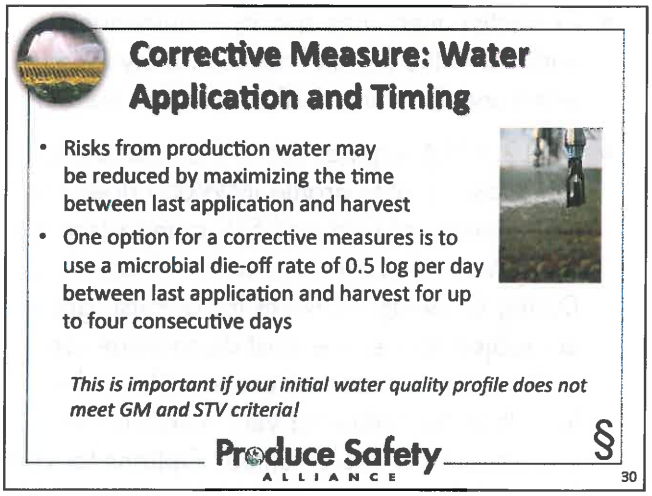

- More days between last water application and harvest reduces risk. If water is applied close to harvest and contacts the crop, there may not be sufficient time for microbial die-off through UV (sun exposure) or desiccation (drying).
- One option for a corrective measure is to use a time interval between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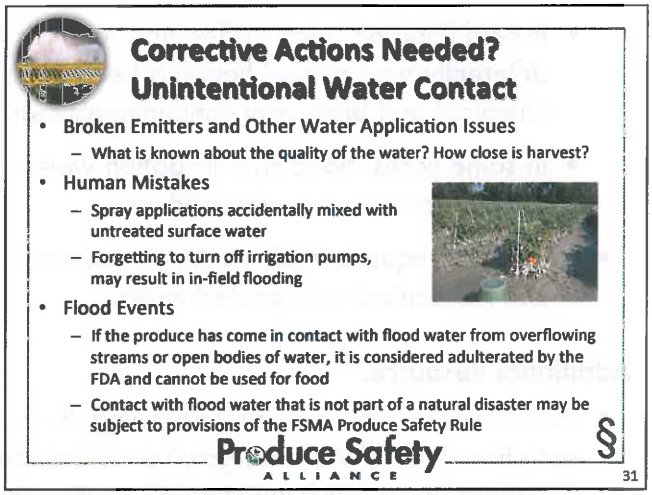

- The term **corrective action** as used in this module is a general term. It is intended to convey actions that are based on Good Agricultural Practices, that are not explicitly required in the FSMA Produce Safety Rule, but that can be used to support and comply with various provisions that are in the 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.
- <u>Broken Irrigation Equipment and Other Water Application Issues</u>
  - 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.
- <u>Human Mistakes</u>
  - 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.

Notes:

- 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.
  - 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:

- FDA Guidance for Industry: Evaluating the Safety of Flood-affected Food Crops for Human Consumption: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/EmergencyResponse/ucm287808.htm

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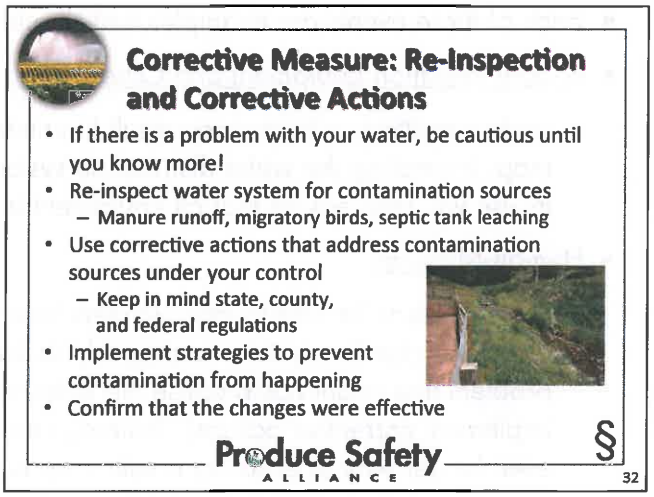
- § 112.45(b)(2) describes one of the three corrective measures in the FSMA Produce Safety Rule: re-inspect the entire affected agricultural water system and make changes to address any "known or reasonable foreseeable hazards" that are under the farm's control (refer to slide *Corrective Measures*).



Notes:

- 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.

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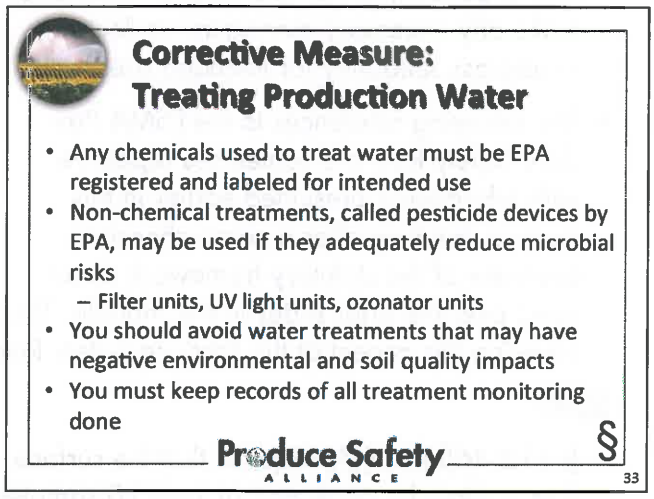
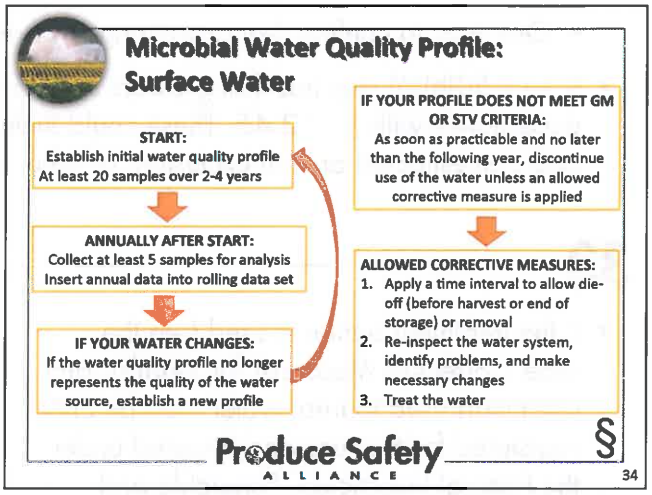


- If the treatment option is used (see the slide *Corrective Measures* for details), any chemicals used to treat water must be EPA-registered for that use and targeted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) before they can be lawfully used.
- Non-chemical options such as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

Notes:

- 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.

34 *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.

Notes:

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.

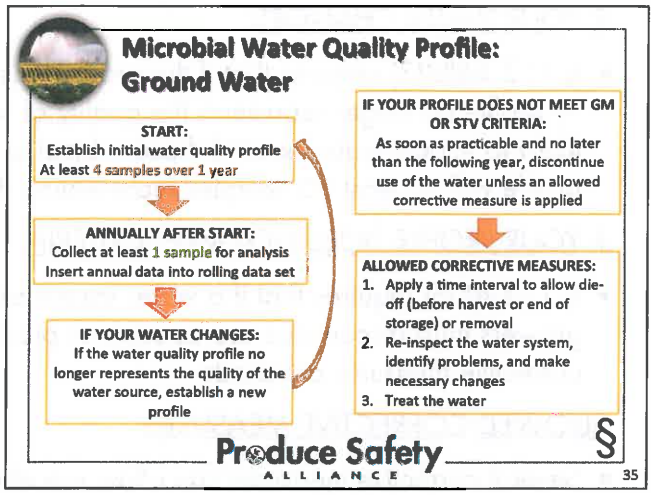
ALLOWED CORRECTIVE MEASURES:

- 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.* Provision 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. Provision 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.*
    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.*

Notes:

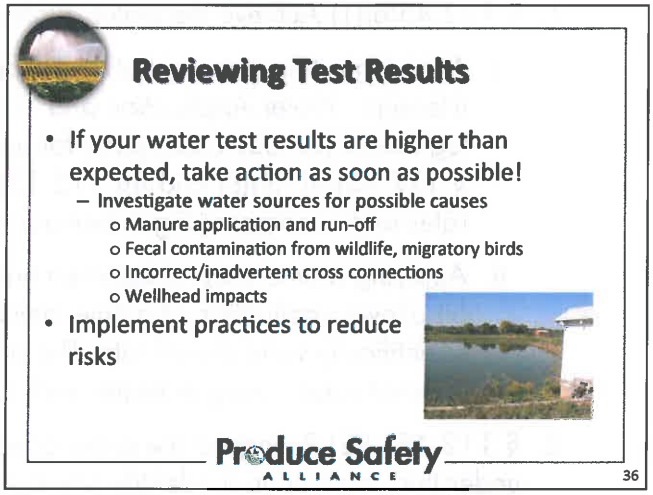
35 *Additional Information*

- 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*

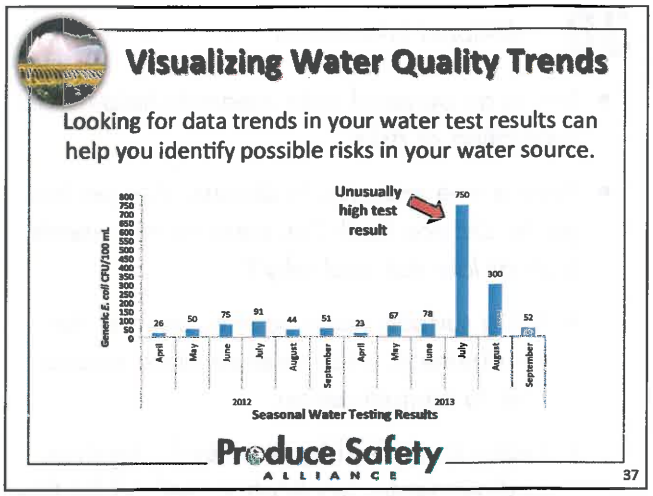
- This slide is optional.
- Testing water does not end when the sample is sent to the lab. The results should be reviewed and used to make decisions that enhance produce safety.
- If the water quality results are high growers should stop and consider whether it is safe to use the water for production 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.
  - Changing the application method (use drip instead of overhead irrigation).
  - Changing the water source (use well water instead of surface water for frost protection).

Notes:

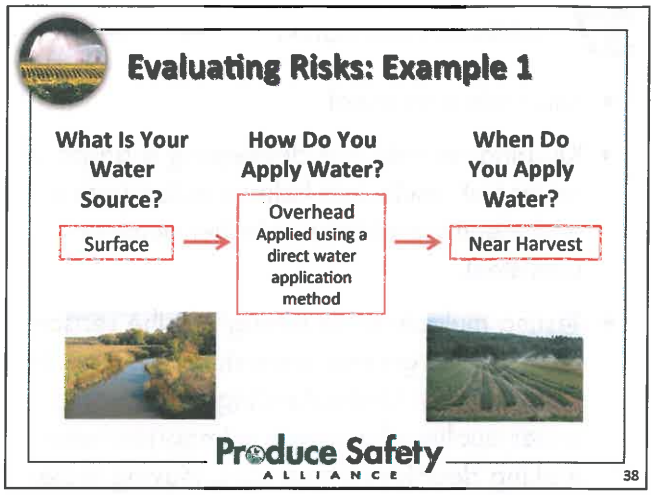
37 *Additional Information*



- 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.

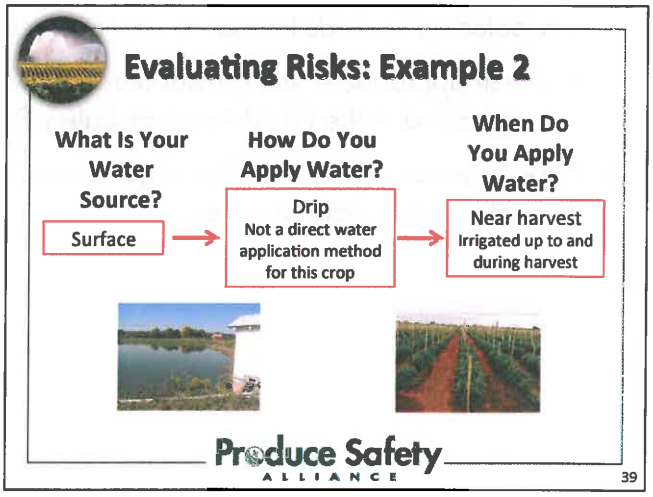
Notes:

38 *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.

39 *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).

Notes:

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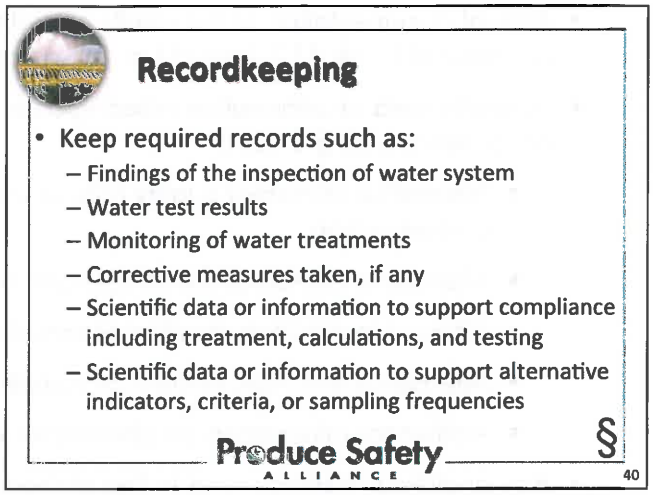

- Records for all analytical water tests must be kept, as well as any corrective measures that are taken to identify and reduce risks that may be present in the water or the water delivery system.
- Template logs are provided to assist growers with this recordkeeping process. Be sure the grower knows 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. Provision § 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.

Notes:

- 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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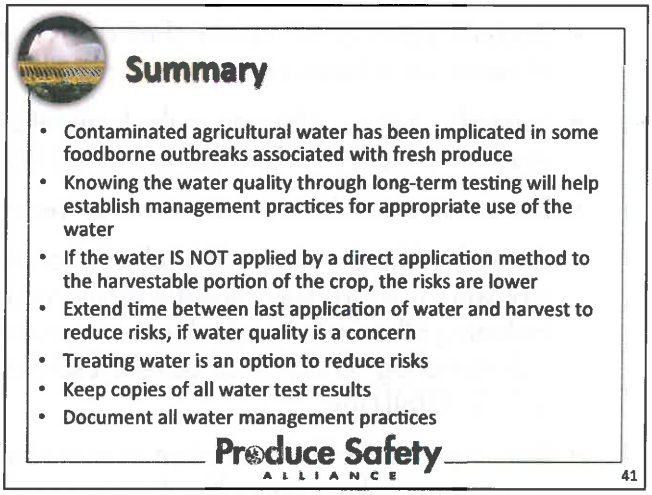

- Surface water can be used in the production of fresh produce, but growers should be aware of the microbial quality and the risks that may exist.
  - Water use decisions are made by 1) long-term testing for generic *E. coli* and calculating a microbial water quality profile and 2) water system inspection. 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.

Notes:

Produce Safety ALLIANCE

Agricultural Water—Part 2

Cornell University

5-2) Agricultural Water
Part 2: Postharvest Water

Learning Objectives
Module 5—Part II: Postharvest Water

Objective 1:
Understand the water quality criteria required for use in harvest and postharvest practices on covered produce.

Objective 2:
Identify ways postharvest water may become contaminated before and during use.

Objective 3:
Understand the conditions that lead to cross-contamination and infiltration, and ways to reduce these risks.

Objective 4:
Understand the purpose of adding antimicrobial products, including sanitizers, to postharvest water.

Objective 5:
Describe key practices to maintain and monitor the quality of water used in postharvest activities (e.g., sanitizer level, pH level, turbidity, ORP, temperature).

Objective 6:
Identify records needed to properly document and monitor the microbial quality of postharvest water and manage use to reduce the risks of contaminating fresh produce.

Objective 7:
Describe corrective actions that may be taken if postharvest water management fails to maintain adequate water quality or if there is reason to believe postharvest water is contaminated.

Critical Concepts

- Types of postharvest water uses and ways they impact produce safety
- Knowing water quality criteria for agricultural water used during and after harvest
- How to reduce the risk of cross-contamination by monitoring water quality and using sanitizers to maintain water quality during use
- Key water quality variables in postharvest water systems, including pH, temperature, and organic material buildup
- When water needs to be changed and how to properly dispose of grey water
- Available antimicrobial products (including sanitizers), how to select an appropriate product, and the importance of reading and following labels
- SOPs for workers to guide postharvest water management practices, such as adding sanitizer to wash water or when to change batch water
- Monitoring and recordkeeping practices for harvest and postharvest water management

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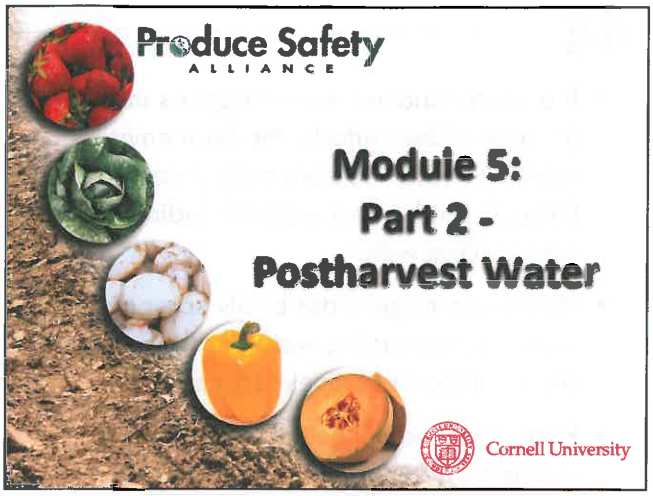
- This is the second part of the Agricultural Water Module.
- This section will focus on agricultural water uses during and after harvest of the produce crop.
- Postharvest water encompasses water that meets the definition of agricultural water and is used during and after harvest which can include agricultural water used in the field during harvest as well as during packing or holding activities.



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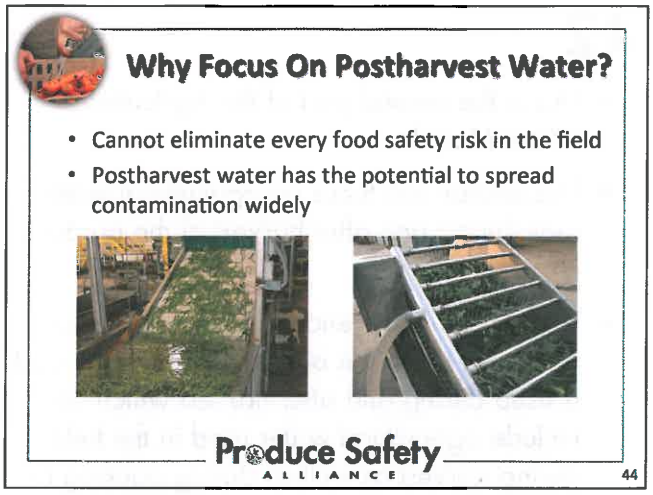
- If a contamination event happens in the field (in spite of best efforts, the farm environment will never be zero risk), it could spread through postharvest water including washing and cooling water.
- Human pathogens are easily spread through water, so managing water through appropriate sanitation practices reduces risks.
- Postharvest water quality management, including treatment (chemical or physical), can be used to reduce cross-contamination risks.



- Managing postharvest water quality can reduce food safety risks, but also can reduce risks from plant pathogens that could lead to postharvest rot and quality deterioration.

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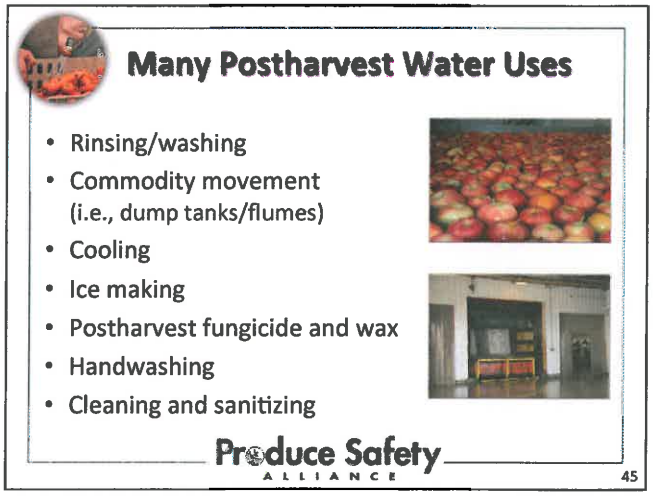
- Water is used in many ways during produce harvest, washing, cooling, and packing. Postharvest water management is important because there are many opportunities for spreading contamination if water is not managed properly.



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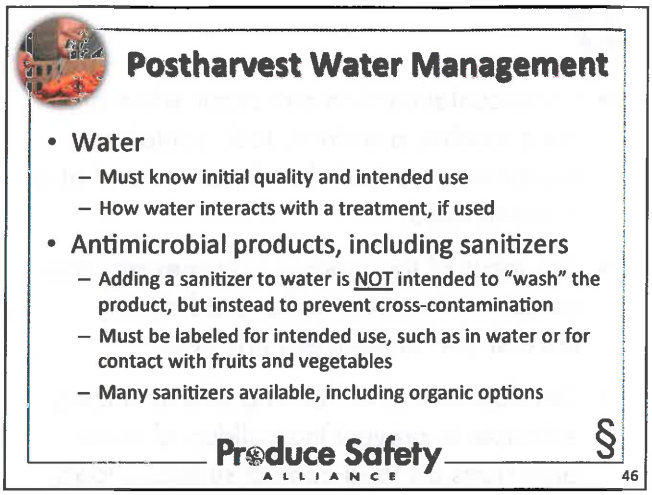

- For postharvest water management, there are two main things that growers will need to understand and manage, 1) the water quality at the start of use and, 2) water management strategies such as water treatments used to reduce cross-contamination risks by the water.
- **Sanitizers** are generally considered to be part of a broader group of substances called antimicrobial pesticides. These antimicrobial pesticides can be used for antimicrobial treatments. The antimicrobial product label will describe approved uses, such as for water or for food contact surfaces, as well as approved concentrations or dosages. EPA regulates and registers antimicrobial and chemical pesticides.
- One misconception is that sanitizer added to water is meant to 'wash' the produce—instead sanitizers are used to prevent the spread of contamination via water.
- Treatments of water that contact the produce, including the use of sanitizers, must be registered by EPA for that use. Registration information should be on the label, but in some cases the label information is included in paperwork that comes with the product. Growers may need to find additional information from the manufacturer that specifically lists allowable contact with fresh produce or food contact surfaces.
- Always follow the product label, because the label is the law.
- There are many different types of sanitizers available, including organic options.
- § 112.41 specifies that all agricultural water must be safe and of adequate sanitary quality for its intended use.
- § 112.44(a) includes specific microbial criteria for agricultural water used for certain high risk purposes.
- § 112.43 discusses water treatment requirements, if used.
- § 112.48 provides requirements for agricultural water used during harvest, packing, and holding activities.

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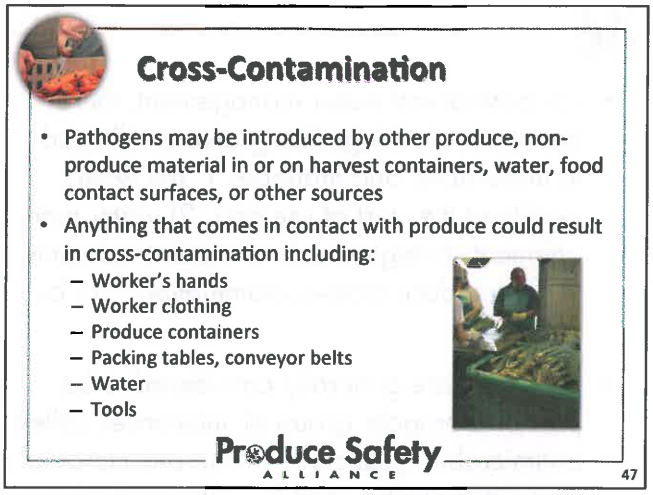

- Cross-contamination can occur when produce touches a surface, tool, container, equipment, worker's hands, or water that is contaminated.
- The focus of this module is to prevent cross-contamination from water used during harvest and postharvest practices.
- Development of a cleaning and sanitizing schedule to prevent the buildup of microorganisms on food contact surfaces, tools, equipment, and harvest containers is very important and will be discussed in more detail in the next section of the curriculum, **Module 6: Postharvest Handling and Sanitation**.
- Be sure to remind participants that it is important to cover worker health and hygiene requirements during worker training (especially handwashing) so workers know how to recognize and reduce risks throughout harvest and postharvest handling.

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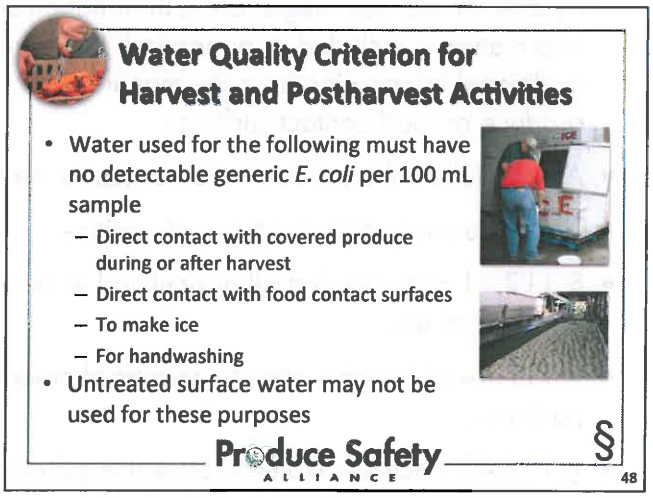

- Water that is used for harvest and postharvest activities must meet the standard of no detectable generic *E. coli* based on a 100 mL water sample. Untreated surface water must not be used for postharvest uses (§ 112.44(a)). This is a different microbial criterion than applied to production water (water used during growing activities), as discussed in Part I of this module.
- Water quality must be tested using EPA method 1603 (modified mTEC) or an equivalent method in accuracy, precision, and sensitivity as described in §§ 112.151(a) and (b).

Notes:

- §§ 112.44(a)(1) to (4) explicitly covers certain postharvest uses:
  - Used as sprout irrigation water. *Please direct any sprout producers to the Sprout Safety Alliance since educational materials have been developed specifically for this commodity.*
  - Any water that directly contacts covered produce during or after harvest activities (e.g., washing, hydro-cooling)
  - Any water that directly contacts food contact surfaces
  - Used to make ice that directly contacts covered produce and/or food contact surfaces
  - Used for washing hands during and after harvest activities
- If generic *E. coli* is detected in the 100 mL water sample or if the agricultural water is determined to not be safe or of adequate sanitary quality for its intended use, the grower must immediately discontinue its use (§ 112.45(a)).
- Before resuming use of the water source and/or water distribution system for postharvest uses, § 112.45(a) requires that growers either:
  1) Re-inspect the entire affected agricultural water system to the extent it is under their 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, as applicable, adequately ensure that their agricultural water meets the microbial quality criterion in § 112.44(a); or
  2) Treat the water in accordance with the requirements of § 112.43.
- § 112.43(a)(1) requires that when agricultural water is treated in accordance with § 112.45(a)(2) any method used to treat agricultural water 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.

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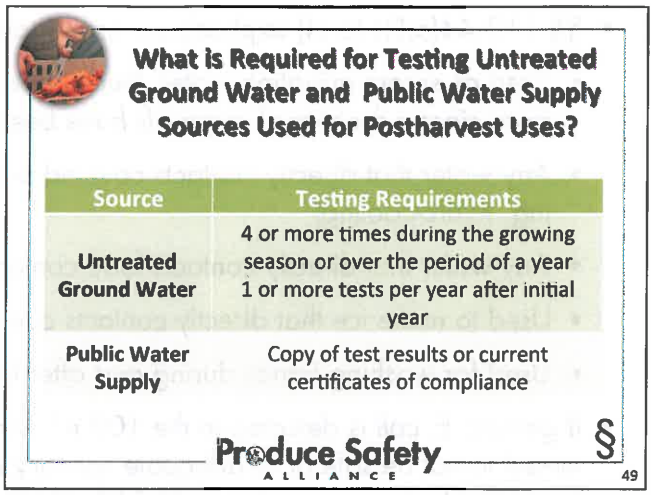

- § 112.46(c) requires that untreated **ground water** sources, such as well water, must be tested during an initial year and annually thereafter.
  - Initial year: At least 4 times during the growing season or over a period of a year, and based on these results, determine appropriate use.
  - Subsequent years: At least 1 time during the growing season or over the period of a year.
  - Agricultural water samples must be representative of the intended use.
  - If test values in subsequent years exceed the water quality standard (no detectable generic *E. coli* in 100 mL water), water sampling must be resumed to at least four times per growing season or year.
- Postharvest uses were listed in this module, slide *Water Quality Criterion for Harvest and Postharvest Activities.*
- §§ 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 public water supply water is held in containments open to the environment prior to using it as agricultural water, it would be considered equivalent to untreated surface water and it would not be suitable for use as postharvest water (§ 112.44(a)).

Notes:

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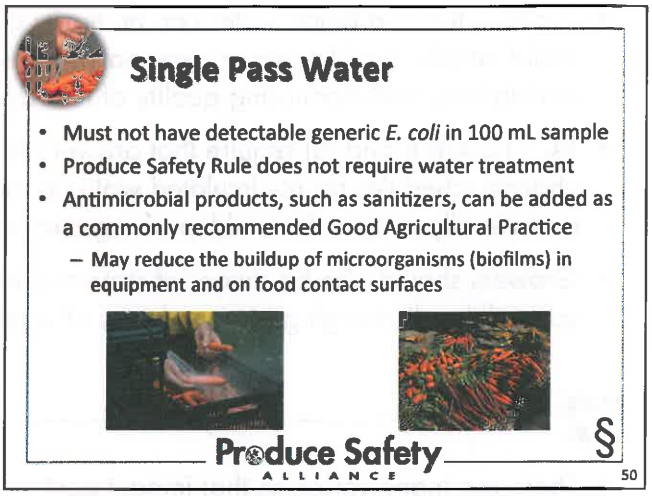
- Single pass water must have no detectable generic *E. coli* in a 100 mL water sample (§ 112.44(a)(2)).
- Although the FSMA Produce Safety Rule does not require treatment of single pass water, addition of sanitizer should be considered.
  - When used in water that contacts equipment and food contact surfaces, sanitizers may reduce buildup of microbes and **biofilms** on equipment surfaces, brushes, and rollers.



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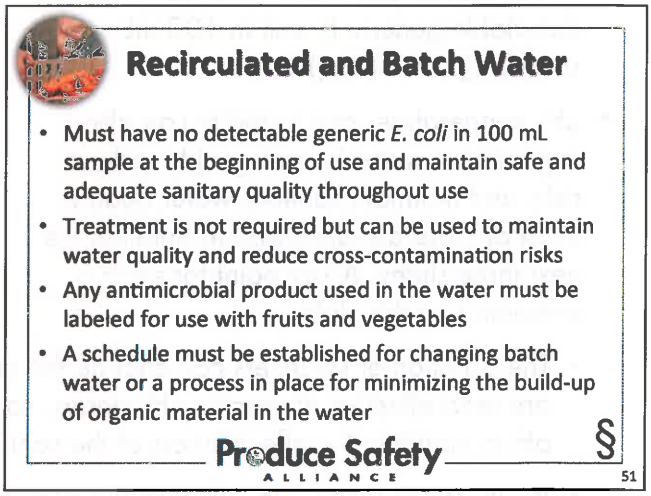
- All recirculated and batch water must begin with a microbial water quality that has no detectable generic *E. coli* in 100 mL water sample (§ 112.44(a)) and is safe and of adequate sanitary quality for its intended use (§ 112.41).
- A sanitizer is one way to prevent build-up of microorganisms in the water AND to prevent cross-contamination to fresh produce that contacts the water.



- Any sanitizer used in harvest and postharvest activities must be labeled for use in water that contacts fresh produce.
- Use of a sanitizer, or other physical or chemical treatment, is not required in the FSMA Produce Safety Rule, but,
  - § 112.41 requires water be safe and of adequate sanitary quality for the intended use; and
  - § 112.48(a) requires water be managed as necessary to maintain its safety.

Notes:

- Recirculated and batch water can be easily contaminated by incoming loads of produce which could introduce a "known or reasonably foreseeable hazard" such as pathogens, so a plan for maintaining and monitoring quality of recirculated and batch water is critical.
- §§ 112.48(a) and (b) require that growers who are covered by the regulation establish water change schedules for re-circulated water to maintain its safety and adequate sanitary quality, and visually monitor for buildup of organic material.
- Growers should also be aware of state and local waste water discharge issues and ordinances if you will be discharging large volumes of waste water.

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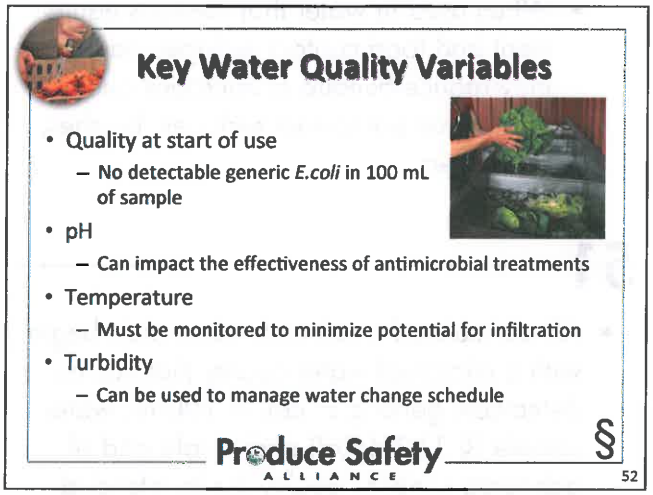

- There are many variables that impact post-harvest water quality and management practices.
- At the start of use, water must have no detectable generic *E. coli* in 100 mL water sample (§ 112.44(a)).
- pH, temperature, and turbidity can also impact how water is managed to reduce risks and maintain sanitary water quality. Each of these are discussed in detail in the next three slides. A key point for each is presented on this slide.
  - The addition of sanitizers can change the pH of the water. Some sanitizers, such as chlorine, are most effective at specific pH ranges, so growers may need to monitor and alter the water pH to maintain the effectiveness of the sanitizer. More details are provided in the next slide.
  - Water temperature can influence the occurrence of infiltration, which may introduce pathogens to the interior of the produce. The FSMA Produce Safety Rule requirements for water temperature (§ 112.48(c)), intended to minimize potential for infiltration, are described in detail in the *Temperature* slide of this module.
  - Turbidity can be used as an indicator of when water should be changed and is discussed more in the *Turbidity* slide of this module.

Notes:

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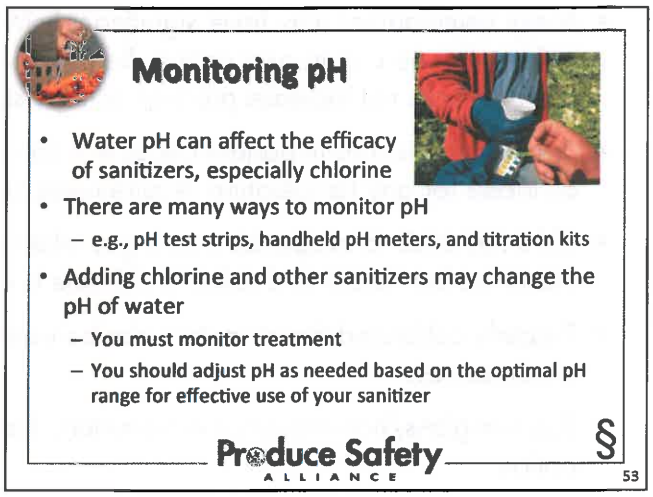

- Water pH can affect the efficacy of sanitizers, especially chlorine.
- § 112.43(b) requires monitoring of treatments for agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.
- pH test strips are the most common way to get a general understanding of pH levels. They can be purchased for a low cost but they are not as sensitive or accurate as other methods, such as an electronic pH meter or titration kit. Some farms choose to use multiple monitoring methods throughout the day. Be sure to check the expiration date of any type of monitoring strips or titration kit.
- Adding a sanitizer can change the pH of the water, so monitor and adjust as needed. When modifying the pH be sure to use an approved food grade product such as citric acid or acetic acid.

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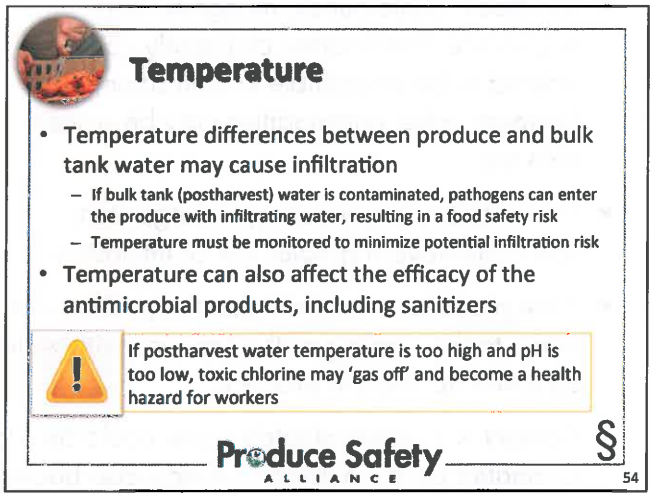

- § 112.48(c) requires that you must maintain and monitor the temperature of water that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.
- Differences between water temperature and temperature of harvested produce may cause infiltration to occur (explained on the next slide).

Notes:

- Many commodities may have significant field heat and water may be used to cool the produce before storage and transportation. Be sure that the system you are using to cool produce is effective and does not increase produce safety risks.
- Temperature is also important because it can affect how well a sanitizer works. Be sure to read all labels for any temperature requirements before using a sanitizer.
- Chlorine tends to evaporate into a gas when the water temperature is too high so be cautious about worker health and safety if chlorine is used with warmer water temperatures.
- Properly calibrated thermometers can be used to monitor both water and produce pulp temperatures.
- Use non-glass/non-mercury thermometers; handheld infra-red thermometers are a non-contact option.

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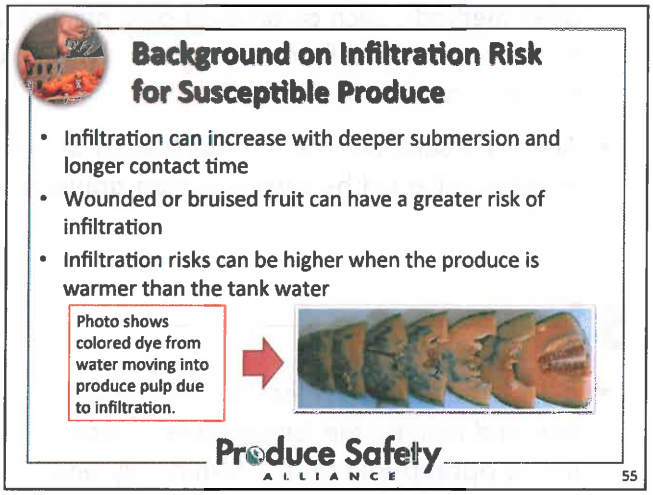

- There can be a higher risk of infiltration if the produce is submerged rather than sprayed with water or floated. The longer the produce is in contact with the water, the higher the risk.
- Tomatoes, cantaloupes, mangoes, and apples are commodities commonly considered to be susceptible to infiltration; however, other commodities may be susceptible too.
- Fruit with bruises, wounds, or large stem scars can have a greater risk of infiltration.
- If the produce is warmer than the postharvest water, especially in bulk water situations such as dump tanks, cooling of the produce with water may create a vacuum inside and cause water to be taken up into the produce.
- Contact with contaminated water could be problematic, as the produce may be not only contaminated on the outside, but may also become contaminated on the inside by infiltration water.
- Photo note: Blue dye shows movement of water into warm cantaloupe after submersion in cold wash water with dye.

Notes:

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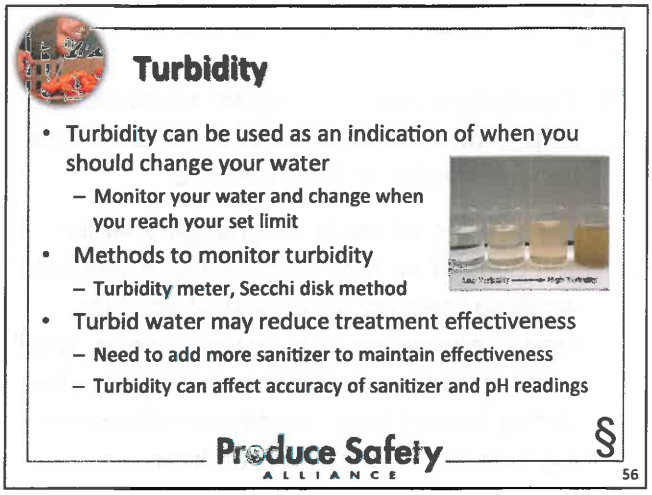

- Turbidity is the level of water cloudiness. Water may become turbid after one load or multiple loads of produce. Removing soil, leaves, and other debris prior to running produce through a bulk or batch water cooling or washing system can reduce turbidity in the tank.
- § 112.48(b) requires that those subject to the rule visually monitor the quality of water that is used during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).
- Turbidity can be measured and monitored using a variety of methods such as electronic turbidity meters or turbidity tubes equipped with a Secchi Disk.
- Reducing turbidity is key because suspended soil and organic matter can interfere with water quality tests such as pH and chlorine strips. Organic matter can also bind or 'consume' sanitizers, making them less effective.
- Some antimicrobial products, including sanitizers, are less impacted by turbidity, so growers may want to choose a product that functions better in these conditions if turbidity is difficult to manage in a particular washing system.

Additional Resource:

- Top FAQs about Produce Wash Water Management for Small-Scale and Direct Market Farms (Including the Secchi Disk method): http://www.centerforproducesafety.org/amass/documents/document/105/FINAL%20CPS%20Webinar%20Slides%209.21.2012_Updated.pdf

Notes:

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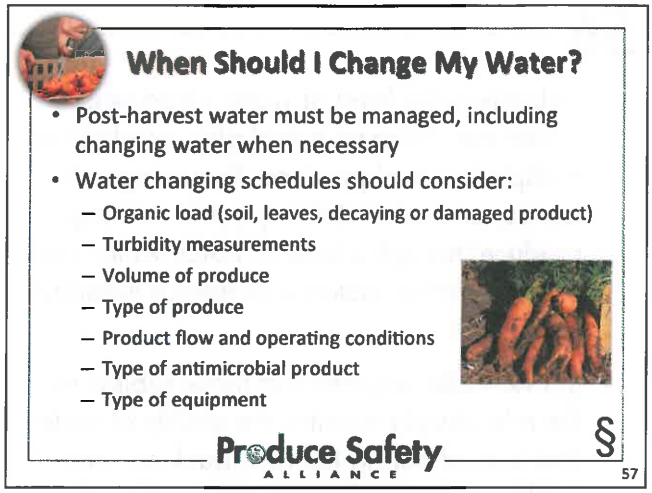

- Changing water on a regular schedule can help reduce the chances of cross-contamination from water to fresh produce.
- The specific schedule for changing water will depend on how much produce you are washing/cooling, what type of produce, type of equipment (e.g., large scale vs. small scale, presence of filtration device), weather during harvest (e.g., muddy conditions during harvest), and type of sanitizer.
- § 112.48(a) requires that postharvest water must be managed, as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).

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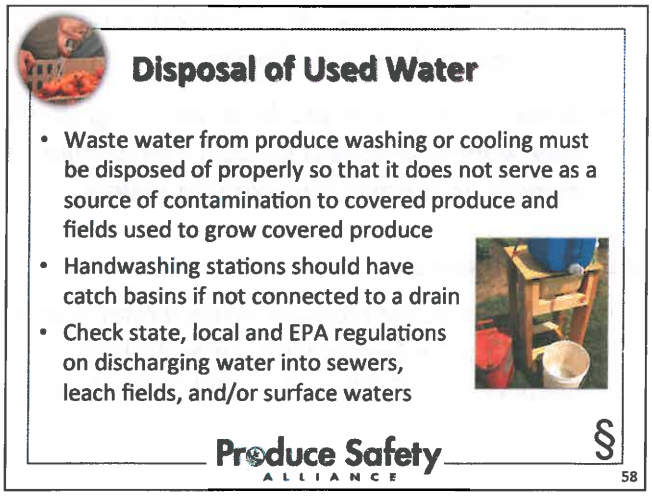

- Used water from washing and cooling produce must be properly disposed of so that it does not serve as a source of contamination to food contact surfaces and other areas used for covered activities (including production and packing areas) (§§ 112.132 and 112.133).
- § 112.130(c) requires appropriate disposal of waste associated with handwashing facilities and taking appropriate measures to prevent waste water from handwashing facilities from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

Notes:

  - Waste water should be discharged away from production and packing areas, preferably down a drain or into a catch basin.
- Always check local and EPA regulations before discharging water into sewer systems or the environment, especially if the water contains a sanitizer or other chemical additive.
  - Aquatic organisms can be sensitive to chlorine and other sanitizers; therefore, make sure that any waste water discharged to natural areas will not adversely affect surrounding vegetation or wildlife.

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- There are many different types of sanitizers available to use in postharvest water systems.
- A commonly used sanitizer is chlorine because it is inexpensive, however, it can be corrosive to certain materials such as stainless steel.
- Ozone, peroxyacetic acid, and hydrogen peroxide are other options for postharvest systems.
- There are many organic options available. Be sure growers check with their organic certifier before they use a sanitizer to make sure it is acceptable. Synthetic substances allowed for use in organic crop production can be found in 7 C.F.R. § 205.601 (2015).

Additional Resources:

- Suslow, T. (1997). Postharvest Chlorination. University of California, Division of Agriculture and Natural Resources. http://ucfoodsafety.ucdavis.edu/files/26414.pdf
- Suslow, T. (2004). Ozone applications for postharvest disinfection of edible horticultural crops. University of California, Division of Agriculture and Natural Resources. http://anrcatalog.ucdavis.edu/pdf/8133.pdf
- Suslow, T. (2006). Making sense of rules governing chlorine contact in postharvest handling of organic produce. University of California, Division of Agriculture and Natural Resources. http://anrcatalog.ucdavis.edu/pdf/8198.pdf

Notes:

- University of California Davis: Postharvest Technology Yellow Pages: http://postharvest.ucdavis.edu/yellowpages/?maincat=31

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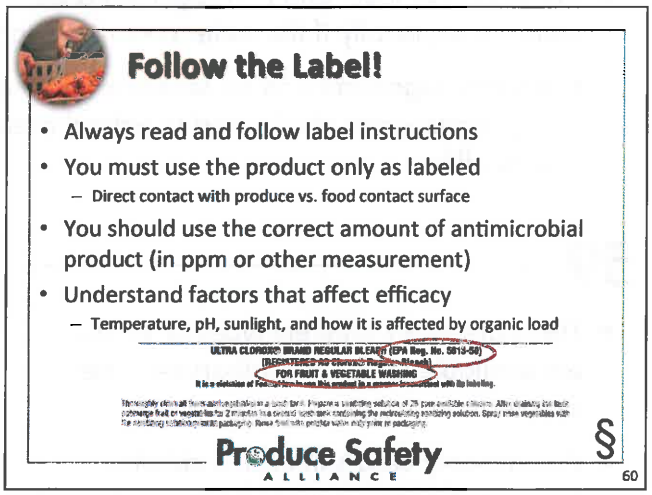

- Not all sanitizers are approved for use in water that contacts fresh fruits and vegetables.
- Be sure to read the labels and check any local, state and federal requirements and registration lists of approved products. U.S. EPA maintains a list of antimicrobial product registration.
- Growers should understand how to calculate the amount of sanitizer needed for the volume of water based on the target concentration of the sanitizer to make sure it is effective at controlling their target microorganisms, and write the steps and target sanitizer concentration into Standard Operating Procedures for their staff to follow.
- Growers should review § 112.43 because it contains several sections that discuss requirements for safety and sanitary quality of water, including use of water treatments, delivery, and monitoring. All of these requirements have been discussed earlier in this module.

Additional Resources:

- Suslow, T. (2001). Water Disinfection: A Practical Approach to Calculating Dose Values for Preharvest and Postharvest Applications. University of California, Division of Agriculture and Natural Resources.http://anrcatalog.ucdavis.edu/pdf/7256.pdf
- US-EPA Antimicrobial Products Registered with the EPA as Sterilizers: http://www.epa.gov/sites/production/files/2015-09/documents/list_a_sterilizer.pdf

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- Each sanitizer will have its own specific approach to monitoring.
- Some monitoring can be done automatically through in-line systems that both monitor and inject sanitizer when necessary.
- § 112.43(b) requires that those subject to the rule must monitor any water treatment at a frequency to ensure the treated water is consistently safe and of adequate sanitary quality and/or meets the relevant microbial quality criteria, as applicable.
  - For any treatment method, including use of sanitizers, growers covered by the rule must monitor at a frequency sufficient to maintain sanitizer concentration and pH at effective levels under their operating conditions.
  - For example, if the sanitizer level drops 30 minutes into a run and it is only being monitored once every 2 hours, this is not frequent enough monitoring and the monitoring frequency may need to be increased.
- If growers have any questions about monitoring sanitizers, they should contact the sanitizer supplier.
- ORP meters are another option for monitoring the effectiveness of sanitizers in water (described in the *Oxidation Reduction Potential* slide, optional).

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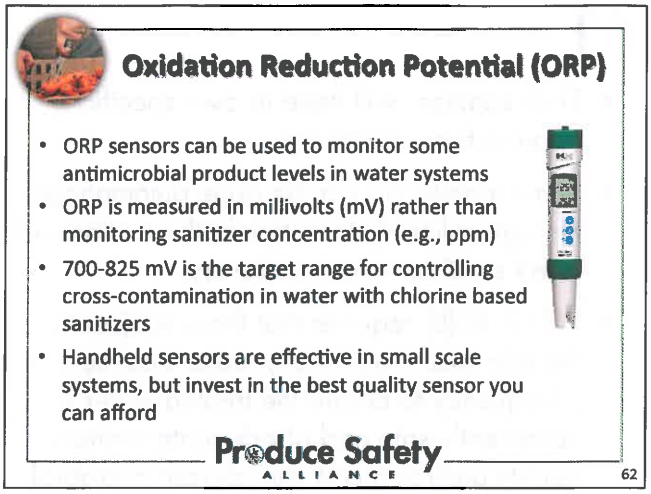
62 *Additional Information*



- This slide is optional.
- Oxidation Reduction Potential "is the potential (voltage) at which oxidation occurs at the anode (positive) and reduction occurs at the cathode (negative) of an electrochemical cell…an oxidizing chemical pulls electrons away from the cell membrane, causing it to become destabilized and leaky. Destroying the integrity of the cell membrane leads to rapid death" of microorganisms, including pathogens. (Suslow 2004)
- ORP can be used to determine the amount of sanitizer to add to water to reach the ideal voltage of 700–825 mV.
- ORP works well with chlorine, but does not work well with hydrogen peroxide or peroxyacetic acid treatments.

Additional Resource:

- Suslow, T. (2004). Oxidation-Reduction Potential for Water Disinfection Monitoring, Control, and Documentation. University of California, Division of Agriculture and Natural Resources. http://anrcatalog.ucdavis.edu/pdf/8149.pdf

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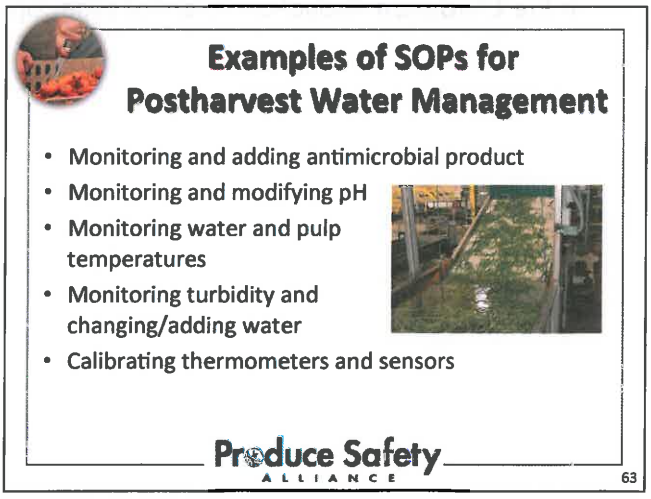

- These are just suggestions for **Standard Operating Procedures (SOPs)** that could be developed to aid in postharvest water management—there may be others that could be used, depending on the type of operation and activities being done on the farm.
- SOPs should be shared during worker training programs so workers know exactly how to do jobs critical to postharvest water management.

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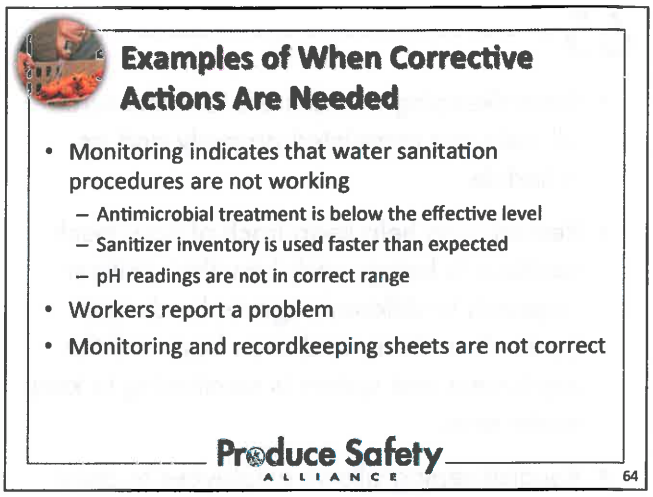

- With monitoring in place, it is important to consider when it might be necessary to use corrective actions. Here are a few scenarios where corrective actions may be necessary to protect the safety of the produce.
  - Example #1: Monitoring indicates water sanitation procedures are NOT working properly. Recordkeeping sheets may show that growers have used much more of the sanitizer product than they were expecting, which might indicate the automatic dispenser is not functioning or a worker is not measuring properly. This may require retraining workers or calibrating equipment.
  - Example #2: A worker notices a problem with the dosing meter while they are working. It is very important that workers feel empowered to speak up and report things that seem wrong or out of place. The farm should investigate the report and determine if a corrective action is needed.
  - Example #3: A review of recordkeeping sheets indicates monitoring is not happening on the set schedule. Growers should re-check monitoring practices such as if computer records are not being saved properly or if a worker is not logging their tasks properly.
- These scenarios might mean that growers need to re-treat the water with additional sanitizer, test water sources again for proper sanitizer and pH levels, evaluate whether the water could pose a food safety risk to any produce that it touched, or retrain workers. The important thing is to follow up when something goes wrong so that it is less likely to happen again!

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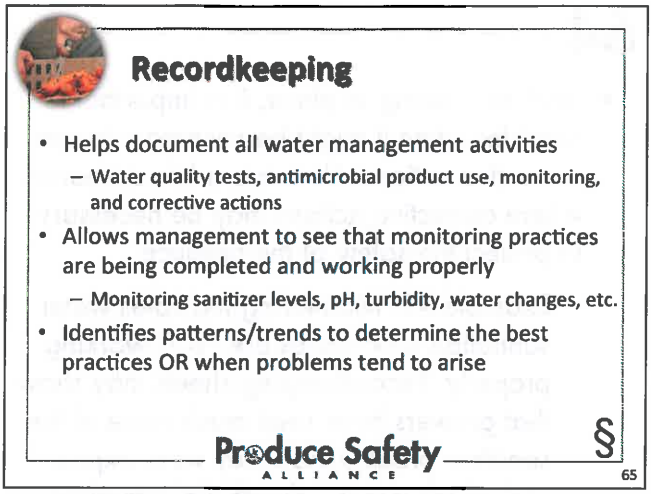

- Recordkeeping is important to make sure all tasks are completed properly and on schedule.
- Records can help keep track of how much sanitizer is being used, how the sanitizer responds to different organic loads and types of produce, and even how well the equipment and system is functioning to keep water safe.
- Recordkeeping allows employees to document tasks they have completed (in real time) and for management to see monitoring practices are being completed.
- Proper management and review of records can help identify trends or problems over time. Records that are never reviewed have less value because management is not benefiting from the recordkeeping investment.
- §§ 112.50(b)(1) through (9) requires that those subject to the rule must establish and keep the following records that are relevant to postharvest water, specifically:
  1) The findings of the inspection of the agricultural water system in accordance with the requirements of § 112.42(a).
  2) Results of any analytical tests conducted on agricultural water to comply with FSMA Produce Safety Rule provisions.
  3) Scientific data or information growers rely on to support the adequacy of the methods used to satisfy §§ 112.43(a)(1) and (2) for water treatment.
  4) Documentation of the results of water treatment monitoring as required by § 112.43(b).
  5) 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).

Notes:

6) Documentation of actions taken in accordance with § 112.45. Provision § 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.

7) Annual documentation of the results or certificates of compliance from a public water system as outlined in §§ 112.46(a)(1) or (2), as applicable.

8) Scientific data or information that were relied upon to support any alternative established and used on the farm in accordance with § 112.49.

9) Any analytical methods you use 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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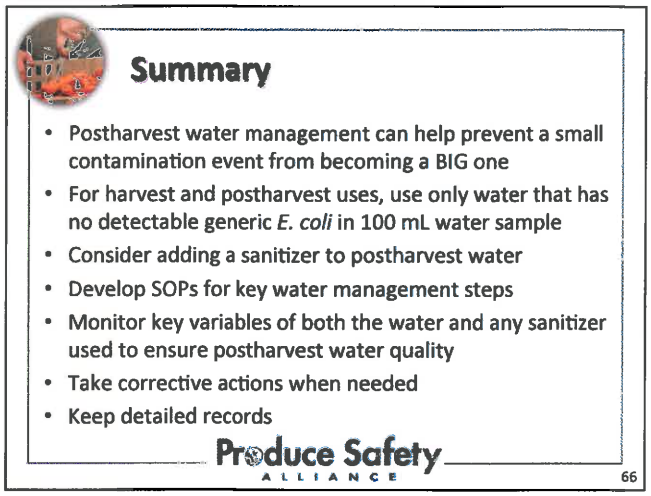

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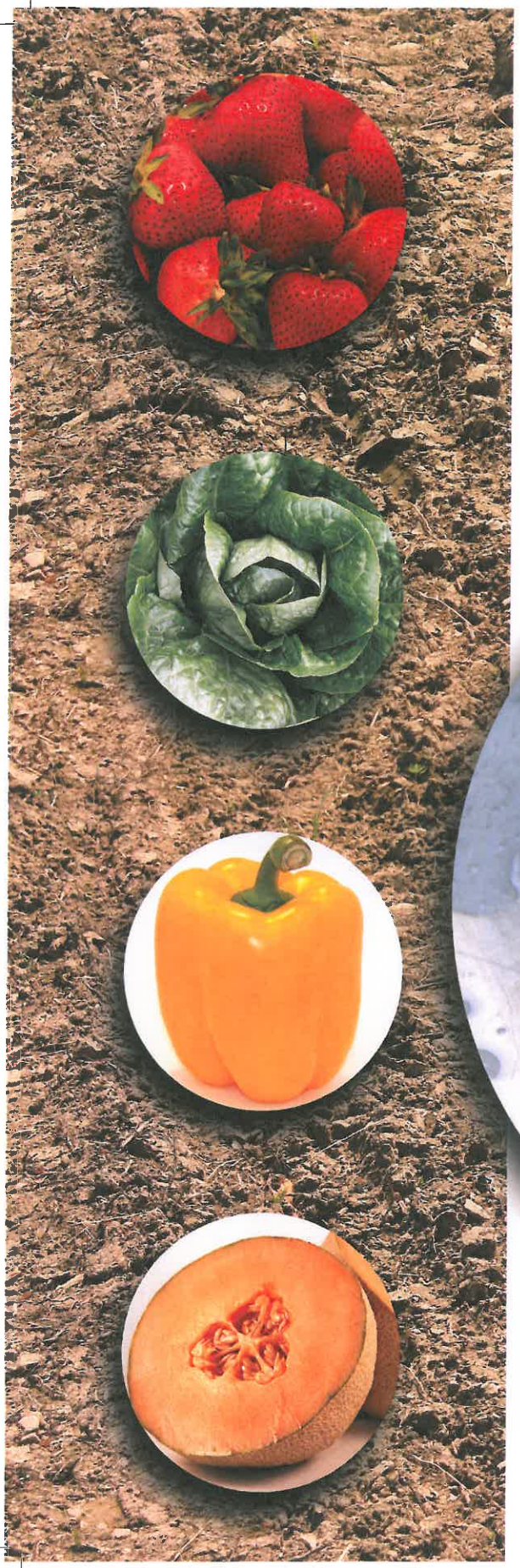

Produce Safety
ALLIANCE

Postharvest Handling and Sanitation

6) Postharvest Handling and Sanitation

Cornell University

Learning Objectives
Module 6: Postharvest Handling and Sanitation

Objective 1:

Identify potential routes of contamination associated with harvesting, washing, packing, storage, cooling, and transportation activities.

Objective 2:

Identify key practices that can be implemented and maintained to reduce identified risks in produce handling areas.

Objective 3:

Identify the steps involved in cleaning and sanitizing food contact surfaces.

Objective 4:

Define key parts of a pest control program that will reduce or eliminate rodents, birds, insects, and other pests from postharvest handling areas.

Objective 5:

Describe key practices for transporting fresh produce that will minimize produce safety risks.

Objective 6:

List critical practices that need to be monitored during postharvest handling to ensure sanitary practices are being followed.

Objective 7:

Describe corrective actions that could be taken to reduce the risk of contaminating produce during postharvest handling.

Objective 8:

Identify key records to document postharvest handling practices that prevent the contamination of fresh produce.

Critical Concepts

- Common produce safety risks that occur during postharvest handling
- Principles of basic and advanced sanitation
- Define zones within packing areas to prioritize cleaning and sanitation efforts
- Understand the difference between cleaning and sanitizing
- Principles of sanitary design and construction, including retrofitting equipment
- General packing area maintenance and appropriate packing containers
- Pest control management in produce packing and storage areas
- Considerations for sanitary transportation of produce
- Standard Operating Procedures (SOPs) that can be developed for postharvest activities
- Chemical and physical food safety risks that may exist on the farm and in packing areas
- Corrective actions and recordkeeping that can be used to reduce produce safety risks

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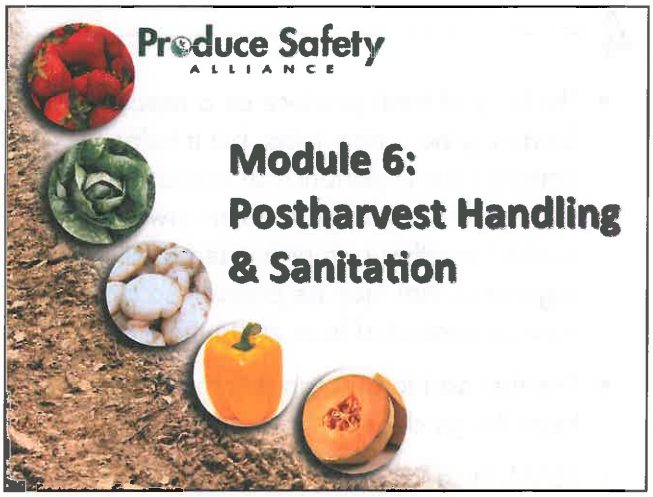
- **Module 6: Postharvest Handling & Sanitation** encompasses practices in the field during harvest, as well as during postharvest handling, packing, and holding activities.



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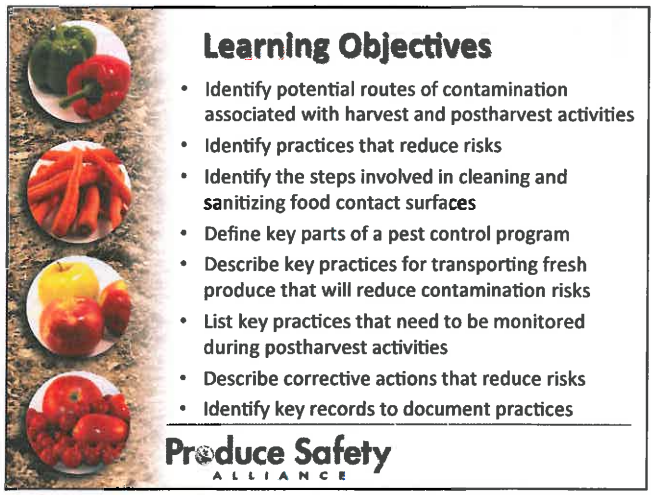

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- Thinking of fresh produce as a ready to eat food may be a new idea, but it helps to highlight the importance of sanitation. Fruits and vegetables that are eaten raw are not cooked or otherwise processed to kill microorganisms that may be present, so produce must be protected from contamination.
- The first part to any sanitation program is to keep things clean.
- FSMA Produce Safety Rule—Subpart K (§ 112.111–§ 112.116) includes standards for growing, harvesting, packing, and **holding** activities; Subpart L (§ 112.121–§ 112.140) includes standards for equipment, tools, buildings, and sanitation. Both of these areas are discussed throughout this module.

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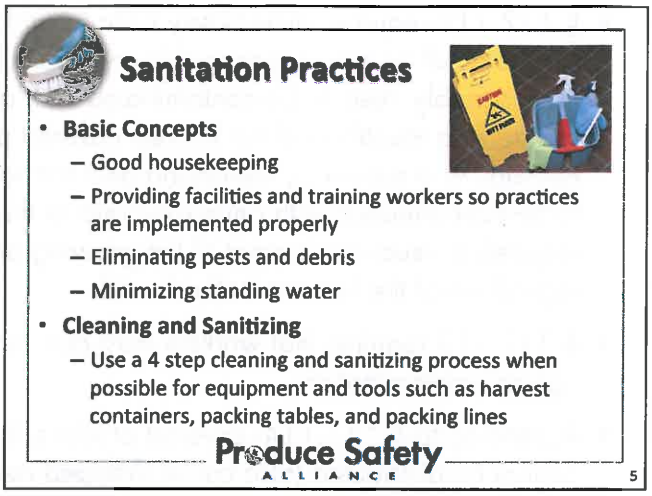

- Basic housekeeping is the first step. Organize the farm so that produce handling areas are separate from tractor repair, animal care, or other farm tasks that could introduce food safety risks.
- Some basic practices are required in the FSMA Produce Safety Rule and they are covered in detail later in the module, including disposing of trash and eliminating pests.
- In practical terms, this could mean sweeping, emptying trash and cull piles/containers daily, cleaning up spills, and developing pest control programs.
- Once basic practices are in place, implement the four steps to cleaning and sanitizing. Cleaning and sanitizing surfaces are required in some cases, such as for food contact surfaces. It is not possible to sanitize every surface, but when possible, the four steps should be completed to keep reusable harvest containers, tools, grading tables, and packing equipment clean and to reduce the presence of microorganisms. The full four steps to cleaning and sanitizing are reviewed later in this module.

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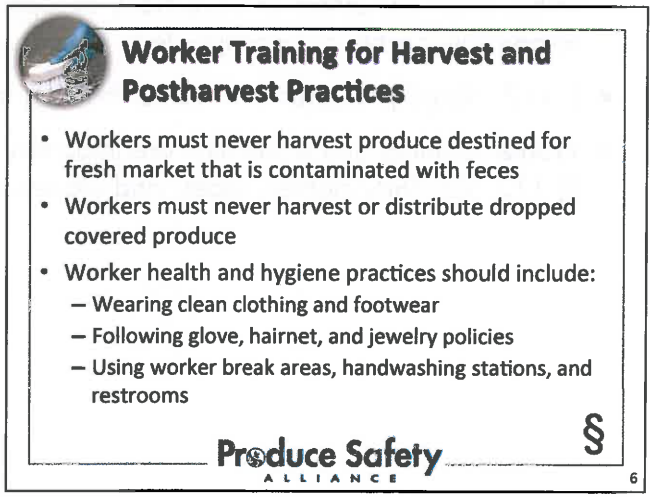

- Workers are key to ensuring harvest and postharvest activities are done properly, so they must be trained. Worker training was covered in **Module 2: Worker Health, Hygiene, and Training** but here are some specific requirements that might be valuable to cover again.

Notes:

- § 112.112 requires immediately prior to and during harvest activities, those subject to the rule must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.
- § 112.113 requires that workers must also harvest covered produce in a manner that protects against contamination.
- According to § 112.114, covered produce that drops to the ground before or during harvest cannot be distributed (also called **dropped covered produce** in the glossary). Crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or crops that are intentionally dropped to the ground as part of harvesting (such as almonds) are not included in this dropped covered produce requirement.
- § 112.22(b) requires that persons who conduct harvest activities for covered produce must also receive training that includes all of the following: (1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards; (2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and (3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.
- § 112.22(a)(1) requires that worker training include principles of food hygiene and food safety.
- Worker clothing and equipment are important and there are requirements for hygienic practices (§ 112.32). Dirty clothes, shoes, and gloves can lead to cross-contamination of produce.

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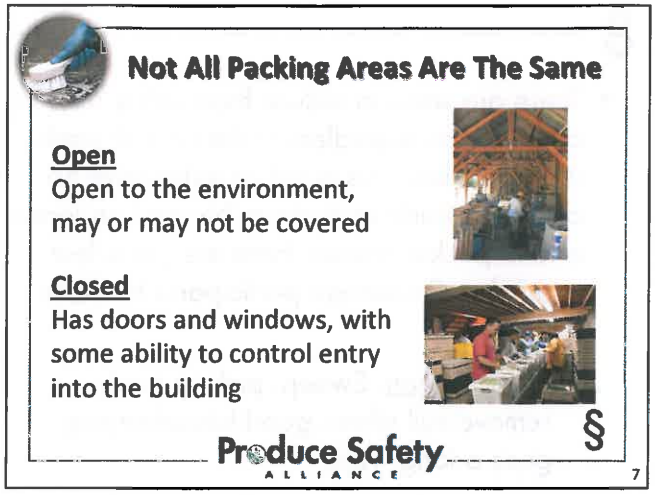

- Not all packing operations are designed or used the same way. Some packing areas are closed to the outside environment, much like a food production facility. Others are open to the outside making them more susceptible to contamination.
- When thinking about how to manage food safety risks during postharvest handling, take into consideration the level of control that is possible in the packing environment.
  - If using an open packing area (such as 'four sticks and a lid', tent or pavilion)—prevent pests such as roosting birds and keep the area as clean as possible to discourage other pests.
  - Environmental contaminants such as blowing dirt and field runoff may also be a potential source of contamination if the packing shed is open.
  - Closed packing areas have a greater level of control, simply because they have walls, windows, and doors. Keeping pests out and keeping the area clean still takes effort, so be sure door seals are in place and windows are screened to reduce pest entry. A pest control and monitoring program must be in place and those regulatory requirements are covered later in this module.
  - Regardless of the type of packing area, it is a requirement to clean and, when necessary and appropriate, sanitize food contact surfaces.
- § 112.122(a) states that both fully and partially enclosed buildings used for covered activities, including those that have a roof but no walls are subject to Subpart L of the rule.
- § 112.126(a) requires that buildings must be suitable size, construction, and design to facilitate maintenance and sanitary operations. This includes providing adequate space for equipment and storage, keeping floors, walls, ceilings, fixtures, ducts, and pipes clean and in good repair, and taking precautions to separate produce and food contact surfaces from potential contamination.

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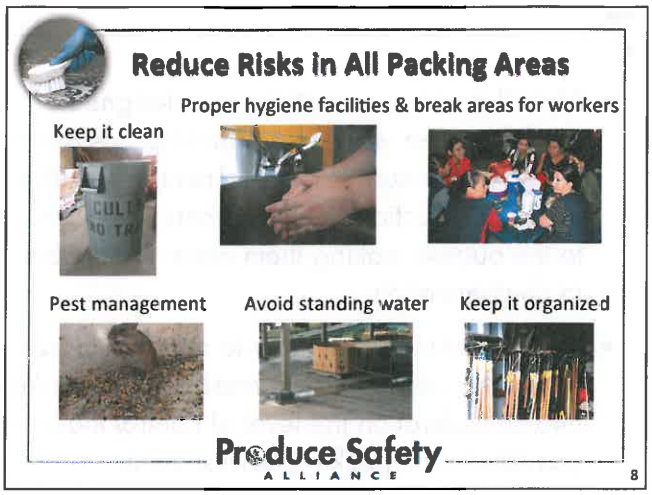

- There are ways to reduce food safety risks in all situations regardless of the type of packing operation. This is not an exhaustive list of all the practices that can be used on farms and in packinghouses these are just a few examples. Encourage participants to share other ideas.
  - Keep it clean: Sweep, pick up trash, remove cull piles—good housekeeping goes a long way!
  - Separate produce handling areas from other farm activities such as vehicle repair, spray mixing, and storage.
  - Provide proper hygiene facilities for workers. Toilets, handwashing facilities, and separate eating and break areas are key for making sure workers do not contaminate fresh produce.
  - Avoid standing water and condensate: Whether in a closed operation or open packing area, take effort to reduce standing water in equipment and on the floor (or ground). Standing water can support the growth and persistence of pathogens such as *Listeria monocytogenes* and splash onto fruits, vegetables, and equipment, in turn spreading contamination throughout the packing area.
  - Pest management: All packing areas should have a pest management program. Closed operations have more ability to exclude rodents and other pests, but pests can still be managed in open operations.
  - Separate covered produce from exempt produce.
  - Keep it organized: Having a cleaning process and place for tools and equipment can help ensure that they are in good working condition and clean for the next use. Some growers will use color labeling (such as 'green is clean') or designate areas for dirty and clean equipment to be placed when returning from the field. Having a system can minimize confusion, increase efficiency, and help reduce risks by ensuring important cleaning and sanitation steps are done properly each day.

Notes:

- This slide does not contain references to the FSMA Subpart requirements. Many of the FSMA requirements outlined in Subpart K and L are fairly general and broad in scope to facilitate scalability and flexibility in reducing food safety risks on a variety of farms and packinghouses. It is suggested that growers review the requirements in Subpart K and L to develop practices for their farm to satisfy these requirements.

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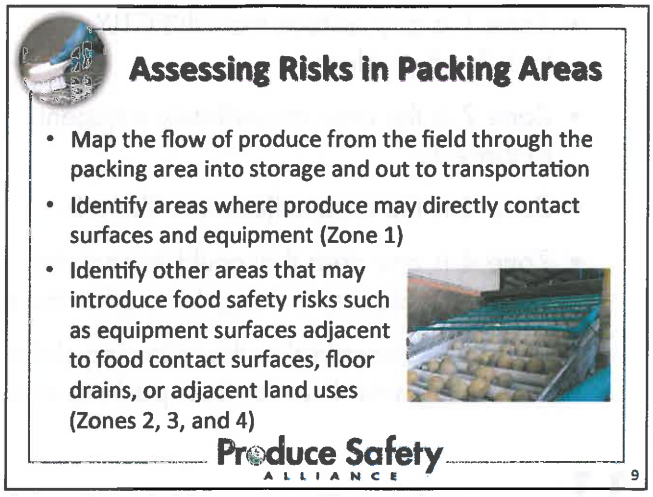

- As in the field, consider the risks from workers, water, soil, animals, adjacent equipment surfaces (such as spray bars), floor drains, and any adjacent land uses that can introduce contamination into packing and storage areas.
- A good way to begin risk assessment in the packing area is to map the flow of produce from the field through the packing area, including storage and loading onto transportation vehicles.
- Identify all surfaces that contact the produce as well as where incoming produce from the field and washed/packed produce might cross paths in the packing area or cooler.
- Food contact surfaces are considered Zone 1. The other zones (2, 3, and 4) correspond to areas beyond the direct food contact surfaces. These **zones** will be reviewed in the next few slides.
- Make a list of produce safety risks that are identified during the survey of harvesting, packing, storage, and transportation practices, so they can be addressed during implementation of the food safety plan.

Additional resource:

- Hardin, M. (2013). Guidance on Environmental Monitoring and Control of *Listeria* for the Fresh Produce Industry. United Fresh Produce Association. http://www.unitedfreshshow.org/files/environmental_monitoring_and_control_of_listeria.hardin.pdf

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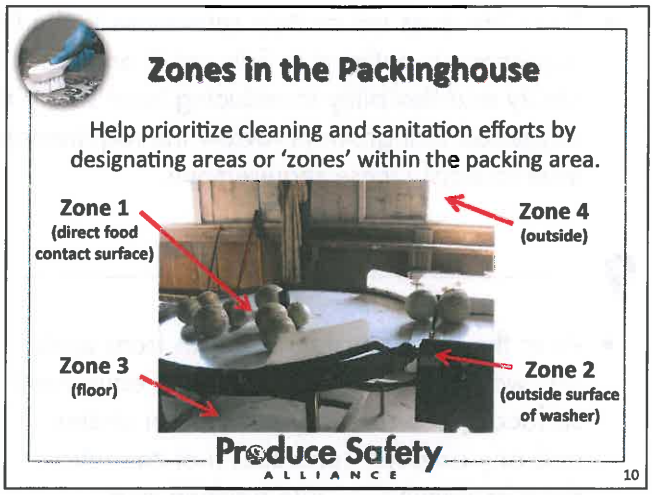

- By defining zones in the packinghouse, growers can target cleaning and sanitation efforts in different areas that may affect fresh produce.
  - Zone 1 is any surface that DIRECTLY contacts fresh produce.
  - Zone 2 is the area immediately adjacent to Zone 1.
  - Zone 3 is the area adjacent to Zone 2.
  - Zone 4 is any area that could impact the safety of produce, but may be outside the packing or produce handling environment.
- Each zone is described in the following slides and can help growers prioritize food safety risks and cleaning schedules for their packing area.

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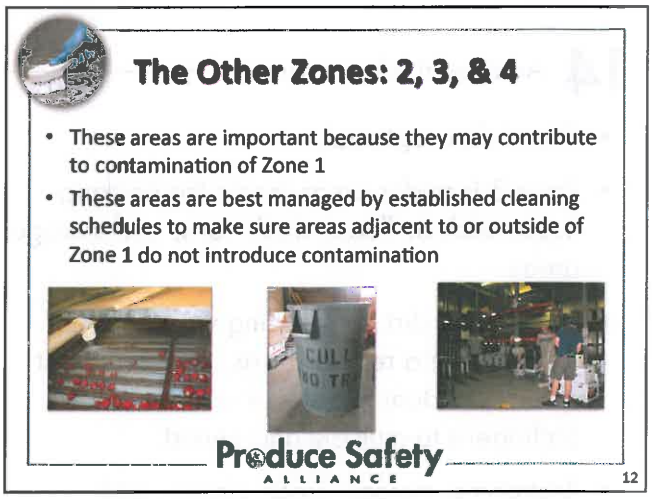
- Zone 1 surfaces are DIRECT food contact surfaces—e.g., any surface that the produce may contact such as belts, rollers, brushes, sorting tables, workers' hands, bins, or sinks.
- Remember to assess sanitary design before buying new equipment. Equipment that is easy to clean is much more likely to be maintained and cleaned in the production environment.
- § 112.123(d)(1) requires all food contact surfaces of equipment and tools used in covered activities be inspected, maintained, and cleaned and, when necessary and appropriate, sanitized to protect against contamination of covered produce.
- Cleaning and sanitizing practices in Zone 1 should come first to reduce food safety risks.

Notes:

- § 112.123(d)(2) requires that growers also maintain and clean **non-food contact surfaces**, tools, and equipment when necessary to prevent contamination of produce. Areas described in this module as Zones 2, 3, and 4 are likely to be in this category.
- § 112.111 requires that those subject to the rule who grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, they must take measures during these covered activities, as applicable, to: (a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and (b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.
- For farm management purposes, it may be easier to handle both covered and excluded produce in ways that meet regulatory expectations so that there are only one set of practices on the farm. Each farm should evaluate the best way to meet regulatory requirements, buyer requirements, and farm needs.

12 *Additional Information*

- This slide is optional.
- If the growers are only field packing or do not have packinghouses or sheds, this information may not be useful.
- The slides that follow provide more detailed information on these packing area zones, if this topic is relevant to the group being trained.



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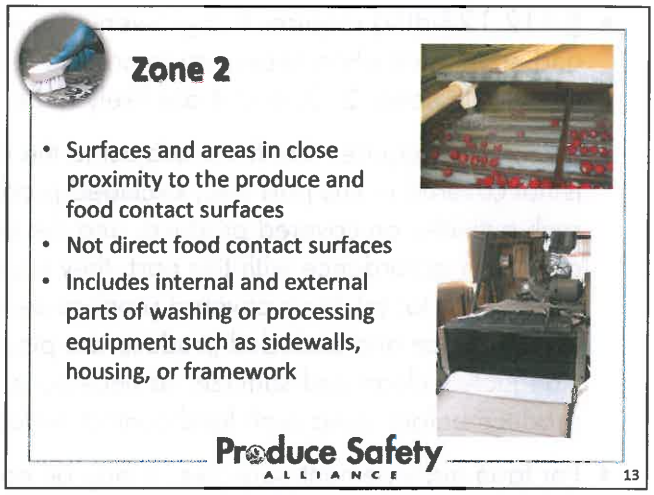
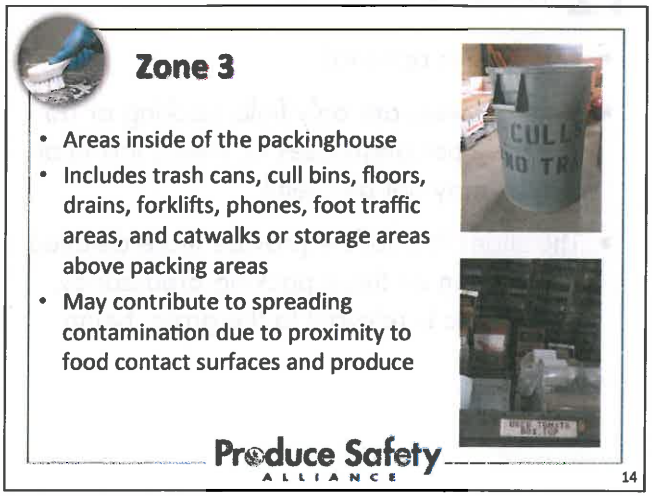


- This slide is optional.
- Zone 2 includes surfaces which are not in direct contact with produce, but are in close proximity to the produce. While these areas pose an indirect food safety risk, they still may contribute to contamination. This may include spray nozzles, equipment housing, sidewalls, and other nearby surfaces.
- Most commonly, these areas are overlooked because they are not often visible or easily accessible. For example, the interior walls of washing equipment may not be easily accessed, leading to rust or a buildup of microorganisms (i.e., **biofilms**). This buildup could slough off and contaminate other areas of the equipment or the produce directly.

14 *Additional Information*



- This slide is optional.
- Zone 3 includes areas inside the packinghouse such as floors, trash cans, and storage areas.
- If cull piles, dirt, or standing water are not removed on a regular basis, they could act as an attractant to pests or a reservoir for pathogens to multiply and persist.
- Restrooms, storage areas, drains, and catwalks, especially if they are above packing or washing equipment, can contribute to contaminating produce.

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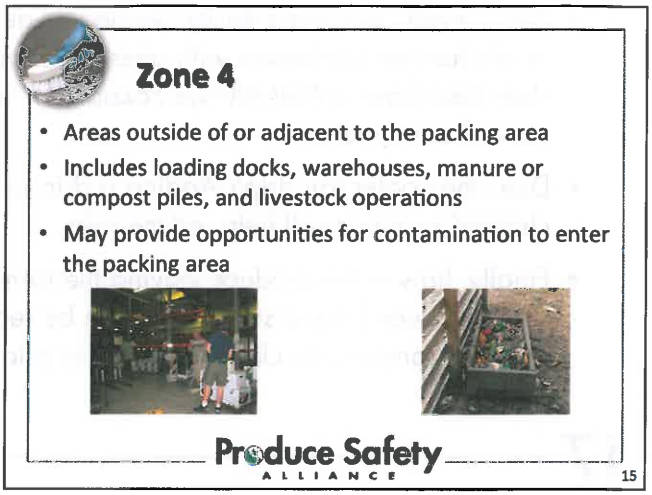
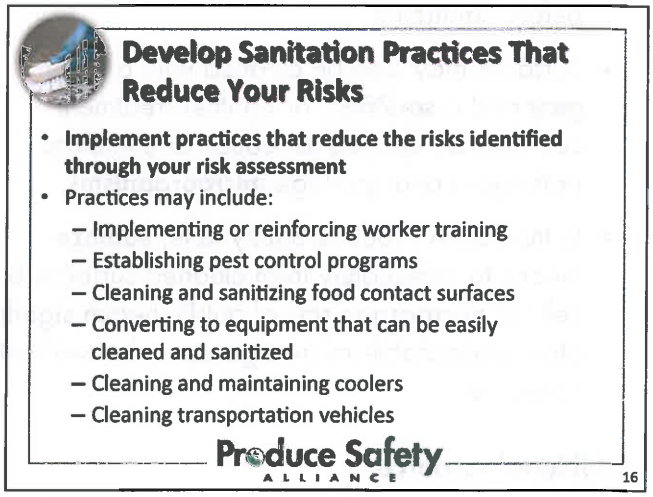
15 *Additional Information*



- This slide is optional.
- Zone 4 includes areas beyond the packing area. Exterior environmental factors such as manure or compost piles, domesticated animals, traffic from loading docks, and even adjacent land uses can all present opportunities for contamination to enter the packing area.
- Things that can reduce risks include removing soil from the bottom of harvest bins before they enter the packing area, designing patterns of movement around the farm to eliminate unnecessary traffic into the packing area, installing foot baths at entry doors to the packing area, and other practices that reduce movement of contamination from outside into the packing area.

16



- Once a map of the flow of produce through the packing areas has been developed and growers have identified the biggest risks, they should develop a plan to implement practices that reduce those risks.
- If the risks involve concerns about the cleanliness of worker hands as they pack produce, growers may need to begin training or improve worker training programs.
- Here are a few sanitation practices to evaluate and consider implementing:
  - Are the belts and brushes that move produce dirty and/or frayed? Growers may need to establish a cleaning and sanitizing program and SOPs.
  - Are birds roosting in the rafters? Putting up netting or closing open doors to prevent entry may be practices that are needed for pest management.

Notes:

- Are harvest containers easily cleaned or designed for single use? Consider replacing broken or old harvest containers with ones that can be cleaned and sanitized more easily. See the slide *Best Case Is Not Always Possible* for information regarding use of wood bins or wood harvest containers.
- Does the cooler fan drip? Adding a drip pan to prevent water from dripping on packed and cleaned produce will help reduce risks.
- Finally, how is the produce leaving the farm and getting to customers? Are the transportation vehicles clean? Food safety risks can be reduced by cleaning the vehicles or requiring the trucking company to clean the vehicles prior to loading produce.

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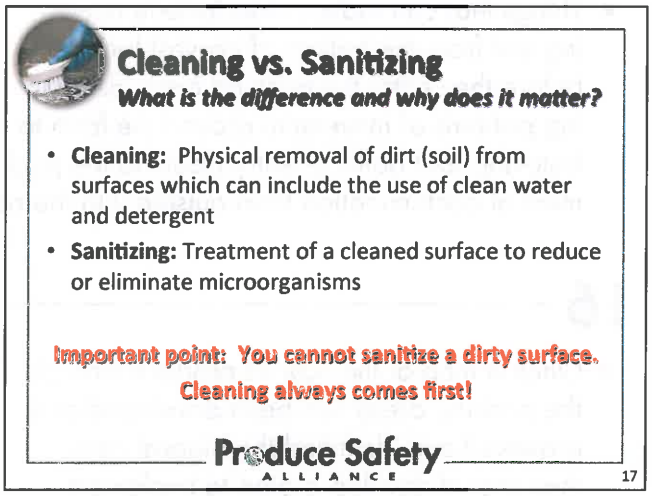


- A dirty surface CANNOT be sanitized! Not all surfaces can be sanitized, but all surfaces can be cleaned! This may include sweeping, wiping off tables, or brushing/rinsing off dirt from harvest totes. Cleaning must be done before sanitizing.
- Surfaces may also be cleaned with a **detergent** and a **sanitizer**, or another treatment can then be applied to reduce or eliminate pathogens and spoilage **microorganisms**.
- In the FSMA Produce Safety Rule, **sanitize** means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Additional resource:

- Schmidt, R. (2009). Basic Elements of Equipment Cleaning and Sanitizing in Food Processing and Handling Operations. University of Florida/IFAS Extension. http://edis.ifas.ufl.edu/fs077

Notes:

18

- There are four steps to cleaning and sanitizing as outlined in the next few slides.
- Always use clean water that is free from generic *E. coli* for all sanitation steps.
- § 112.44(a)(3) requires no detectable generic *E. coli*/100 mL in water used to contact food contact surfaces.
- First, remove any obvious dirt and debris from the food contact surface. This can be done using a brush to sweep, air to blow off, or water to rinse off debris.
- Avoid cleaning with high pressure washers or air compressors, as this could spread pathogens and other debris over a large area.

19

- Be sure to use an appropriate detergent for the type of soil that needs to be removed. Some detergents are designed to remove fats (e.g., from animal slaughter) while others may be more effective at removing carbohydrates (e.g., sugars from fruit), or proteins, so select the detergent that removes the type of soil that is present.
- Detergents must be approved for use on food contact surfaces.
- Apply the detergent at the level recommended on the label and physically scrub the surface to remove any soil.
- Removing the soil and other organic build-up can help minimize the formation of **biofilms**.

Notes:

Additional Resources:

- Liu, N.T., et al. (2015). Effects of Environmental Parameters on the Dual-Species Biofilms Formed by *Escherichia coli* O157: H7 and *Ralstonia insidiosa*, a Strong Biofilm Producer Isolated from a Fresh-Cut Produce Processing Plant. *J Food Prot*, 78(1), 121–127.
- Srey, S., Jahid, I.K., & Ha, S.D. (2013). Biofilm formation in food industries: A food safety concern. *Food Control*, 31(2), 572–585.

20

- Rinse the surface with clean water that is free of any detectable generic *E. coli*. Make sure all of the detergent and soil is removed.
- As mentioned in an earlier slide, § 112.44(a)(3) requires no detectable generic *E. coli*/100 mL in water that contacts food contact surfaces.

21

- **Sanitizers**: A substance that reduces the amount of microorganisms to acceptable levels, typically for use on food contact surfaces. Sanitizers are generally considered to be part of a broader group of substances called antimicrobial pesticides. The antimicrobial product label will describe approved uses, such as for water or for food contact surfaces, as well as approved concentrations or dosages.
- Apply a sanitizer approved for use on food contact surfaces. Ensure that the product is the proper concentration per the label instructions.

Notes:

- § 112.123(d)(1) requires that those subject to the rule must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.
- Apply and use sanitizers according to label instructions. There may be a 5th step if the sanitizer requires a final rinse, so be sure to read and follow the label.
- Allow the surface to air dry.
- Document this as a **clean break** if the farm separates lots using this process.
- In organic operations, the application of a sanitizer may need to be followed by a potable water rinse. Follow the certifier's requirements for application and residue management on food contact surfaces.

Clean Breaks

- Establishing a 'clean break' after taking these steps to clean and sanitize food contact surfaces can help limit the amount of product subject to a recall or withdrawal. Many produce packers establish lots to trace their products and to limit risk to their business if a food safety contamination event occurs. Whether a packer determines a lot by date, grower, field, buyer, or some other means, a sanitation 'clean break' is needed before and after the production of that lot to consider it separate from other production lots. In a number of recent produce-related food safety events, the lack of a defined clean break resulted in a **recall** that covered the entire production season (Chapman and Danyluk, 2013).
- Documentation is key to establishing a clean break. Be sure to keep records of when, how, and what was cleaned in the packinghouse as well as any monitoring steps and who did the cleaning. These records will help establish distinct lots.

Reference:

- Chapman, B., & Danyluk, M. (2013). Establishing Lot Size through Sanitation Clean Breaks in Produce Packing Facilities. University of Florida/IFAS Extension. http://edis.ifas.ufl.edu/fs234

Notes:

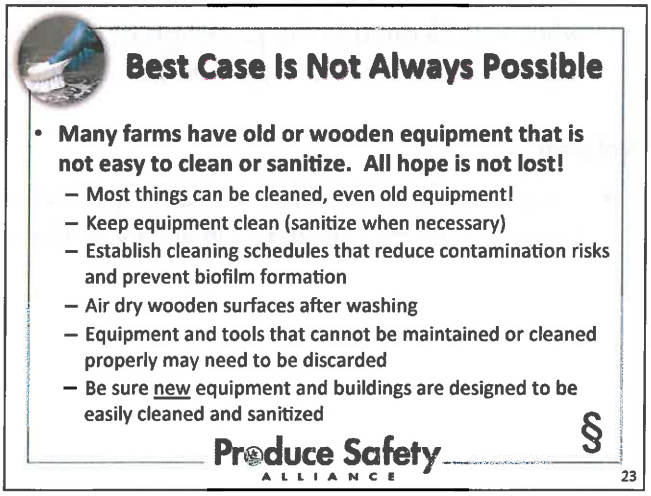
22

- The art and science of developing materials and building equipment that can be easily cleaned and sanitized is called **sanitary design**. If growers plan to build a new packinghouse or buy new equipment or harvest containers, it is important to select materials that are easy to clean and sanitize.
- Requirements associated with equipment, buildings, and tools can be found within Subpart L.
- Specifically, § 112.123(a) requires those subject to the rule to use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained.
- Effective sanitary design will also reduce the time and money needed to properly clean and sanitize surfaces, so it is not just important to produce safety but will help save money.

Additional Resource:

- Schmidt, R., & Erickson, D. (2005). Sanitary Design and Construction of Food Equipment. University of Florida/IFAS Extension. http://edis.ifas.ufl.edu/pdffiles/fs/fs11900.pdf

23



- Some things in the packing and storage area are constructed of materials that may be difficult to clean and sanitize. Wooden bins, because they are a porous surface, are one example.
- Just because the equipment and containers used on the farm are difficult to maintain and clean does not mean that good practices cannot be implemented. Remember, this is about risk reduction, not risk elimination.

Notes:

- Keep equipment clean. Establish cleaning schedules that ensure equipment is not left to sit with plant (vegetative) debris on it overnight. This gives microorganisms a chance to establish themselves and form biofilms which are difficult to remove. If there are plans to buy new equipment or build a new packinghouse or storage area, look for equipment that is easy to clean and sanitize, and was built with principles of sanitary design in mind. Growers can consult local university or extension specialists, State Department of Agriculture or Public Health personnel, or county sanitarians for a second opinion if they are unsure what to buy or how to retrofit equipment safely.
- Assess equipment and tools, those that are not in good repair and cannot be maintained (cleaned and/or sanitized) may need to be discarded.
- § 112.123(b)(1) requires tools and equipment be installed and maintained to facilitate proper cleaning of the equipment and adjacent spaces.
- § 112.123(d)(1) requires those subject to the rule to inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

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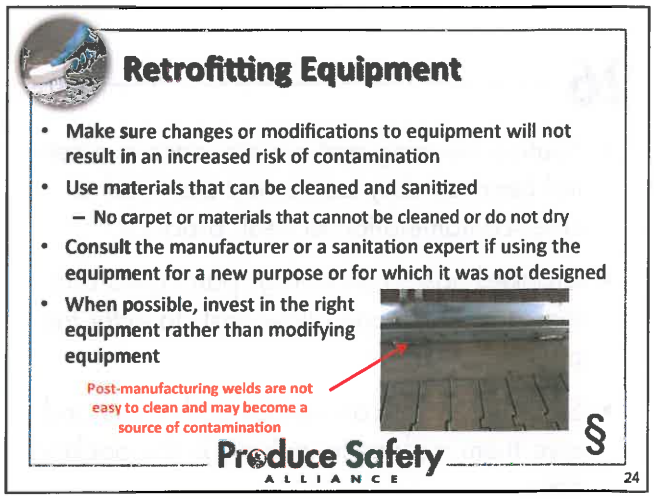

- Many farms have limited resources. Retrofitting and repurposing equipment is one way to cut costs and utilize already available tools and equipment on the farm. Unfortunately, retrofitting equipment and using it in ways that it was not originally designed can introduce risks. For example, post-manufacturing welds can provide niches for pathogens to hide.
- Review modifications and changes to determine if niches where pathogens can grow or opportunities for biofilm formation have occurred.
- § 112.123(c) requires seams on food contact surfaces of equipment and tools must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

Notes:

- Avoid materials that cannot be sanitized—e.g., carpeting on packing lines or other materials that do not dry and could spread contamination as they contact produce.

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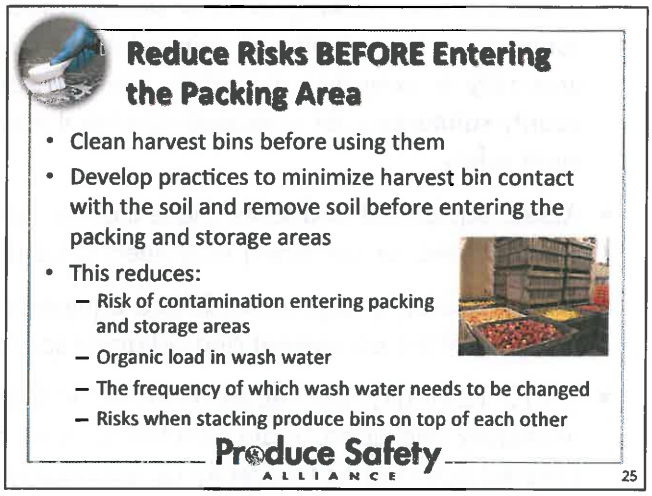

- To keep packing areas clean, it is best to prevent dirt and debris from entering.
- Keep packing and storage areas clean by removing dirt and debris from the outside of the bins before they enter.
- Stacking harvest containers can introduce contamination to produce below if the bottom of the container is not clean.
- Sanitizers may be less effective if there is a large organic load (from dirt or leaves on/in bins) in the wash water. By keeping bins clean, sanitizers are less likely to be impacted and water will need to be changed less often.

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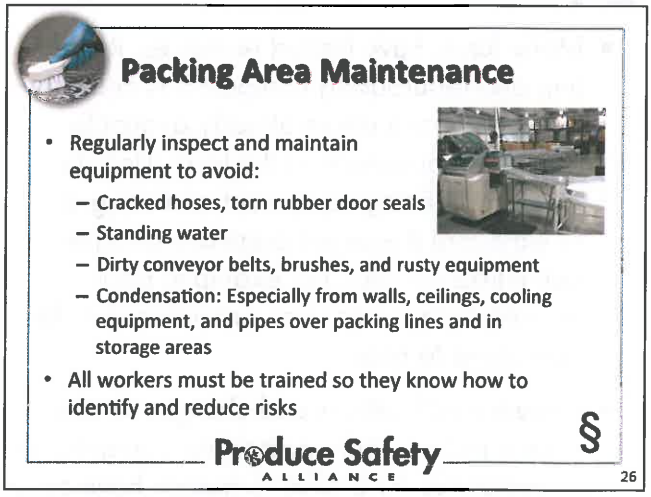

- Routine cleaning and maintenance is essential because dirty equipment can lead to cross-contamination of fresh produce.
- Cracked hoses can harbor pathogens and torn door seals can allow pests to enter the packing area.
- Standing water can harbor pathogens and give them a place to multiply in the packing area.
- Condensation in packing, cooling, and storage areas should be eliminated or minimized because water can support microbial growth and contamination can easily be transferred to produce (e.g., by splash or from equipment).

Notes:

- § 112.126(b) requires measures be implemented to prevent contamination of covered produce and food contact surfaces in buildings, as appropriate, considering the potential for such contamination through (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and (2) Drip or condensate.
- Workers must be trained to correct problems with harvest containers or equipment, or report such problems to the supervisor (§ 112.22(b)(3)). These problems may include old or broken harvest containers or equipment that might need to be replaced.

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- Packing containers and produce packaging can be a source of contamination if the containers are not clean.
- Keep packing materials, cases, bags, or boxes in a clean, dry area that is covered and off the ground so that it does not become contaminated by pest droppings or other environmental factors such as windblown dirt or dirt from catwalks above storage areas.
- Single-use, food grade plastic liners can be used inside packing containers to provide a clean surface.
- § 112.116 requires that food-packing material (including packaging materials) be adequate for their intended use, which includes being cleanable or designed for single-use, and unlikely to support growth or transfer of bacteria. If food-packing materials are reused, steps must be taken to ensure that food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.
- § 112.115 requires covered produce to be packaged in a manner that prevents the formation of *Clostridium botulinum* toxin, if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

Additional Resource:

- Sugiyama, H., & Yang, K.H. (1975). Growth potential of *Clostridium botulinum* in fresh mushrooms packaged in semipermeable plastic film. *J Appl Micro*, 30(6), 964–969.

Notes:

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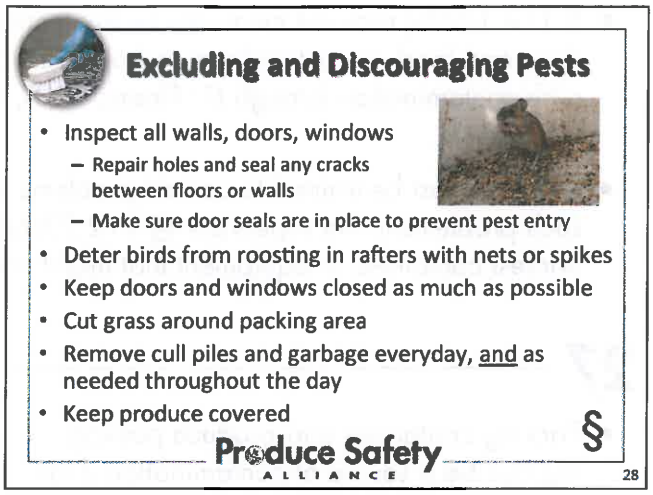

- Pests such as birds and rodents can carry human pathogens in their feces. They can also be an issue to the quality and integrity of the produce.
- § 112.128 requires that pest control programs in buildings must:
  - Take measures to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests, including routine monitoring for pests as necessary and appropriate.
  - For fully-enclosed buildings, there must be measures in place to exclude pests.
  - For partially-enclosed buildings, growers must take measures to prevent pests from becoming established or remove them, when present.
- A pest management plan should be developed for excluding or eliminating pests from the packing and storage areas.
  - In closed operations, inspect walls, windows, and door seals to keep pests out. Mice can fit in a pencil-sized hole and rats through a hole the size of a quarter.
  - Deter birds from roosting by using netting or rafter spikes.
  - Keep areas outside the packing area clear and free of debris and tall grass, which may provide places for pests to live and hide.
  - Remove trash and culls every day and as needed throughout the day, so they do not become an attractant to pests.
  - Keep produce covered to protect it from bird droppings or pest activity.

Notes:

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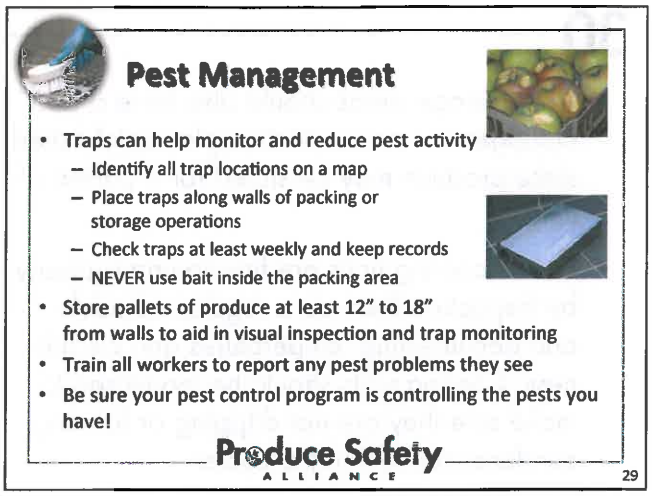

- This slide provides more specifics about setting up a pest management program.
- Traps can be used to monitor and eliminate pests. If monitoring identifies a problem, growers should take action. Remember, § 112.128 includes routine monitoring for pests.
- Identify all traps on a packing area map and monitor on a daily basis for activity. Growers may need to hire an outside pest company to help them deal with a problem.
- Traps can be used inside the packing and storage areas, but be sure they are unbaited otherwise pests may be drawn into the area.
- Keep pallets and produce boxes away from walls and off of floors to help monitor pest activity. Rodents find comfort in keeping to side walls where they can escape and hide easily.
- Workers should be trained to notify the grower or farm manager if they find evidence of a pest problem such as droppings, damaged product, or traps that are continually having to be emptied.
- Records should be kept of all pest management practices. If hiring a pest control company, growers should have them fill out a log sheet. Growers can review log sheets to verify that the program is working and to make sure there are no other pest problems they need to address.

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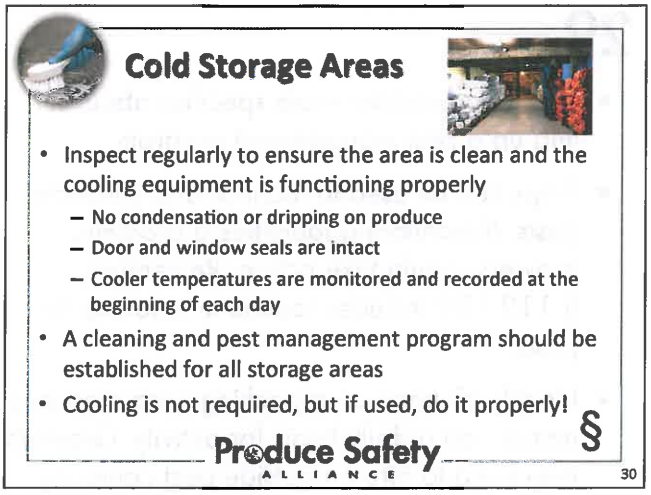

- Cold storage areas should also have a pest management and sanitation plan established since produce may be stored for a period of time.
- Ensure cooling units are functioning properly by inspecting them on a regular schedule and documenting temperatures and cleanliness. Cooling units should be monitored to make sure they are not dripping or forming condensation within the cooler.
- Condensate pans should be sloped and drained out of the room or directly to a drain, not onto the floor.
- Take cooler temperatures at the beginning of each day to be sure they are functioning properly.
- § 112.126(b)(2) requires those subject to the rule must take measures to prevent contamination of covered produce and food contact surfaces in their buildings from drip or condensate.
- § 112.124 requires that instruments (such as thermometers) used to measure, record, and regulate temperature or other conditions in order to prevent the growth of microorganisms must be kept (a) accurate and precise, (b) adequately maintained, and (c) adequate in number for their designated uses.
- Cooling is not required for the FSMA Produce Safety Rule, but if coolers are used, proper steps should be taken to ensure they are maintained and monitored to prevent produce safety risks.

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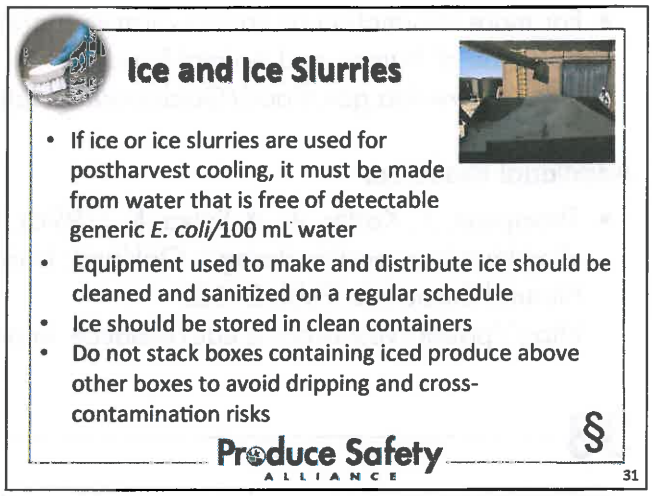

- If using ice that directly contacts produce, such as for cooling, the ice must be made from water that is free of detectable generic *E. coli*/100 mL water (§ 112.44(a)(2)).
- Ice should be stored in clean containers in a clean area. A schedule should be set to clean and sanitize ice machines and ice storage areas.
- If stacking boxes containing ice or produce that has been hydro-cooled, understand that water is likely to drip onto boxes and areas below, so take into account any risks that might need to be minimized, such as standing water.

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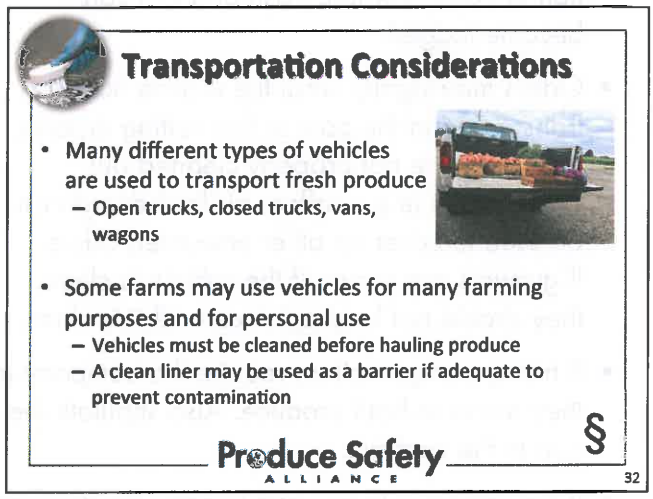

- Ideally, the vehicle that transports produce should only be used to transport produce, but this is not always possible, especially on small farms.
- § 112.125 requires that equipment used to transport covered produce (a) be adequately cleaned prior to transporting produce and (b) adequate for use in transporting covered produce.
- § 112.123(e) requires if those subject to the rule use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, they must do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.
- If the vehicle is used for transporting anything besides produce, such as carrying live animals or compost, it should be cleaned and sanitized before being used to haul produce.

Notes:

- For more information on sanitary transportation, see the FSMA Proposed Rule on Sanitary Transportation of Human and Animal Food: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm

Additional Resource:

- Thompson, J., Kader, A., & Sylva, K. (1996). Compatibility chart for fruits and vegetables in short-term transport or storage. Oakland: University of California, Division of Agriculture and Natural Resources. Publ. 2156. http://postharvest.ucdavis.edu/produce_information/CompatibilityChart/

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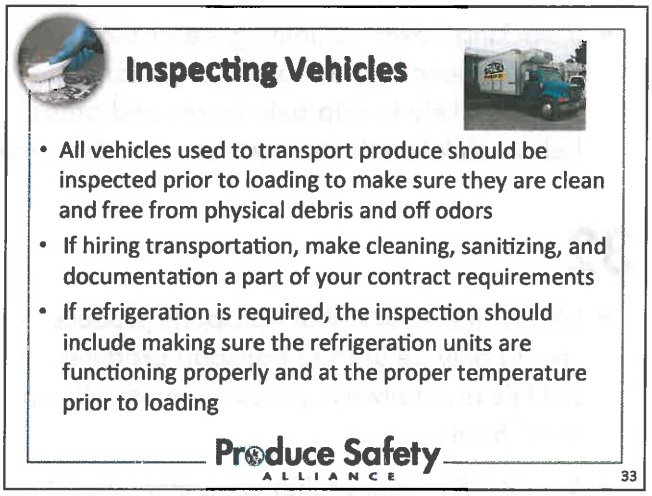

- Check for physical hazards in the vehicle prior to loading, such as splinters, nuts and bolts, or any other small objects. Pay attention to corners where trash and dirt can become lodged.
- Odors may signify what the vehicle has transported in the past or that rotting organic residues were not properly cleaned out. Other odors (e.g., coffee, air fresheners) can be used to cover up other unwanted odors. If growers are unsure if the vehicle is clean, they should not load produce until it is clean.
- If hiring transportation, require the company to clean and sanitize trucks (if necessary) before they arrive to haul produce. Also stipulate the recordkeeping logs they need to fill out and maintain in the contract.
- If the vehicle is to be used to keep the produce cool, ensure that the cooling unit is functioning properly before loading and that all door seals, air chutes, and side walls are in good condition.

Notes:

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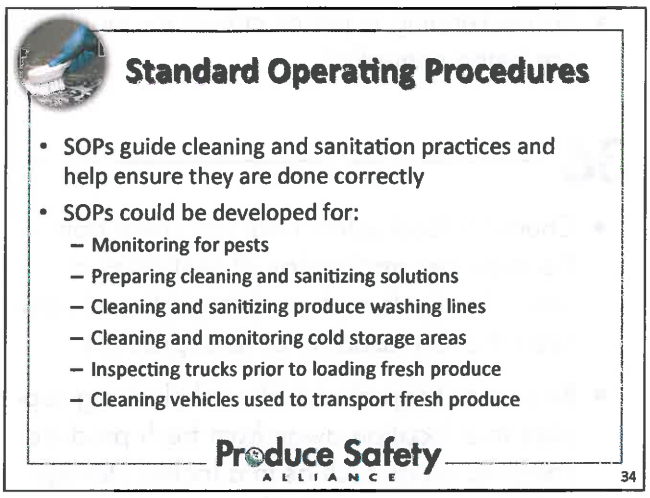

- SOPs outline what tasks need to be done and how to perform them, especially in the packing area.
- A list of some possible SOPs growers might want to consider including in their food safety plan are listed on this slide.
- Be sure to write clear and concise SOPs that anyone could follow. To test an SOPs' effectiveness, growers should give it to someone else to read. Ideally, growers should watch someone carry out the task to see if it is clear what needs to be done. If it works, great. If not, it should be revised as necessary.

Additional Resource:

- Bihn, E.A., Wall, G.L., Schermann, M., Amundson, S. and A. Wszelaki (2014). Farm Food Safety Decision Trees. http://gaps.cornell.edu/educational-materials/decision-trees

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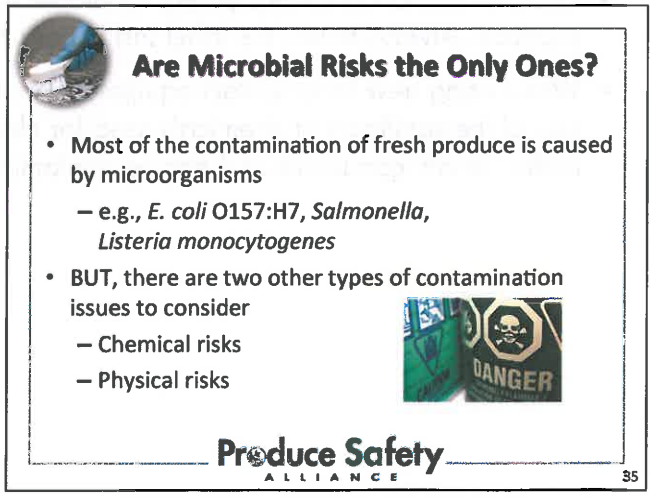

- This curriculum and FSMA Produce Safety Rule are focused primarily on reducing microbial food safety risks; however, there are two other types of food safety risks that exist—chemical and physical risks.
- These two risks are briefly discussed here since some of them may be more common in the packing and storage areas where produce is close to chemical storage (e.g., detergents, sanitizers) and physical hazards in the packing area (e.g., glass from lights and metal parts of equipment).
- Other chemical risks worth mentioning are allergens. They are not discussed in any detail in this curriculum but are covered in the FSMA Preventive Controls for Human Foods Rule and the Food Safety Preventive Controls Alliance curriculum.

Notes:

- Recordkeeping is just as critical for monitoring that chemical and physical food safety hazards are being controlled.

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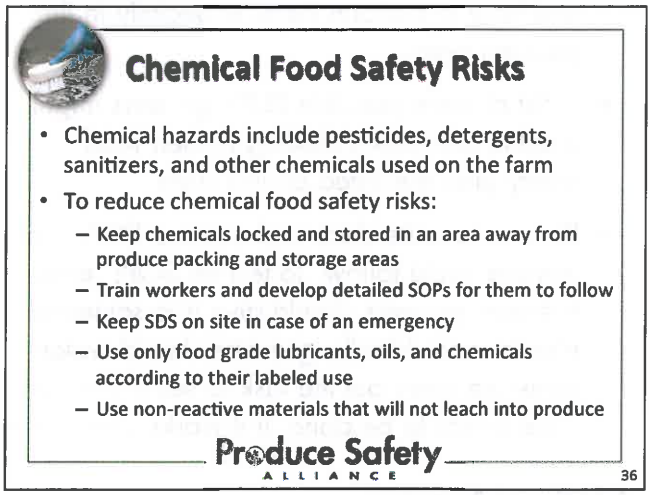

- Chemical food safety risks can come from the improper application of pesticides or other chemicals such as detergents and sanitizers that are used on or near produce.
- Be sure to keep chemicals and cleaning supplies in a location away from fresh produce handling areas such as in a locked storage cabinet or separate shed.
- Be sure workers are trained to follow SOPs that clearly define when and how much of the chemicals need to be used to complete the task properly.
- **Safety Data Sheets (SDS)** should be on site or easily accessible in case of a medical emergency.
- Oils and lubricants for equipment should be food grade if they are used anywhere near fresh produce. Always follow the label instructions for application and proper use.
- When using new food contact equipment on the farm, be sure the material is not reactive with any of the sanitizers or chemicals used for cleaning and sanitizing. Heavy metals can leach under certain conditions and end up contaminating produce.

Notes:

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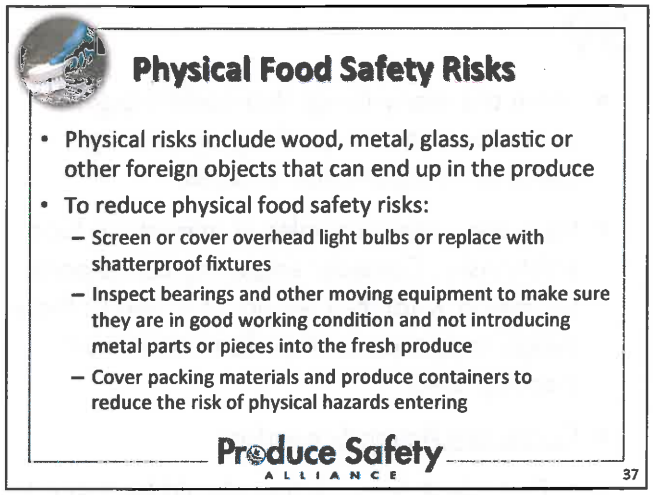
- Physical food safety risks can be present if any foreign material comes in contact with produce or produce handling equipment.
- Broken glass from light fixtures is a physical hazard, especially in the packing and storage areas. Sleeves and light guards should be used to keep glass light bulbs from shattering onto produce or into packing and storage areas.
- Metal from equipment (e.g., nuts, bolts) can present additional physical risks. Some farms may want to install metal detectors to make sure metal does not end up in the finished product. If the product is going to a food processing facility, such as apples to a baby food manufacturer, the processor may also require metal detectors.
- Wood splinters are also a risk and may be common when using wood pallets or bins.
- Set a schedule to inspect equipment and packing areas to reduce the risks of physical hazards contaminating produce and produce handling, storage, and transportation areas.



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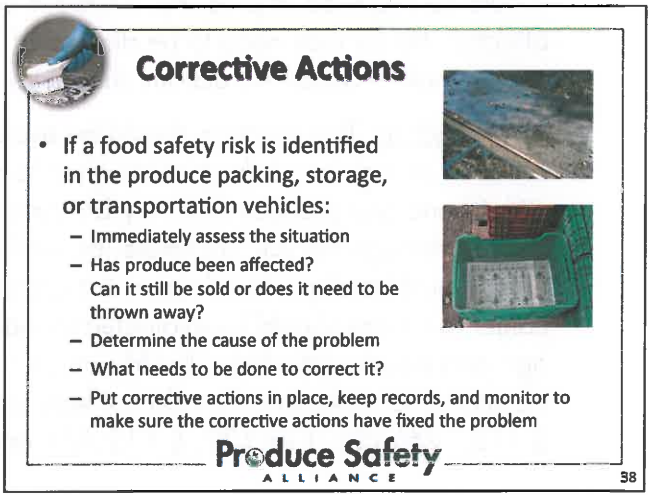
- A corrective action should be taken and documented if food safety risks are identified in the packing, washing, storage, or transportation of produce.
- Think about both short term and long term solutions. How can the situation be fixed immediately? How can the event be prevented from occurring again in the future?
- Corrective actions can help fix a problem, determine its cause, and modify practices to make sure it does not happen in the future.



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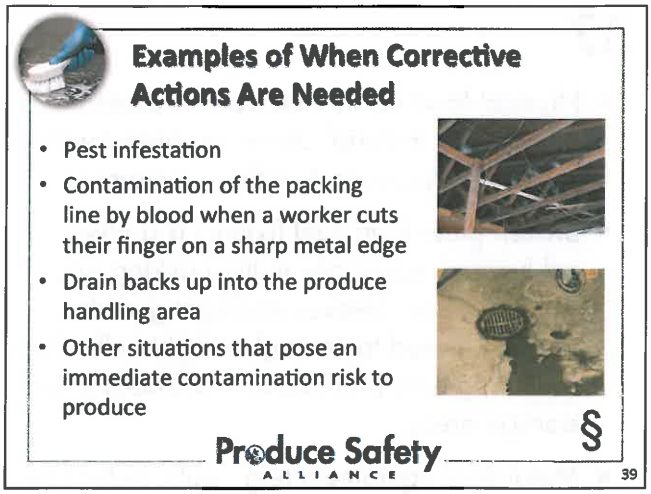

- There are many things that could trigger a corrective action in packing and storage areas or transportation vehicles.
- Here are some examples of immediate food safety risks. Consider engaging participants by asking what they would do if one of these things happened on their farm or in their packing area.
- Corrective Action Scenarios:
  - Pest infestations: Action should be taken to remove and manage pest infestations. This could be done by hiring an outside pest control company or by setting traps, putting up bird netting, or other actions. Inspect any stored produce and make sure it has not been contaminated by the pests. Review § 112.128(a).
  - Injured worker in packing area: Workers should first seek medical attention. First aid kits should be provided and workers should be trained on how to use the kits properly. Surfaces that may have come in contact with bodily fluids, such as vomit, blood, etc., must be cleaned and sanitized. Any produce that has come in contact with vomit, blood, or other bodily fluids should be disposed of properly. If there is concern that a large volume of produce has been affected, the lot may need to be discarded. Notify the owner/manager about injuries and contamination issues. All actions should be documented. Review Subpart D.
  - Drain backup: This situation should be evaluated as to whether it may have affected the produce storage or packing areas, the shoes of workers who may have come into contact with it, and any produce that may be contaminated. If the sewage/contaminated water was tracked through the packinghouse (by workers or equipment), cleaning and sanitizing of the area should be done. In addition, the proximity of the produce and produce packing lines or contact surfaces should be evaluated to make sure they have not become contaminated. Sewage and waste water lines should not run over packing lines, but if they do, they need to be monitored to make sure they do not leak onto produce or food contact surfaces. Review § 112.126(a)(2), 112.129, § 112.131 and 112.133.

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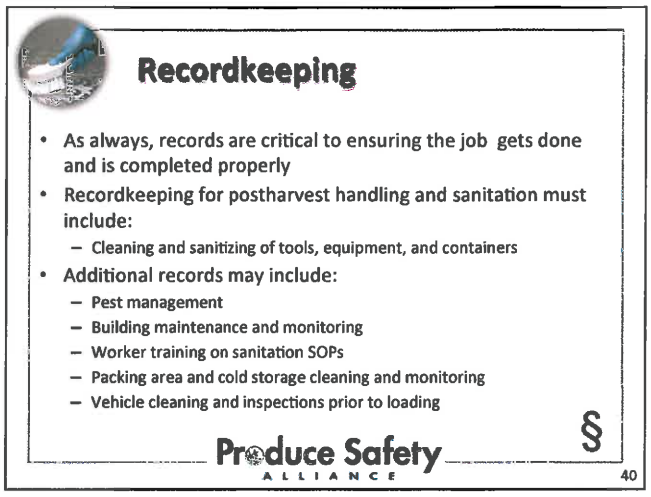

- Recordkeeping can be facilitated in the packing area by attaching recordkeeping logs to clipboards hung in convenient locations or inserted into plastic sleeves taped to the walls where the activity is happening.
- There are many cleaning and sanitation practices that need to be done on the farm. This may mean delegating some of the tasks to others. Be sure all workers know what their responsibilities are and what records they need to fill out.
- § 112.140(b)(2) requires that growers subject to the rule must establish and keep documentation of the date and method of cleaning and sanitizing of equipment to this part used in covered harvesting, packing, or holding activities.
- **Template** logs and SOPs related to sanitation can be found at: http://gaps.cornell.edu/educational-materials/decision-trees/log-sheets-sops#sanitation

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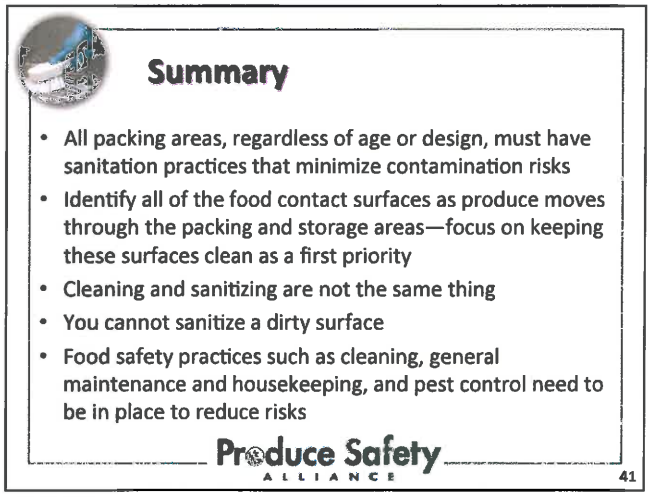

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Produce Safety ALLIANCE

How to Develop a Farm Food Safety Plan

Cornell University

Learning Objectives
Module 7: How to Develop a Farm Food Safety Plan

Objective 1:
Name essential parts to include in a Farm Food Safety Plan.

Objective 2:
Describe why one qualified person should be designated as the person responsible for the food safety plan on every farm.

Objective 3:
Conduct a risk assessment of the farm's practices and environment.

Objective 4:
Describe management steps and practices to reduce identified risks.

Objective 5:
List key steps involved in developing a traceability system that is able to trace produce one step forward (to buyer) and one step back (to field), including establishing lots and clean breaks.

Objective 6:
Identify resources available to assist in developing a Farm Food Safety Plan.

Critical Concepts

- Key reasons and benefits of developing a Farm Food Safety Plan
- Designating a person in charge and the value of being committed to food safety
- Basic components to include in a Farm Food Safety Plan
- Three steps to developing a plan: assess risks, develop practices, and document
- How to use knowledge and resources to your advantage
- Steps to develop an effective traceability program for your farm
- How to define produce 'lots' and conduct a mock recall
- The need and value of establishing a 'clean break'
- Understand produce labeling and modified requirements for FSMA exempt growers

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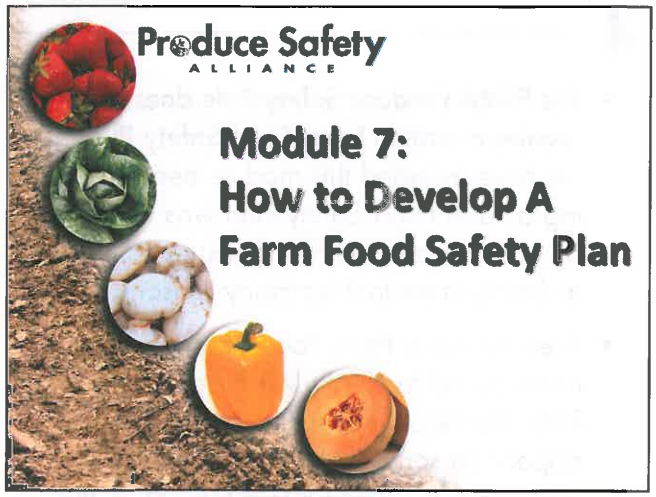
Produce Safety
ALLIANCE
Module 7:
How to Develop A
Farm Food Safety Plan

Notes:

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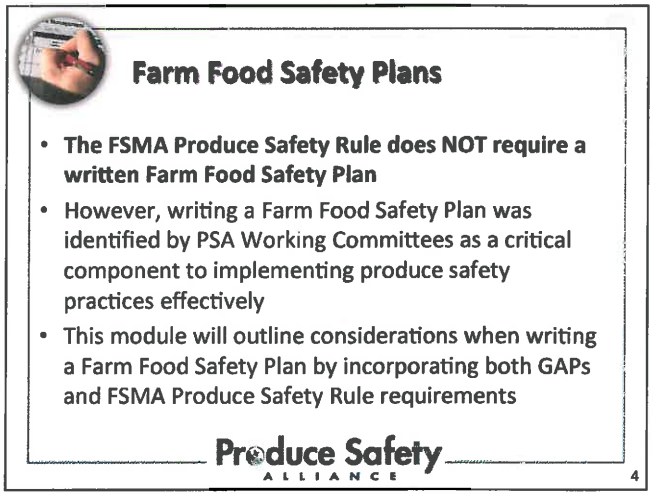
4

- **The FSMA Produce Safety Rule does not require a written Farm Food Safety Plan** but we have included this module because writing a Farm Food Safety Plan was identified by growers and the PSA working committees as being important for many reasons.
- Even though a Farm Food Safety Plan is not required by the FSMA Produce Safety Rule, the regulatory section symbols (§) may appear on some of the slides to indicate requirements which were discussed in the previous six modules and how to incorporate those considerations into a written Farm Food Safety Plan.



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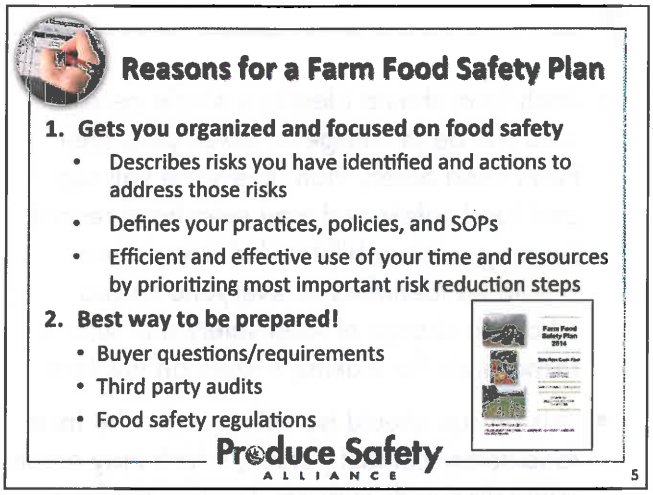

- First, a written food safety plan helps growers get organized and focused on produce safety. During this training, assessing risk has been discussed. Once growers assess their risks, writing a plan allows them to outline practices that will reduce the risks. It is a place to keep their policies and SOPs. It also helps growers use resources wisely by investing time and money in practices that reduce the biggest risks first.
- A Farm Food Safety Plan will also help growers be prepared for buyer questions and third party audits. To have a third party audit, the farm or packinghouse needs a plan. It can also help growers show they are following federal and state regulations.

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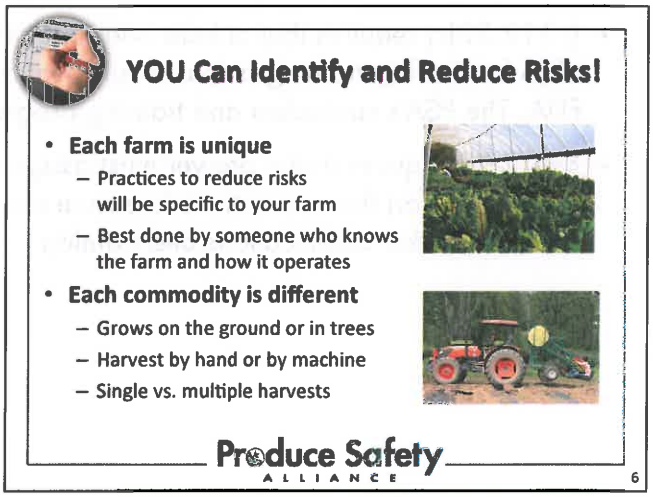

- Every farm is unique and the risks on the farm will be specific to each operation.
- Developing a Farm Food Safety Plan is best done by someone on the farm (most likely the grower!)—because they know the farm best and are capable of assessing risks on the farm. Growers know about the agricultural water they use, soil amendments, and harvest practices.
- The commodities grown on the farm will also impact the assessment of risks and practices that are included in the Farm Food Safety Plan. Unique produce characteristics such as netted skin or smooth, where the crop grows (e.g., on the ground or in a tree) and past food safety concerns may impact what practices are implemented to reduce risks.
- The key thing for growers to know and understand is that they can assess risks and implement practices that reduce risks. Remember, the focus is on risk reduction, not risk elimination.

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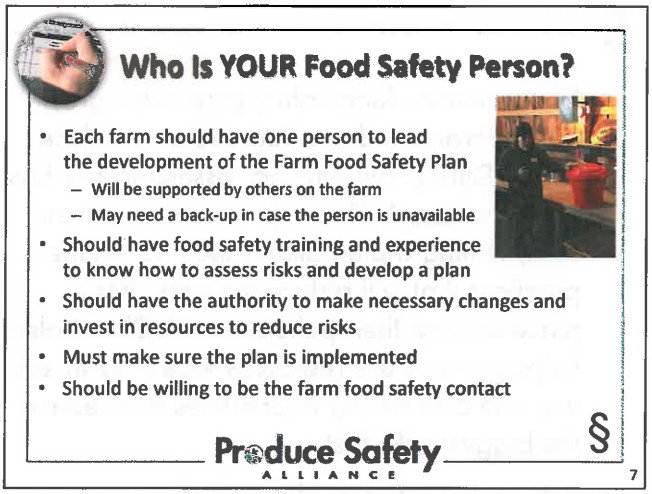
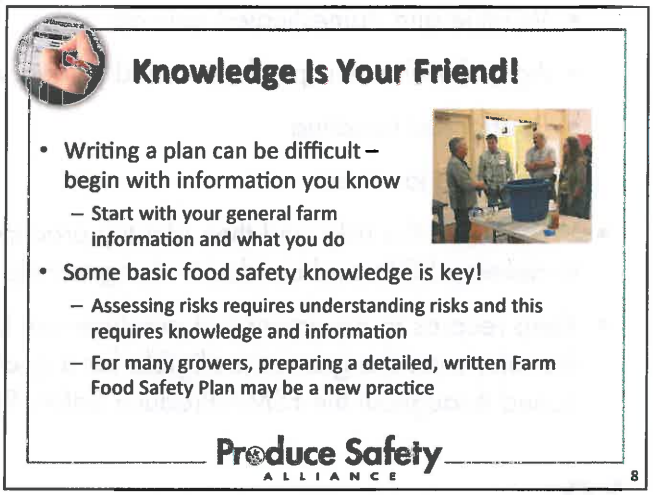


- Each farm should identify a single person who will be in charge of developing their Farm Food Safety Plan. Everyone will support food safety and may even have record keeping responsibilities, but one person should be identified so everyone knows who is in charge of food safety and who is responsible for making it work on the farm.
- This person should be willing to be the farm food safety contact person, which may mean interacting with auditors, leading the farm food safety team, and training workers.
- The food safety person should have the authority to make changes, when necessary, and invest in resources to make sure food safety practices are in place, including the required equipment to make sure tasks are being completed properly.
- § 112.22(c) requires that at least one supervisor or responsible party from the farm must complete food safety training at least equivalent to the standardized curriculum recognized by the FDA. The PSA's curriculum and training program is one way to satisfy this requirement.
- § 112.23 requires that a grower must assign or identify personnel to supervise (or otherwise be responsible for) their operations to ensure compliance with the requirements of Subpart C which relate to worker qualifications and training.

Notes:

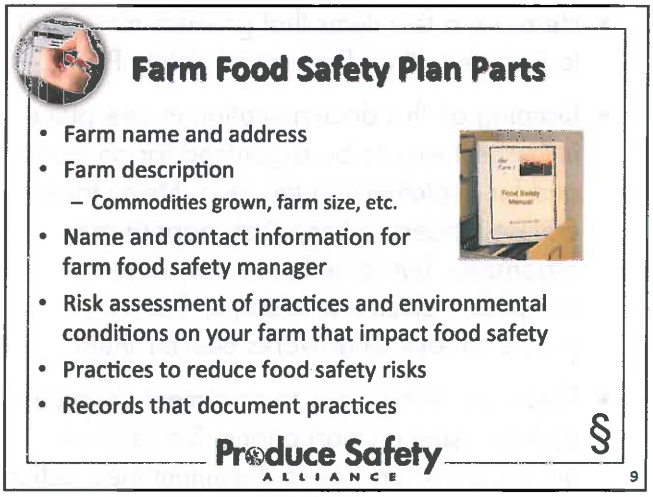
8 *Additional Information*

- This slide is optional.
- The hardest part of writing the plan is getting started. At first, stick to the basics of produce safety that have been outlined in the previous modules. Once growers have a system down, it will be much easier to add and modify.
- The more growers know, the better they will be at assessing risks and making progress on their Farm Food Safety Plan.



9

- A Farm Food Safety Plan can have many parts.
- Writing down the farm name and address, a short farm description that provides information about how long they have been farming, the commodities they grow, and the farm size are all good things to include and an easy way for the grower to begin writing their Farm Food Safety Plan.
- Be sure to include the name and contact information of the food safety contact person for the farm.



- Next, a risk assessment of production practices and growing conditions should be conducted for each area on the farm. Production practices may be different for each commodity, so be sure to account for any differences when assessing risks. If growers are not sure where to begin, they should take a moment to consider areas that could impact food safety on their farm such as:
  - Workers and facilities they use, such as toilets and handwashing sinks
  - Soil amendments, with particular attention to those that include raw manure and other amendments of animal origin

Notes:

  - Wildlife and domesticated animals
  - Agricultural water (production and postharvest uses)
  - Postharvest handling
  - Adjacent land use
- Write down the risks and then identify practices that will reduce those risks. Growers may need to develop SOPs and conduct training to help workers implement the required practices.
- Keep records to document that practices are being done properly. Some records are required in the rule, even if a grower is eligible for a qualified exemption. Records requirements are mentioned throughout the FSMA Produce Safety Rule and in Subpart O.

10

- Here are a few items that growers may want to include in their Farm Food Safety Plan.
- Keeping all this documentation in one place is the best way to be organized for an audit and for implementing the plan. Many farmers use binders to keep their paperwork organized, but some have now moved to completely electronic systems. Growers should choose what works best for them.
- There are many ways to document practices, such as using a smart phone. Some growers use smart phones to document their actions by taking photos of log sheets and white board notes. They catalogue the photos by date to keep records organized. Remind growers to back up their data daily if using electronic recordkeeping.
- Some records are required by the FSMA Produce Safety Rule, such as:
  - Worker training dates, information covered, who was trained (§ 112.30(b))
  - Agricultural water test results (§ 112.50 (b)(2))
  - Agricultural water system inspections (§ 112.50 (b)(1))
  - Monitoring treatment of biological soil amendments of animal origin (§ 112.60(b)(1)(i) or § 112.60 (b)(2))

Notes:

- Other records are not required but are a useful part of a Farm Food Safety Plan and assist with traceability efforts. Some to consider include:
  - Water change schedules for postharvest uses
  - Management of sanitary facilities, such as when restrooms are cleaned and restocked
  - Soil amendment applications
  - Actions taken to minimize wildlife intrusion into fields
- FSMA Produce Safety Rule Subpart O—§ 112.161–112.167 includes information on record-keeping requirements for making and keeping records.

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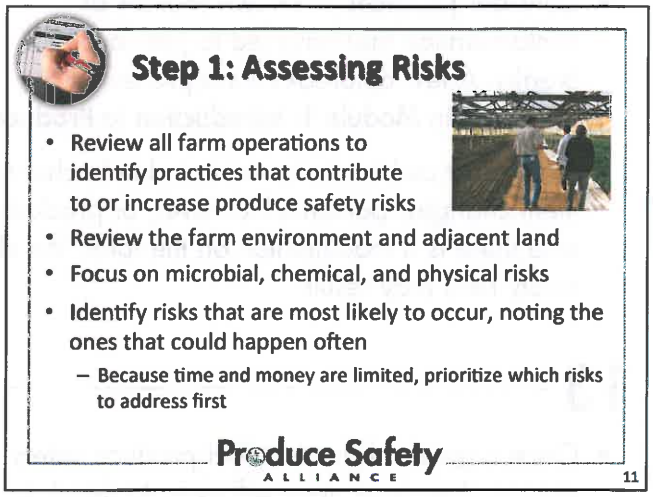

- The first step is to assess likely risks on each farm by reviewing practices, the farm environment, and adjacent land use to identify things that could introduce or increase food safety risks.
- Identify the practices and conditions that have the greatest impact on produce safety and those that may occur most frequently.
- The last six modules have detailed where risks could exist and steps that can be taken to minimize risks, so growers can use these modules as a resource to help complete a risk assessment for their farm.

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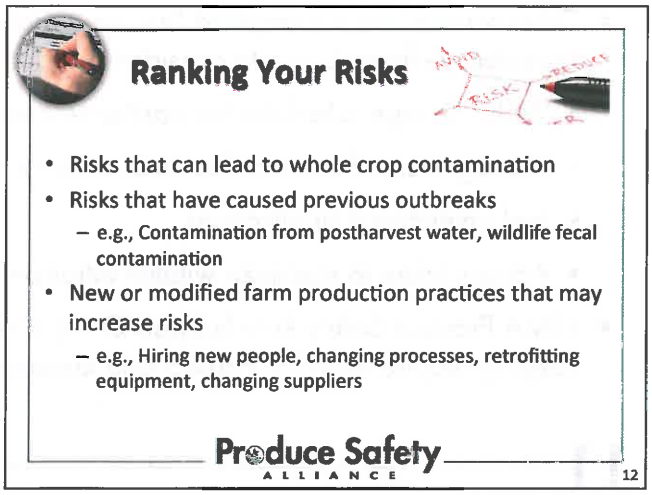

- Time and money are limited, so farm resources need to be directed toward addressing the biggest risks first.
- In ranking risks, prioritize those that put the entire crop at risk. For example, overhead irrigation of crops with poor quality water the day before harvest could impact the safety of the entire crop.
- Consider practices or known sources of contamination that have led to previous outbreaks. A few outbreaks were presented as examples in **Module 1: Introduction to Produce Safety**.
- Many past outbreaks have been due to changes that were made on the farm, including equipment changes, personnel turnover, or production practices that introduced unintended risks. Any time there is a modification on the farm, the change should be assessed to determine if any food safety risks may result.

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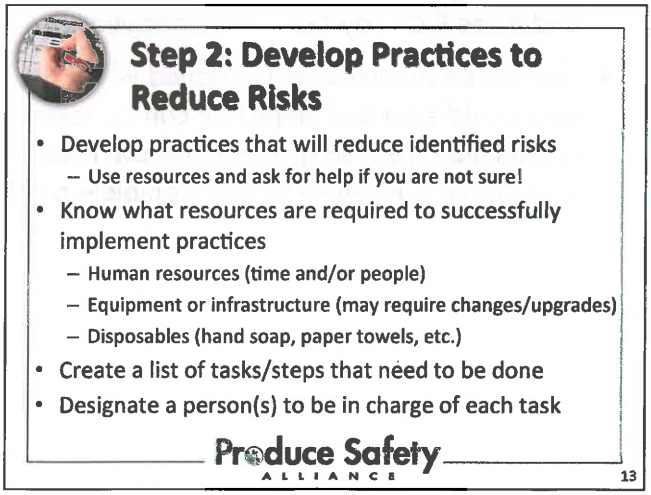


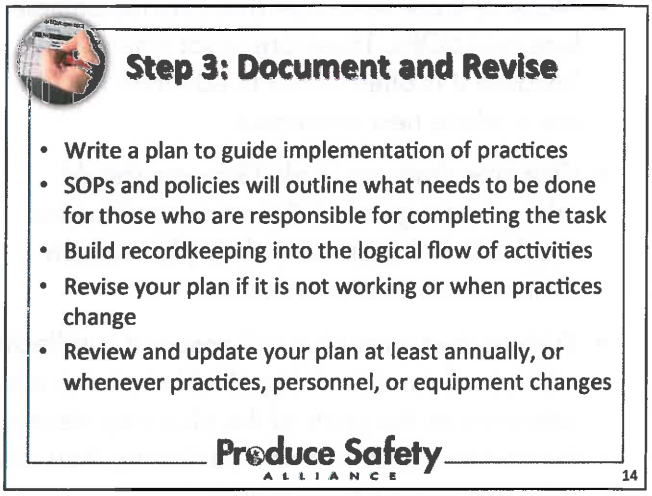
- Once a grower has identified produce safety risks on their farm, they will need to develop practices to reduce risks. Growers may need to prioritize which ones to address first if they have several risks and also are limited by human and financial resources.
- If growers are having trouble coming up with practices to reduce risks, they should ask for help. They could call their local extension educator or another farmer who has experience. The Produce Safety Alliance website (www.producesafetyalliance.cornell.edu) hosts a list of state collaborators and contact information so that growers can get help locally. There also are many educational websites and publications that are available.

Notes:

- Growers should identify resources they need to successfully implement produce safety practices including time, people, equipment, and infrastructure. Making a list is a good way to gather this information and predict the costs associated with implementation.
- Growers should designate someone to do each task. This will likely require training so everyone knows what to do and when.

14

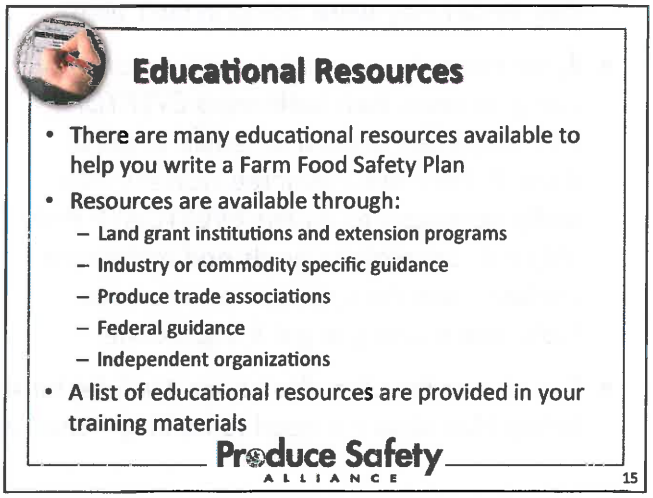
- Although a written Farm Food Safety Plan is not required by the FSMA Produce Safety Rule, it is highly encouraged.
- Build recordkeeping into food safety practices to document that things are getting done properly and on time.
- A Farm Food Safety Plan is a LIVING document. This means it needs to be updated or changed when practices, workers, or situations change or if things are not working as expected.



- During the production season (especially in the first year after writing the plan) it is a good idea to sit down monthly and review the plan to make sure it is addressing all of the critical areas to minimize produce safety risks according to how the farm is actually functioning.
- Review the plan at least yearly, even if things are going smoothly.

15 *Additional Information*

- This slide is optional.
- There are many resources available to help growers develop a Farm Food Safety Plan. A list of resources is included in the PSA training materials; however, there are other materials available that may not be listed on this sheet. Feel free to use the resources that work the best for the growers attending the training.



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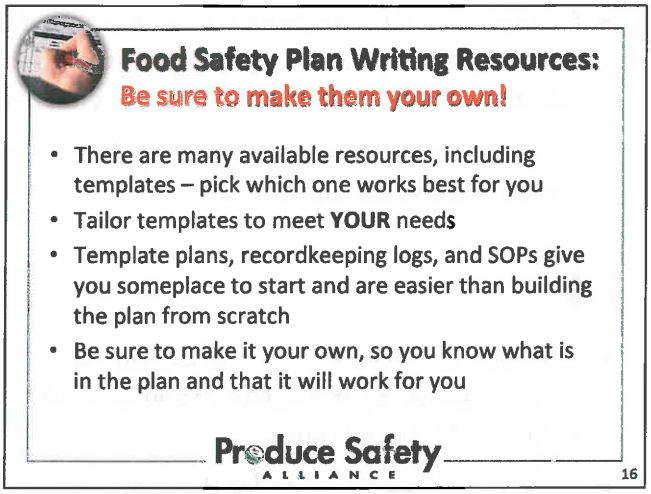
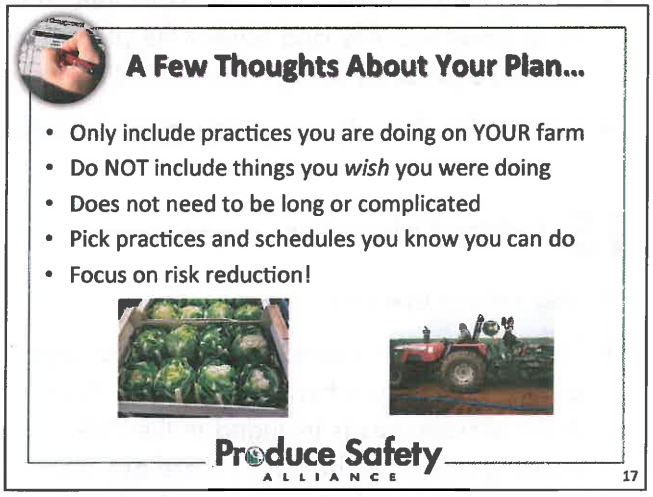


- It is important to remind growers that even if they use a Farm Food Safety Plan **template**, they still should tailor the plan to reflect their practices.
- Many of these resources also provide sample logs and SOPs. These are great time savers because it is often easier to edit than to create a whole new document.
- One size does not fit all. Growers should take advantage of all the resources that are available, but make sure their plan reflects their conditions and practices.
- Writing their own plan will ensure it is reflective of the activities that happen on their farm and will save them time if they decide to have a food safety audit. Growers should be prepared to reference all the parts of the plan they developed when the auditor visits their farm. The less time the auditor needs to spend reviewing their plan, the less the grower may need to pay if the audit is based on an hourly charge.

17



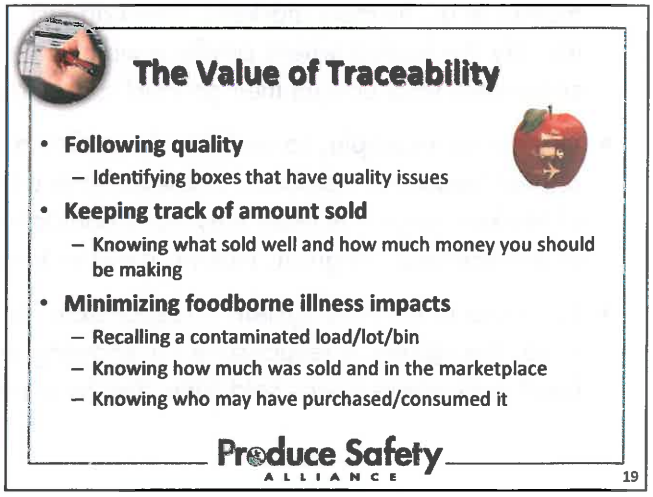
- Say what you do and do what you say. Growers should never write down things that they WISH they were doing in their plan.
- If, for example, a grower says they are going to clean their bathrooms EVERYDAY, then they need to set a schedule to get it done. If there are only three workers, is it really necessary to do this EVERYDAY? Probably not. Set realistic goals and make sure workers have the appropriate resources, tools, and training to get the job done.
- The clearer the plan, the easier it will be for everyone to follow and complete. A Farm Food Safety Plan does not need to be long—short and concise is ideal.

Notes:

18

- Traceability is the ability to track a product through the food production and distribution system. In the case of fruits and vegetables, this includes back to the field where it was grown and forward to any subsequent handling, storage, and sale. Traceability also means the grower can identify any relevant inputs used during production including the source of soil amendments, fertilizers and any chemicals applied to the crop.
- Growers are usually only a part of this production chain system and so are only responsible for a part of the traceability.
- In the next few slides, the benefits of traceability for the farm and how to develop a traceability program are discussed.
- Traceability is not covered in the FSMA Produce Safety Rule because it will be covered in the future in a separate rule that covers food more broadly.

19



- Traceability is important to food safety, but it has other benefits to every farming business.
- Traceability allows growers to follow quality, so that if there is a complaint, they know who picked, packed, and transported the boxes. It is also good for keeping buyers honest since it allows growers to follow when they sold each lot should a buyer "lose" it in the cooler for several weeks.
- Many growers have said that adding traceability has allowed them to keep better track of what sells well at particular markets and the money they should be making, especially growers who sell at farmers markets and who have not previously documented the amount of produce they take to market each week.

Notes:

- From a food safety perspective, traceability allows a grower to perform a recall of a product if there is contamination or some other food safety issue, so that the impact to consumers and the farm is as small as possible. Traceability allows growers to know how much was sold into the marketplace and who might be at risk.
- Traceability does involve paperwork, but this recordkeeping is a benefit both for the safety and quality of produce—not to mention a good business practice to keep track of produce sold.

20

- Traceability means being able to trace product one step forward and one step back.
- At the farm level, this means identifying the field where it was grown and the buyer/location who bought it. This also means knowing what inputs were used during crop production.
- It is not necessary to trace product all the way to the consumer since this could be several steps beyond the farm. If growers direct market (e.g., farmers markets), they can just identify the market where produce was sold. Growers do not need to identify all the individual consumers who bought their product at the market.
- As another example, some farms have Community Supported Agriculture (CSA) programs or annual/seasonal members. Growers have a traceability advantage in working with these types of markets since it is likely they have contact information for everyone who is part of their CSA or membership program, making it easier to contact the group if there is a problem.
- Everyone in the food system is responsible for their part, so if growers wholesale to a grocery store, the retailer is responsible for knowing where they got the produce (one step back: the farm) and where it was sold (one step forward: in a particular store).

Notes:

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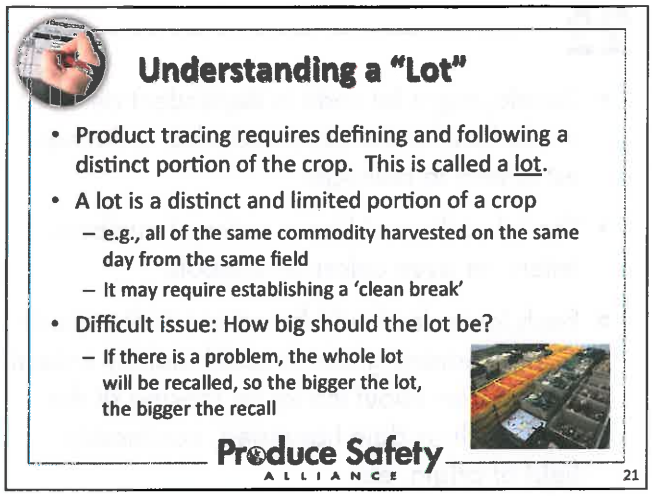

- To develop a traceability system, growers need to break produce into 'lots'. A lot is a distinct and limited portion of the crop that can be grouped and identified. For small farms, it may be all the tomatoes harvested on the same day from the same field that received similar inputs (e.g., soil amendments, irrigation water, protective sprays).
- It can be very difficult to decide how to define a lot. The bigger the lot, the more difficult it would be to recall, since one large lot may be sent to many different buyers. Having very small lots means keeping track of many different lots. If there is a recall, larger lots may mean recalling a significant portion of the crop, whereas smaller lots may limit the volume of the recall. There is no perfect answer. The decision should not be arbitrary, instead it should be based on how the farm functions considering things like the volume and commodities produced. Each grower needs to decide the best system for their farm.
- Growers might also consider potential sources of contamination when deciding where a logical break between lots might be (i.e., if contamination happens in the field, or a portion of a field, assigning lots by field makes sense).
- If a packing line is used, a '**clean break**' should be established between lots. See **Module 6: Postharvest Handling and Sanitation** for a discussion on establishing 'clean breaks'.

Additional Resource:

- Chapman, B. & Danyluk, M. (2013). Establishing Lot Size through Sanitation Clean Breaks in Produce Packing Facilities. University of Florida/IFAS Extension. http://edis.ifas.ufl.edu/fs234

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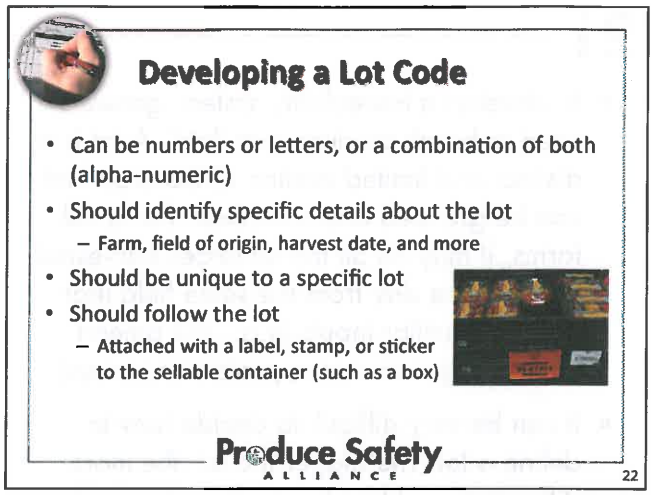

- Developing a lot code is dependent on what works best for the farm and what is the easiest system to manage.
- The lot code could be a series of numbers, letters, or even colors or symbols.
- Each lot code should be unique to the specific lot, meaning growers could identify critical information about the lot by looking at the code such as date harvested, commodity, field of origin, etc.
- The lot code should follow the lot. It could be attached to the product itself or to the sellable container. Putting the lot code on any paperwork that travels with the produce may also be helpful in the event that a problem is identified but the product and its packaging is no longer available.
- **Tip**: Buyers may request a specific way to label lots for traceability, so be sure to ask if the buyer has any particular labeling requirements.

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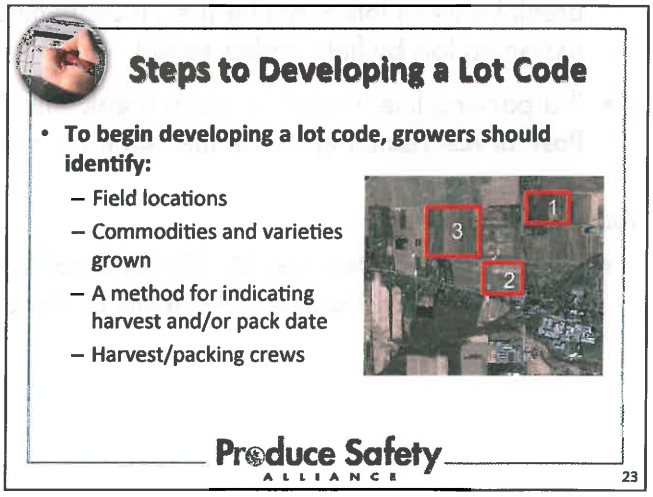

- Field and farm identification can be established using a farm map on which specific areas have been delineated and given a number or other identifier.
- Each commodity should have its own identifier and some farms choose to include the variety if they grow multiple types of that commodity (e.g., Roma tomatoes, Early girl tomatoes).
- Dates can be written in a variety of ways, such as MM-DD-YY or by using a **Julian date** (day 1-day 365). Some growers prefer Julian Dates because they are not easily recognized by consumers and allow for a simple 3 digit date.

Notes:

- If only a few people work on the farm, then identifying harvest or packing crews is not essential since the grower knows everyone who works on the farm. Identifying harvest and packing crews is more critical for farms who employ large numbers of workers if there is a problem with the produce, or an outbreak associated with pathogens that are spread by humans, such as Hepatitis A. If growers are already keeping track of crews/workers for piece rate pay, they may be able to use that system in their traceability system.

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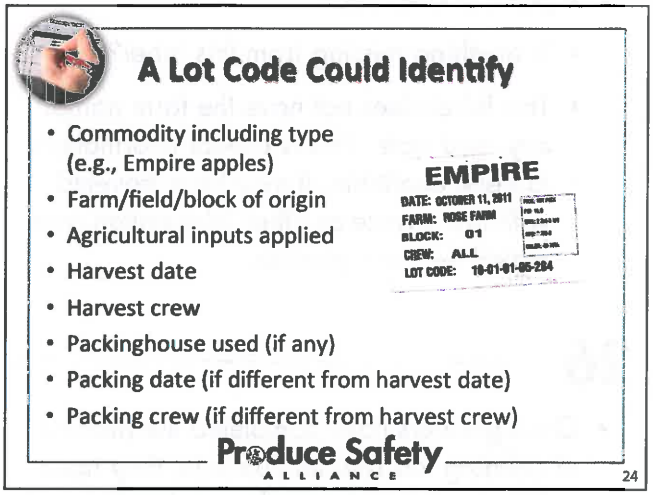
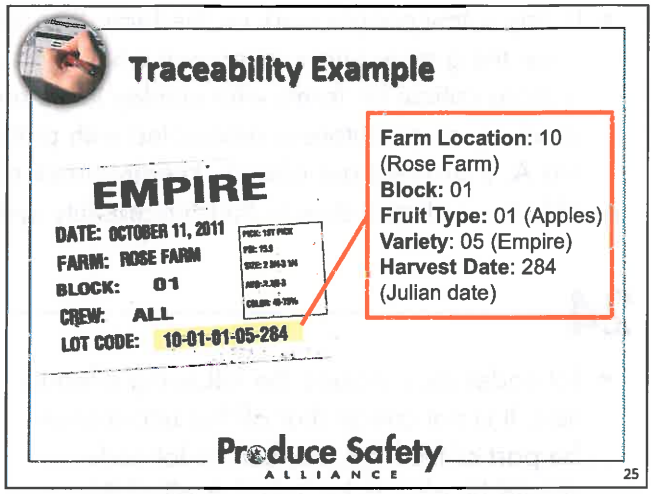


- Lot codes may include the following information. It is not critical that all this information be part of the lot code, but the lot code should be able to be linked to all of this information through farm records.
- In addition to basic information about the produce and the date it was harvested, it is helpful to keep information about the agricultural inputs that were used to produce that specific crop. For example, soil amendments that were used or sprays that were applied to crops, in case any food safety problems arise. Having information about the agricultural inputs may provide insight as to whether an input may have been a source of contamination to the crop.
- Like the Farm Food Safety Plan, the lot code should be tailored to the individual operation and the information that is needed to distinguish one lot of produce from another.

Notes:

25 *Additional Information*



- This slide is optional.
- This is just one example of how a grower may choose to create a lot number for their product.
- A point of discussion:
  - Is anything missing from this label?
  - This label does not have the farm name, city, and state. This is critical information to have available. It may have traveled with the invoice or other information associated with this product.

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- Once growers have completed the process of defining lots and lot numbers, they need to figure out how to get the number to travel with the lot. This is called labeling.
- Labels can be simple or complex, handwritten or bar codes—but the important part is that the lot number travels with the produce lot.
- There are many options. Pick the one that works best for the farm and one that is affordable. More expensive systems may save time, but not always. Growers should investigate which labeling options will work best for their operation.
- Most traceability systems label the sellable container. Some will label each piece, but this is not required and not always possible.
- If the containers are unloaded or co-mingled, the ability to fully trace each piece is impacted. This is OK—it just simply limits the extent to which the produce can be traced.
- There is no perfect system because of the complexity of the distribution system, but growers should consider traceability and how to put a system in place.

Notes:

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- Growers who are eligible for the qualified exemption in § 112.5 will need to comply with modified requirements for labeling.
- § 112.6 (b) outlines labeling requirements for those who are eligible for qualified exemptions.

1. When a food packaging label <u>is</u> required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.
2. When a food packaging label <u>is not</u> required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.
    - This requirement could be satisfied using a handwritten poster made with a marker and posted at the farm market stand or CSA pick up site if the grower direct markets. This provides contact information for the farm in case there is an issue with the produce.
3. The complete business address must include the street address or PO box, city, state, and zip code for domestic farms, and a comparable full address for foreign farms.

Notes:

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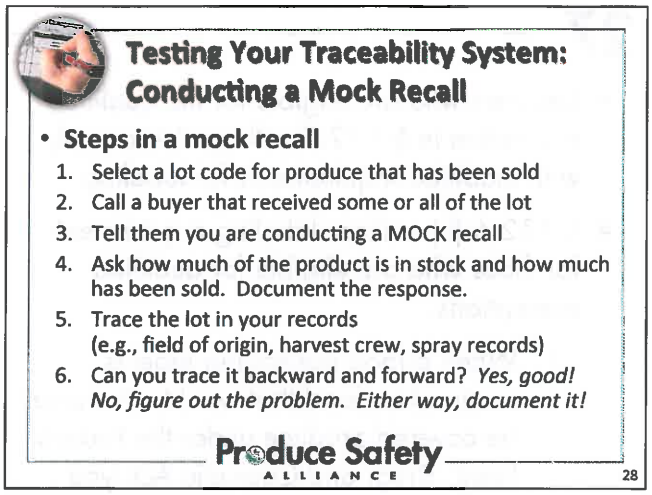

- Once a product tracing system is in place, it should be tested with a **mock recall**. This will help growers assess if the system would work in a real recall and give them an opportunity to correct the system if it does not work.
- Ideally, growers contact a buyer who is expecting them to perform a mock recall. Growers should be sure to alert buyers that they are conducting a MOCK recall and not a real recall, otherwise there could be some pretty serious confusion!
- Make sure farm records can be traced back as well. Do growers know the field where it was grown, the date of harvest, spray records for the crop, and harvest crew? If so, their traceability system works. If not, growers will need to figure out the problem and fix it.
- Set a timeline for receiving and documenting answers to traceability questions. Each step in the process should be rapid to allow quick action—Less than 2 hours total is ideal!
- Finally, make sure to document all mock recall actions.
- Growers may want to consider developing a crisis management plan for issues such as recalls and other farm emergencies.
- A crisis management plan should include emergency contacts (e.g. key farm personnel, family contacts, lawyer, industry/grower organization contacts), daily tasks that should be completed on the farm in case the grower is not there, buyer contacts, and any other key info that would provide insight into farm operations should the grower be injured, ill, or worse. The worst time to develop a crisis management plan is during a crisis. A small amount of planning can go a long way in handling a crisis situation, so that the crisis is as short as possible with as little impact to the farm as possible.

Notes:

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Summary

- The best person to write the plan is someone who knows the farm and has food safety knowledge
- Identify someone to be in charge of food safety
- Farm Food Safety Plans should include assessing risks, any actions taken to reduce risks, and recordkeeping
- Simple is best: write what you do, not what you hope to do
- Traceability = one step forward and one step back, as well as inputs to the crop throughout production
- Establishing lots, lot codes, and labeling are necessary for developing a traceability system
- Finally, follow the plan and update as necessary

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Notes:

Produce Safety
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Module 7 – How to Develop a Farm Food Safety Plan

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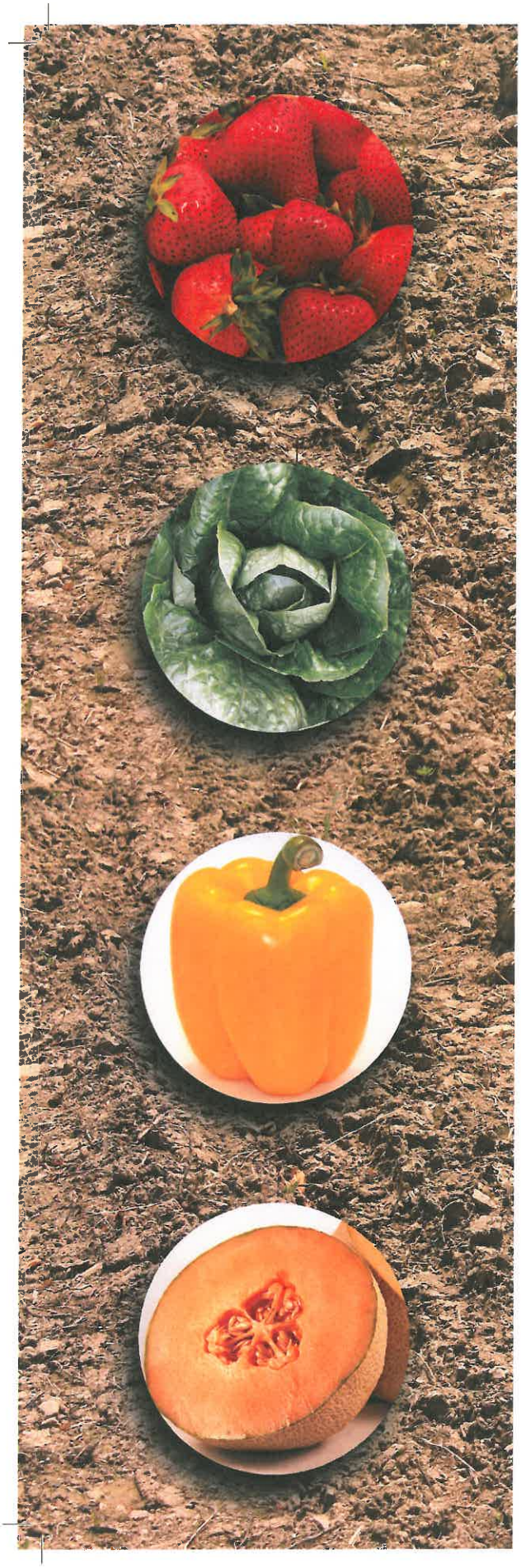

Produce Safety ALLIANCE

Glossary

Cornell University

Glossary

**Indicates a FSMA Produce Safety Rule definition outlined in Subpart A – General Provisions § 112.3(c) or within the codified language of the rule. In some cases, the definitions below have been abridged. Please refer to General Provisions § 112.3(c) or codified language for the complete definitions. The remaining glossary terms have been adapted from existing educational materials or reflect standard produce industry use.*

Agricultural Tea*

A water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purpose of this rule.

Agricultural Tea Additive*

A nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural Water*

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).

Application Interval*

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Animal Intrusion

Wildlife or other animal activity in produce growing and handling areas that leaves observable evidence in the form of animal feces, urine, tracks, or crop damage. Animal intrusion should be evaluated during the growing season and immediately prior to harvest to minimize risks of produce contamination from animal fecal material that may contain human pathogens.

Biofilm

A complex structure of different microorganisms adhering to a surface and protected by glue-like carbohydrates secreted by the microorganisms. Once the microorganisms attach to food contact surfaces as a biofilm, they are very difficult to completely remove.

Biological Soil Amendment*

Any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological Soil Amendment of Animal Origin*

A biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term "biological soil amendment of animal origin" does not include any form of human waste.

Cleaning

Physical removal of dirt (soil) from surfaces which can include the use of clean water and detergent.

Clean Break

A break in production where all the food contact surfaces on the production line are cleaned and sanitized with a documented, verified, and validated process.

Colony Forming Unit (CFU)

A measure of viable cells quantifying the number of bacteria in a sample based on an analysis that measures how many visible, viable colonies (large mass of bacterial growth) form when a liquid sample (or sample dilution) is placed onto an Agar surface for growth. This calculation is based on the assumption that each colony stems from the deposition of a single bacterial cell onto the agar surface that divides over several generations. Results are reported in CFU/100 mL.

Co-Management

Practices that minimize the risk of fecal contamination and resulting microbiological hazards associated with food production while simultaneously conserving and protecting soil, water, air, wildlife, and other natural resources.

Come-Up Time

The time to achieve the appropriate temperature in a composting system for the reduction or elimination of harmful microorganisms.

Communicable

Able to be transmitted from one person to another; contagious or infectious.

Composting*

A process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131°F (55 °C)), followed by a curing stage under cooler conditions.

Corrective Actions

Actions taken to correct a problem and identify why it occurred in order to prevent it from happening again. Some corrective actions can be anticipated ahead of time if a problem is likely to occur. For example, a corrective action can be outlined for what to do after animal intrusion into a field, including the actions workers need to take to reduce food safety risks. These prevention-oriented corrective actions should be documented in the Farm Food Safety Plan.

Covered Activity*

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. This includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm". Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. The FSMA Produce Safety Rule does not apply to activities of a facility that are subject 21 CFR part 117.

Covered Produce*

Produce that is subject to the requirements of the FSMA Produce Safety Rule in accordance with §112.1 and §112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

Cross-Contamination

Contamination of one food item with microbial pathogens from another food item, water, surface, or other object. Sources of cross-contamination may include pathogens transferred to produce through contaminated wash or irrigation water, improperly applied manure, animal feces, packing lines, worker hands, harvest bins, or trucks.

Cull Pile

A pile of discarded plant material or produce. Cull piles may become an attractant to pests or a source of nutrients for the growth of bacterial pathogens.

Curing*

The final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.

Detergent

A cleaning agent that contains surfactants that reduce surface tension between food surfaces and dirt (soil) or other debris. Detergents aid in lifting dirt off of surfaces. Detergents are used in the cleaning process before a sanitizer.

Direct Water Application Method*

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.

Dropped Covered Produce*

Covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground such as carrots, crops that grow on the ground such as cantaloupe, or produce that is intentionally dropped to the ground as part of harvesting such as almonds. Covered produce unintentionally dropped to the ground during harvest is also considered dropped covered produce, according to the FSMA Produce Safety Rule (§ 112.114).

Facility

Any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities (21 CFR §1.227).

Farm*

(i) **Primary Production Farm** is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood) or any combination of these activities. The term "farm" includes operations that, in addition to these activities: (A) Pack or hold raw agricultural commodities; (B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in (i)(C)(2)(i) of this definition; and (C) Manufacture/process food, provided that: (1) All food used in such activities is consumed on that farm or another farm under the same management; or (2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of: (i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing); and (ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and (iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or (ii) **Secondary Activities Farm** is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in (i)(B) and (C) of this definition.

Farm Food Safety Plan

A written document that outlines the farm's food safety practices and may include recordkeeping logs, Standard Operating Procedures, and other supporting documents that help growers implement food safety practices. A Farm Food Safety Plan is not required for the FSMA Produce Safety Rule, but is required for many third-party food safety audits.

Farmers' Market

A farmers' market is a physical location where more than one farmer, and sometimes other vendors, sell products they have grown or raised directly to consumers. The products sold often include fresh fruits and vegetables, but may also include, meat, eggs, dairy products, baked goods and processed foods produced on the farm.

Food Contact Surfaces*

The surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. This includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Foodborne Illness Outbreak

The occurrence of two or more cases of illness resulting from eating or drinking the same foods contaminated with the same pathogen. In the case of botulism, only one illness is required to be recognized as an outbreak.

Geometric Mean (GM)

A measure of the central tendency of your microbial water quality data, the average of log-transformed values. The geometric mean is a required criterion of the Microbial Water Quality Profile for agricultural water (§ 112.44(b)(1)).

Good Agricultural Practices (GAPs)

Any agricultural management practice or operational procedure that reduces microbial risks or prevents contamination of fruits and vegetables on the farm or in packing areas.

Good Manufacturing Practices (GMPs)

Standards published in the Code of Federal Regulations (Title 21, Section 117, Subpart B) to ensure the safety of foods by outlining sanitary standards and practices for production and handling.

Green Waste

Biodegradable waste that may be composed of garden or farm waste, such as grass, flower cuttings, hedge trimmings, as well as domestic and commercial plant-based food waste. Green waste cannot be considered zero risk since it may contain physical, chemical, or biological hazards. If the green waste contains any materials of animal origin, including animal feces, it cannot be considered green waste.

Ground Water*

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.

Growth Media*

Material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as stabilized compost, manure, non-fecal animal byproducts or table waste). Liquid-only matrices are not considered to be growth media.

Harvesting*

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard*

Any biological agent that has the potential to cause illness or injury in the absence of its control.

Hazard Analysis Critical Control Point (HACCP)

A process that identifies critical control points (CCPs) where contamination can occur and manages these points as a way of ensuring the safety of the products being produced. HACCP requires processes be monitored at all times and be corrected if the processes exceed the established critical control points. HACCP is commonly used in processing plants but not considered appropriate in fresh produce fields because the necessary level of control is not achievable.

Holding*

The storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity into a processed food. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Infiltration

The movement of water passing into fresh produce during immersion, such as in a dump tank during postharvest handling. Factors that increase the risk of infiltration include temperature differentials, when dump tank water is cooler than the produce pulp temperature; pressure differentials or rapid pressure change, such as when produce is deeply submerged; the presence of surfactants, such as detergents or wetting agents; extended contact time with the water; and the presence of wounds or other openings in the produce.

Inorganic Fertilizer

A chemical fertilizer of synthetic or mineral origin.

Julian Date

The number of elapsed days since the beginning of the new calendar year or another pre-determined starting date in the calendar year. For example, January 23 would have a Julian date of 023 or December 31 would have a Julian date of 365 (during non-leap years).

Lot

A distinct and limited portion of the crop that can be grouped and identified. For small farms, it may be all the tomatoes harvested by one work crew on the same day from the same field that received similar inputs (e.g., soil amendments, irrigation water, protective sprays).

Known or Reasonably Foreseeable Hazard*

A biological hazard that is known to be, or has the potential to be, associated with the farm or in the food.

Manufacturing/Processing*

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Manure*

Animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microorganisms*

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-Type Facility*

An establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

Mock Recall

An evaluation of a farm's ability to trace a specific product lot to the buyer to which it was sold (one step forward) and to farm records indicating all inputs used during crop production (one step back).

Monitor*

To conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

Most Probable Number (MPN)

A statistical estimate of the number of bacteria in a sample determined through laboratory analysis. Results are reported in MPN/100 mL.

No-Harvest Buffer Zone

A defined distance around an identified risk from which produce should not be harvested. No-harvest buffer zones can be established around fecal contamination or around areas of significant animal intrusion to minimize the risk of harvesting produce that has been contaminated.

Non-Fecal Animal Byproduct*

The solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

Non-Food Contact Surface

Surface that does not contact produce directly, but may contribute to the risk of contamination of fruits and vegetables. For example, brush rollers on a sorting or grading table that contact produce directly are considered direct food contact surfaces whereas a gear box attached to the rollers that does not come into contact with produce would be considered a non-food contact surface.

Packing*

Placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201 (gg) of the Federal Food, Drug, and Cosmetic Act.

Parts Per Million (PPM)

A way of expressing very dilute concentrations of substances; in this document it refers to chemical concentration, such as the amount of sanitizer. One ppm is equivalent to 1 milligram (or milliliter) of a chemical per liter of water (mg/L).

Pathogen

A disease-causing microorganism, or other microorganism of public health significance.

Pest*

Any objectionable animal or insect, including birds, rodents, flies, and larvae.

Personal Protective Equipment (PPE)

Equipment worn to minimize exposure to a variety of hazards. Examples of PPE include items such as gloves, eye protection, hearing protection devices (earplugs, muffs), hard hats, respirators, and full body suits.

Policy

A statement that explains practices aimed at achieving a specific food safety outcome. Policies are specific to each farm. Policies should be included in the Farm Food Safety Plan.

Postharvest Handling

Any practices that occur during or after harvest including cooling, culling, washing, and packing.

Postharvest Water

Water that meets the definition of agricultural water and is used during and after harvest of covered produce, or during postharvest handling of covered produce; this can include agricultural water used during harvest activities in the field as well as during packing or holding activities, such as water used in a packinghouse.

Potable

Meets the Environmental Protection Agency (EPA) primary drinking water standards including microbiological quality.

Pre-Consumer Vegetative Waste*

Solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packinghouses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Produce*

Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Produce Safety Rule Codified Language

The specific legal requirements associated with the final Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption published in the Federal Register on November 27, 2015.

Produce Safety Rule Preamble

A section published in the Federal Register on November 27, 2015 associated with the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) that outlines the rationale for the provisions in the codified rule, describes FDA's thinking about the final rule and responses to submitted comments.

Production Water

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 FSMA Produce Safety Rule (112.44(b)).

Qualified End-User*

With respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located: (i) In the same State or the same Indian reservation as the farm that produced the food; or (ii) Not more than 275 miles from such farm.

Raw Agricultural Commodity

Any food in its raw or natural state, including, but not limited to, all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing (FD&C Act. 21 USC §321 201 Part R).

Recall

A voluntary or mandatory action taken by growers, packers, or produce distributors to remove potentially contaminated produce from the marketplace and consumer's homes.

Retail Food Establishment

An establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations (21 CFR §1.227).

Riparian Areas

Interface between land and a river or stream.

Risk Assessment

A process to identify potential hazards on a farm and/or in a packinghouse as well as the likelihood the hazards will impact the safety of fruits and vegetables.

Runoff

Rainwater, leachate, or other liquid that drains over land, leaves the land surface, and enters unintended areas such as streams, fields, or packing areas.

Safety Data Sheets (SDS) *(previously Material Safety Data Sheets (MSDS))*

Documents that contain information on the potential health effects of exposure to chemicals, or other potentially dangerous substances, and on safe working procedures when handling chemical products. SDS are specific to each substance and are provided by the manufacturer.

Sanitary Design

The design, fabrication, construction, and installation of food contact surfaces and food processing equipment to facilitate easy cleaning and sanitation practices. Sanitary design helps prevent buildup of harmful microorganisms and ensure surfaces are constructed of materials that can withstand daily exposure to corrosive food products and/or cleaning and sanitizing agents.

Sanitize*

To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sanitizer

A substance that reduces the amount of microorganisms to acceptable levels, typically for use on food contact surfaces. Sanitizers are generally considered to be part of a broader group of substances called antimicrobial pesticides. The antimicrobial product label will describe approved uses, such as for water or for food contact surfaces, as well as approved concentrations or dosages.

Sewage Sludge Biosolids*

The solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of "sewage sludge" in 40 CFR 503.9(w).

Side-Dressing

Application of a soil amendment to the side of the planted crop row so the nutrients are available in the root zone without damaging the plant.

Soil Amendment*

Any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Standard Operating Procedure (SOP)

Written description of an activity and how to properly complete the activity. An SOP should specify all the materials needed to complete the activity, the frequency with which the activity is conducted, and how to document the activity. An SOP may also include which employees are responsible for completing the activity and provide corrective actions to mitigate the problems that are likely to happen.

Stabilized Compost*

A stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.

Static Composting*

A process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

Statistical Threshold Value (STV)

A measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution. The statistical threshold value is a required criterion of the Water Quality Profile for agricultural water and various tools and worksheets are available to assist with the calculation. (§112.44(b)(2)).

Surface Water*

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.

Table Waste*

Any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

Template

Samples of recordkeeping logs, SOPs, and language to aid in the development of a Farm Food Safety Plan. Templates must be edited to reflect activities on the specific farm represented in the Farm Food Safety Plan.

Total Coliforms, Fecal Coliforms, and *Escherichia coli* (*E. coli*)

Coliforms are bacteria that are found in the environment, soil and intestines of warm-blooded animals. Fecal coliforms are a type of coliform that are more likely to be specifically associated with human or animal fecal material and are a more accurate indication of the presence of feces than total coliforms. *Escherichia coli* (*E. coli*) is within the group of fecal coliforms. 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 and is designated as the indicator organism to meet the agricultural water criteria in the FSMA Produce Safety Rule.

Traceability

The ability to track a food product through the food production and distribution system. In the case of fruits and vegetables, this includes back to the field where it was grown and any subsequent handling, storage, and sale.

Turbidity

The cloudy appearance of water when suspended sediments such as soil and organic matter are present. The level of turbidity is measured in Nephelometric Turbidity Units (NTU). Turbidity is one measurement that can be used to monitor postharvest water for buildup of organic material, and help growers establish an appropriate water-change schedule.

Turned Composting*

A process to produce stabilized compost in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

Visitor*

Any person (other than personnel) who enters your covered farm with your permission.

Water Distribution System*

A system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

Worker

Any person, paid or unpaid, working on a farm that grows or packs fresh fruits and vegetables. This includes growers, farm managers, family members, migrant labor, summer help, and packinghouse employees.

Yard Trimmings*

Purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

Zones

Areas defined by their likelihood to have contact with fruits and vegetables. Zone 1 designation indicates a surface that has direct contact with fruits and vegetables such as harvest containers, conveyor belts, grading tables, rollers, utensils, storage bins, and worker hands. Zone 2 defines an area immediately adjacent to Zone 1 including non-food contact surfaces that are in close proximity to fruits and vegetables, such as internal and external parts of washing or processing equipment. Zone 3 includes areas inside the packing space immediately adjacent to Zone 2 that may contribute to contamination such as trash cans, cull piles, floor drains, catwalks, or restrooms. Zone 4 includes areas outside of the packing area and adjacent to Zone 3 including loading docks, warehouses, or compost piles.