Food Safety

Tuesday afternoon 2:00 pm

**Where:** Gallery Overlook (upper level) Room C & D  
**MI Recertification credits:** 2 (COMM CORE, PRIV CORE)  
**CCA Credits:** SW(1.0) CM(1.0)  
**Moderator:** Phil Tocco, Extension Educator, MSU Extension, Jackson, MI

2:00 pm  E. Coli Presence in Packing Houses  
• Wes Kline, Cumberland County Extension, Millville, NJ

2:30 pm  FSMA On-Farm Readiness Review  
• Phil Tocco, Extension Educator, MSU Extension, Jackson, MI

3:00 pm  Impact of Chlorination and Cover Crops on Pathogen Presence  
• Kathryne Everts, Vegetable Plant Pathology, Univ. of Maryland

3:30 pm  Hows and Whys of Irrigation Water  
• Don Stoeckel, Midwest Regional Extension Associate, OH

4:00 pm  Session Ends
Tomatoes are one commodity where there is concern for water infiltration if fruits are dumped in water during the packing operation. At the present time, only tomatoes are required to have the water temperature monitored in dump tanks. If the operation is using spray bars then temperature monitoring is not required. According to the USDA Tomato Food Safety Protocol - “In systems where tomatoes are submerged or dwell in water, water temperature is monitored and controlled. Water temperature should be at least 10°F above highest measured pulp temperature of tomatoes when entering the water. If operation can demonstrate retention times are never more than two minutes and water submersion does not exceed 1 ft., water temperature shall be controlled to be not less than highest measured pulp temperature.” If fruit temperatures are too high in the summer tomatoes can be put in the shade or better yet in a cold room before packing.

We have been carrying out a study to determine if microbial load is reduced on tomatoes that go through a sanitation step. Five farms across New Jersey were sampled over three years (1000 samples). All the tomatoes were grown on stakes and plastic. In 2013, tomatoes were sampled one time and the other two years twice, early and late. Five samples were taken from different parts of the baskets or bins just prior to dumping then a second sample was taken just before packing. Three farms used dump tanks and then ran the tomatoes under spray bars. Two farms just ran the tomatoes under spray bars. All farms used a sanitizer, either chlorine or hydrogen peroxide/peroxyacetic acid (Sanidate®).

No farms in this study maintained their water temperature 10°F above the fruit pulp temperature. Pulp temperature at most sampling dates was warmer than the water. Some growers are exploring the use of solar to heat their dump tank water.

Packinghouse one (used dump tank and spray bars) had a higher E. coli count at each sampling time after washing. This was especially true at the second sampling date in 2014. When 4 out of 20 fruit tested positive for E. coli prior to washing and 17 out of 20 after. This indicates that cross contamination occurred between tomatoes or further contamination was introduced at the packinghouse. When the equipment was examined there was a return track on the sizer chain which was difficult to clean and sanitize that could have been resulting in contamination of the fruit post washing. In 2015 the E. coli levels dropped to 2 out of 20 prewash versus 3 out of 20 post wash. These levels still need to be lower post wash. It appears the return chain still is not being cleaned properly.

Packinghouse two (used dump tank and spray bars) was able to eliminate E. coli from all samples with their sanitation process going from 6 prior to 0 post wash at one sampling date.

Packinghouse three (used dump tank and spray bars) only had E. coli in the 2013 and first sampling date of 2015. The E. coli count was reduced from 4 pre wash to 1 post wash in 2013, but increased from 0 to 7 in 2015. The second sampling in 2015 returned to 0 for pre and post wash. There is no explanation for this change other than the sanitizer monitoring program may not have been sufficient.
Packinghouse four (spray bars) had an increase in E. coli counts two out of five samplings and a decrease in the other three. Contact time is very short which may be a factor with this system since it is very short time from dumping tomatoes on the line and running under the spray bars.

Packinghouse five (spray bars) had no detectable E. coli for four of five sampling times. One sample tested positive for E. coli prewash for the first date in 2015, but none tested positive post wash. Contact time was longer for this packinghouse compared to packinghouse four.

All packinghouses showed a decrease in total plate or coliform counts 2-3 out of five sampling times after going through the sanitation step, but the amount of reduction varied widely. Each had different sanitary procedures that did result in a wide range of potential bacterial reductions.

Growers should be using a sanitation step if using water when packing tomatoes. This means that the level of sanitizer must be monitored and depending on the sanitizer used the pH may need to be monitored. How often you monitor should be based on run time. If using a dump tank, check the pH just before putting the sanitizer in the tank and if needed adjust the pH. Put in the properly calculated amount of sanitizer then check the concentration. Continue to check the concentration at least hourly. Drain the tank at the end of the day and refill with clean water. Remember the more organic matter that goes into the tank the more often a sanitizer needs to be monitored and added. There was no standardization on a common set of best sanitary procedures among the growers in this study and monitoring times could have been improved.

Along with cleaning the dump tank, all the equipment than comes in contact with the tomatoes should be cleaned and sanitized after each use. This does not mean just cleaning off, but vigorously scrubbing and rinsing then applying a sanitizer. Make sure the person doing the cleaning and sanitizing understands the procedure. The standard sanitization operating procedure (SSOP) should be written down and readily available for review. Any cleaning supplies, brooms, mops, etc. should only be used for cleaning and sanitizing the equipment. Store these items separate from other items. The best way to ensure there is no confusion is to color code everything. This can be done with paint or colored tape.

To determine how a group of growers in New Jersey were doing with cleaning and sanitizing equipment another study was carried out to assess their procedures. Sanitation of produce contact surfaces in a packing house are an important part of reducing food safety risk. Most fresh produce growers are not sampling the produce contact surfaces to evaluate the effectiveness of their sanitation step. Swab sampling for both adenosine triphosphate (ATP) and generic E. coli allowed for evaluation of the effectiveness of sanitation methods used at participant farms.

Five farms from New Jersey participated in the product contact surface sampling project. These farms varied greatly in their size, production methods, sanitation practices and commodities packed. Commodities included baby greens, onions, green beans, apples and tomatoes. Packing line surfaces were swab sampled for both ATP and generic E. coli. Swabs were taken during active packing and after the line had been sanitized. Sanitation practices included the products Simple Green®, Sanidate®, 10% bleach spray solution or soap and water. The objective was to recommend changes to improve sanitation procedures. Best management practice for product contact surface sanitation methods were developed and used to educate fresh produce growers.
Sanitation practices in general reduced organic matter load on the produce contact surfaces, reduced ATP levels and when generic E. coli was found reduced the number to 0 after the sanitation step. Variation in the sanitation step effectiveness were noted, particularly with the post sanitation step ATP numbers and E. coli numbers. When concentrated soap powder was used there was some reduction, but not to acceptable levels. Also, it was determined that when supervising staff were not present or were in a period of transition ATP and generic E. coli levels on packing surfaces were not being managed properly. This resulted in unacceptable levels of ATP and/or E. coli.

What are acceptable levels of ATP and aerobic Plate Counts? This is area of active research, but following is an interim guideline.

Table 1. Example of interim guidance for ATP and Aerobic Plate Count outcomes of harvest and shipping container microbiological swab analysis

<table>
<thead>
<tr>
<th>General ATP-bioluminescence Unit Reading Outcome (Relative Light Units – RLU)</th>
<th>Hard Surface Cleanliness Expectation Outcome</th>
<th>Typical Correlative Aerobic Plate-Count Expectation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 50 RLU</td>
<td>Acceptable - ‘Very Clean’ Acceptable – ‘Reasonably Clean’</td>
<td>&lt; 60 CFU/cm²</td>
</tr>
<tr>
<td>100 ≤ x &lt; 300 RLU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 300 RLU</td>
<td>Corrective Action Needed</td>
<td>1,500 ≤ x &lt; 3,000 CFU/cm²</td>
</tr>
<tr>
<td>≥ 1,000 RLU</td>
<td>Unacceptable – Immediate Corrective Action Needed</td>
<td>&gt; 5,000 CFU/cm²</td>
</tr>
</tbody>
</table>


Fresh produce growers are encouraged to create a standard operating procedure when developing their product contact surface area sanitation program. Training employees and posting directions in the work area are an important way of assuring proper sanitation methods are being used and that there is little variation in the effectiveness of the sanitation step. During times of transition it is important to consider relief staff tasks and ensure they are properly trained or supervised.
Preparing for FSMA: On-Farm Readiness Review

Phil Tocco
MSU Extension

Objectives

• Offer a voluntary pre-inspectional readiness review for covered farms.
• Promote coordination between farmers, regulators, and educators.
• Educate regulators about on-farm conditions.
• Identify educational needs.
• Familiarize non-qualified farms with the regulation.
On-Farm Readiness Review

- Education before Regulation
- Value gained by learning industry/regulatory practices in a spirit of partnership

On-Farm Readiness Review

- Driven by National Association of State Departments of Agriculture (NASDA)

- State Departments of Agriculture
  - Oregon, North Carolina, Florida, Vermont

On-Farm Readiness Review Partners

- FDA
  - Produce Safety, Office of Regulatory Affairs, inspector
- USDA
  - FDA liaison, GAP auditor
- Extension
  - Michigan, New Jersey, Florida, North Carolina
  - Produce Safety Alliance
NASDA Perceived Benefits
• Learning opportunity for both industry and regulators
• Industry exposure to the regulatory process
• Provides regulators an opportunity to build knowledge and skills necessary to uniformly and consistently regulate the fresh produce industry
• Builds awareness of critical food safety practices for farmers
• Provides farmers an opportunity to assess their operations against regulatory provisions
• Assists in building consensus among industry, academia and regulatory stakeholders

How We Got to Now
1. Determine resources needed
2. Identify staff involved
3. Design a strategy for creation and implementation
4. Develop on‐farm review toolkit
5. Test the tool on farms

OFRR toolkit modules*
- Preharvest water
- Preharvest sanitation
- Preharvest worker training
- Preharvest wildlife
- Preharvest soil amendments
- Harvest water
- Harvest sanitation
- Harvest worker training
- Harvest wildlife
- Postharvest water
- Postharvest sanitation
- Postharvest worker training
Pilot

- First pilot test, Grand Rapids, 8/16-18
- 2 farms
  - Celery and blueberries
**Celery farm**
- 200 acres (of ~1,700 in MI)
- Mechanically harvested
- Packinghouse only packs from this farm on two lines
- 10 years experience with 3rd party audits

**Blueberry farm**
- Hand harvest early season, mechanical late season
- Packinghouse only packs from this farm on one line
- 3rd party audits
- Marketing contract

**Pilot**
- First pilot test, Grand Rapids, 8/16-18
  - Day 1 - Extension team visits farms
    - Rutgers, UF/IFAS, NCSU, MSU, PSA
    - 2-3 hours per farm
    - Farm overview, tour, intro to OFRR
    - What to expect, role of partners (FDA)
Pilot
• First pilot test, Grand Rapids, 8/16-18
  • Day 1 PM – Organizational pre-meeting
    • Reduce time of OFRR pilot to ~1 hr
    • Define roles of extension, federal, and state partners
  • Ground rules
    • Extension team leads pilot process
    • No sidebar conversations
    • Primary goal: test and refine the tool, not audit or inspection

Pilot
• First pilot test, Grand Rapids, 8/16-18
  • Day 2 – Full team travels to farms
    • Divide into 2 groups of ~10
      • Preharvest (Celery AM / Blueberries PM)
        • Preharvest water, worker training
      • Postharvest (Blueberries AM / Celery PM)
        • Postharvest water, sanitation

Pilot
• First pilot test, Grand Rapids, 8/16-18
  • Day 3 – Post-visit meeting at Ottawa County extension ~ 2 hours
    • Including all extension, PSA, federal and state regulatory partners, growers, and local extension
Post Pilot

Challenges with tool (extension perspective):
• Bulky
• Can’t interpret rule/provide guidance
• Waiting for FDA guidance
• Avoiding a “gotcha” list

Post-Pilot

Regulators
• Surprised by how extension used the tool.

Post-Pilot

Farm feedback:
• PSR is a new approach (non-prescriptive)
• 3rd party audit alignment (one food safety manual)
• Improve efficiency of tool (weed out N/A questions)
• Want to be able to easily explain to an inspector which sections of the rule/tool aren’t applicable to a given operation rather than being put on defensive
On-Farm Readiness Review Summary

- Final tool should be used by extension as an educational tool or for growers and packers under the Produce Safety Rule to use for self-assessment
  - Other possible uses?
  - Utility of the tool can improve after FDA releases guidance

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Cover Crops and Chlorination: Effects on microbial contamination of soil

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The recently published Food Safety Modernization Act (FSMA) has established new rules and regulations for the production, harvest, storing and handling of fruits and vegetables. However, there are still many areas where we do not fully know how our production practices influence the survival of human pathogens that can cause foodborne illness.

A program at the University of Maryland, led by Shirley Micallef of the Dept. of Plant Science and Landscape Arch. has begun to examine several production practices in the field to evaluate their influence on survival of microbial contaminants. This presentation will discuss two of these studies and explain the implications of the results for vegetable crop producers.

Drip line flushing with Chlorine:
Many vegetable crops are irrigated with drip tape that may be laid on the surface, usually under plastic, or buried up to four inches below the soil surface. Irrigation water has been a source of pathogenic bacteria in previous foodborne illness outbreaks. FSMA has mandated that water distribution systems such as irrigation lines be monitored and maintained. However, where samples should be collected is not clear. This is an important issue, because higher bacterial loads were found at the end of irrigation drip tape than at the source (Pagadala, S., Marine, S.C., Micallef, S.A., Wang, F., Pahl, D.M., Melendez, M.V., Kline, W.L., Oni, R.A., Walsh, C.S., Everts, K.L., Buchanan, R.L. 2015. Assessment of region, farming system, irrigation source and sampling time as food safety risk factors for tomatoes. International Journal of Food Microbiology 196:98–108.)

Attempts to reduce the accumulation and growth of microbial contamination in drip tape irrigation systems include flushing the lines with chlorine during the growing season. The concentration of chlorine that is injected into the system is recommended to be between 5 to 6 ppm, up to a high of 15 to 50 ppm. While the concentration range for chlorine injection is large, the target concentration of residual chlorine at the end of the line is from 1 to 5 ppm. This concentration is expected to reduce the enteric bacteria levels that may survive within the drip tape. However, there is a concern that biofilms (a thick matrix of diverse microbes that stick together and adhere to a surface) will be protected from the effect of the chlorine.

An experiment was conducted as a split-plot design at the University of Maryland Lower Eastern Shore Research and Education (LESREC) farm in Salisbury. The main plots were the sanitizer program, where one half of the drip lines were injected with chlorine (10 ppm of free residual chlorine was maintained within the system), and the other half not injected. Sub-plot treatments were the depth of the line placement in soil. This allowed us to compare lines placed on the surface, at 2 inches and at 4 inches deep. The irrigation water from the ends of the drip irrigation lines was evaluated every two weeks for a three month period.
The general findings from this research were that the levels of indicator organisms that were recovered from the end of the lines were higher than at the source after sanitization. This indicates that there was either an accumulation or growth of bacteria in the drip lines that were being shed into the water passing through the lines. Depth of the drip line didn’t effect bacteria before sanitation. After sanitizer treatment, there were more total coliforms recovered from the drip tape that was buried 2 inches and treated with sanitizer. Likewise, there was a significant increase in the recovery of total coliforms from the ends of sanitized lines over non-sanitized lines for the remainder of the experiment. Acidic water pH levels, which were approx. 5.5, may have led to increased chlorine activity, sloughing off cells and organic matter from biofilms within the drip tape. High organic levels would deplete the residual chlorine and reduce the ability of the chlorine to reduce bacterial populations.

We recommend that groundwater samples be taken from the end of drip lines or within the crop production area. In addition, the pH of the water should be monitored when flushing the system with chlorine to avoid acidic conditions that might increase bacterial levels.

More information about this study can be found at Callahan, M.T., Marine, S.C., Everts, K.L., Micallef, S. 2016. Drip line flushing with chlorine may not be effective in reducing bacterial loads in irrigation water distribution systems. Journal of Food Protection. 79:1021-1025.

**Cover crop effects on microbial survival in soil:**

The use of small grain or legume cover crops that are grown between cash crops in vegetable production has become increasingly common in the mid-Atlantic region of the U.S. Cover crops are used because they provide many ecosystem services such as protecting the soil from erosion, improving soil health, increasing organic matter in soil, and suppressing diseases or weeds. These cover crops also increase beneficial soil microbial populations. It is thought that increasing organic matter in soil will favor microbes that are adapted to soil over enteric bacteria. However the impact of cover crops on the persistence of food-borne pathogens has not been well-studied.

We conducted a study to evaluate the impact of single or multi species cover crops on generic *Escherichia coli* and *Listeria innocua* presence in soil over two years. These non-pathogenic indicator species were introduced into the field at 6 to 8 days after the cover crops were planted in the fall (October), serving as surrogates for enteric pathogens. The cover crops were hairy vetch (*Vicia villosa*), crimson clover (*Trifolium incarnatum*), cereal rye (*Secale cereale*), a mixture of hairy vetch and rye, and a mixture of crimson clover and rye. Bare ground plots were the control and were fallow throughout the fall, winter, and spring. These studies were conducted in an organic field for two years, and for one year in a conventional field that was transitioning to organic production.

Background levels of *E. coli* were generally undetectable, and *L. innocua* was never detected, before the field was inoculated. Following field inoculation, the bacterial surrogate levels were initially high and then declined from fall to late spring. The *E. coli* levels declined most quickly, and by week 5 as temperatures dropped, were below the detectable limit in the organic field in the first year of the study and the transitional field in the second year of the study. In the organic field in the second year it was week 9 before the *E. coli* level was not-detectable. The *L. innocua* population also diminished over time, but more slowly. *L. innocua* was always detectible in the first organic experiment, until week 23 in the second organic experiment, and until week 30 in the transitional experiment. The decline in *E. coli* in soil coincided with a decrease in temperatures. However the population of *L. innocua* in the soils did not seem to relate to temperatures. This bacterial taxon is known for its ability to grow at low temperatures close to freezing.
In general the hairy vetch and rye cover crop mixture supported higher bacterial populations than other cover crops. However there was a lot of variation among the cover crops at different sampling dates. In year one, hairy vetch alone resulted in lower bacterial populations than other cover crops and was similar to the bare ground plots. The same effect was not observed in year two. Although the rye monoculture supported large populations of both *E. coli* and *L. innocua* in year one, rye had one of the lowest bacterial levels in year two.

In general, increasing the organic biomass in the soil should favor microorganisms that are well-adapted to soil, but not enteric bacteria that are thought to be better adapted for the animal gut environment. We did see a rapid decline in *E. coli*, which supports this idea. Although cover crops may have an impact on bacterial population dynamics, they are not the only driving factor. Factors that may impact bacterial population dynamics include bacterial species, time from inoculation, soil temperature and tillage.

In this talk we introduce the Food Safety Modernization Act (FSMA) and the FSMA Produce Safety Rule, compare the requirements of the Produce Safety Rule with Good Agricultural Practices certification, and walk through the requirements in the FSMA Produce Safety Rule that relate to water quality in the production (growing) environment.

**What is FSMA?**

The Food Safety Modernization Act includes seven primary Rules

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Safety Rule)
- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Foreign Supplier Verification Programs
- Accreditation of Third-Party Auditors/Certification Bodies
- Sanitary Transportation of Human and Animal Food
- Prevention of Intentional Contamination/Adulteration

These Rules focus on prevention of food-safety issues, and they cover the entire food system in the United States, including imported foods, from farm to fork. The Food and Drug Administration FSMA web site includes valuable information, such as

- The full text of the Rule, including the Preamble and other front material
- Guidance for industry
- Fact sheets
- Link to the Technical Assistance Network
- Announcements and descriptions of implementation activities
- Other resources

The FSMA Produce Safety Rule includes this summary statement describing its scope and intent.

*To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA or we) is establishing science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA is establishing these standards as part of our implementation of the FDA Food Safety and Modernization Act.*
**Does FSMA replace GAPs?**

The FSMA Produce Safety Rule does not replace Good Agricultural Practices (GAPs) audit programs and a GAPs audit is not a requirement of the Produce Safety Rule. The Produce Safety Rule and GAPs audits are both based on a similar foundation of GAPs, but they are different and separate programs.

Compliance dates for the FSMA Produce Safety Rule are summarized in a table from the Produce Safety Alliance website at [producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule-compliance-dates-timeline](https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule-compliance-dates-timeline). For the most part, the FSMA Produce Safety Rule requirements are not yet in effect: the earliest compliance dates for most provisions is January 26, 2018.

Not all farms that grow produce are covered by the Produce Safety Rule. A variety of exemptions can apply. One place to start looking to see if your farm is covered by the Produce Safety Rule, or if it is eligible for an exemption, is the FDA document titled *Standards for Produce Safety: Coverage and Exemptions/Exclusions for 21 Part 112*.

**What are FSMA requirements for agricultural water?**

Don Stoeckel is a Produce Safety Alliance Lead Trainer; however, the slides and concepts in this presentation are not related to the standardized Produce Safety Alliance Grower Training curriculum.

The content of this presentation narrows in on the requirements of the FSMA Produce Safety Rule for irrigation water (and other water used during growing produce). Before discussing the requirements of the Produce Safety Rule, some definitions are very important. These definitions are given in § 112.3(c):

- **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.
- **Covered produce** means produce that is subject to the requirements of the Produce Safety Rule. The term “covered produce” refers to the harvestable or harvested part of the crop.

**Important point:** water that is not used as agricultural water is not covered by the Produce Safety Rule.

There are ten sections in the FSMA Produce Safety Rule Subpart E: Agricultural Water. They are numbered § 112.41 to § 112.50. Each section has a summary statement provided in the text of the Produce Safety Rule. I have also written a brief summary of the requirements in the section and an impact statement. The impact statement is a general evaluation of changes, if any, a farm might choose or be required to make in order to meet the requirements of the Produce Safety Rule. The full regulatory text can be found online at [www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm).

**§ 112.41 What requirements apply to the quality of agricultural water?**

**Summary**

- Information from the response to Comment 246 in the Preamble of the Produce Safety Rule gives an example that would violate this requirement presence of *(presence of) deceased and decaying deer in the area of the stream under the farm’s control, upstream from where the farm draws its water and at a close distance*

**Things to Consider**

- FDA guidance is expected to be developed and help understand the impact of this requirement
§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

Summary

- Requirements in this section deal with inspection, monitoring, and maintenance of agricultural water systems. Annual inspection is required.
- The system includes the source and distribution system
- Conditions and risks outside of the farm’s control are part of the inspection but corrective action is not required

Things to Consider

- For many farms, any changes may be minor
  - Paying attention and maintaining equipment and systems is already part of the routine on most farms
  - Documentation of the inspection is required in § 112.50
- Some farms may be required to or choose to make changes to their practices
  - Domesticated animals must be kept out of water sources used as agricultural water
  - Some farms may choose to make changes to how water is used, so it is not used as agricultural water

§ 112.43 What requirements apply to treating agricultural water?

Summary

- Water that does not meet the quality criteria in § 112.44 can be treated so that it does meet the criteria
- Treatment must be monitored and results of monitoring must be recorded
- If the water is treated appropriately, it is considered safe and § 112.46(a) says it does not have to be tested for E. coli

Things to Consider

- If chemical treatment is used, follow the label
  - For example, the use statement could be for irrigation water, or other uses during production of produce
  - The target statement should include for control of public health microorganisms

§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

Summary

- For water used during production, two statistics based on long-term E. coli test data are used as criteria:
  - Geometric Mean of 126 or less CFU/100 mL of water AND
  - Statistical Threshold Value of 410 or less CFU/100 mL of water

Things to Consider

- The criteria are new. The values and (or) use of the criteria are different from what is found in other regulations and voluntary guidance documents or voluntary programs.
- Unlike some voluntary programs, such as Leafy Greens Marketing Agreement criteria, there is no single-sample maximum allowed concentration
The grower, the lab, or somebody else will need to calculate the GM and the STV for the farm. Spreadsheets and extension documents are available to help. See, for example, a calculator provided by the UC Davis Western Center for Food Safety (wcfs.ucdavis.edu).

§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

Summary of § 112.45(b)
- Discontinue use if agricultural water does not meet quality criteria within required timeframe unless corrective measures are used
  - Immediately, for qualitative requirement in § 112.41
  - As soon as practicable, for numeric requirement in § 112.44
    - Use must be discontinued within 1 year
- Use can resume after an allowed corrective measure
  - Time interval or process for log reduction. This is a complex set of possible corrective measures.
  - Re-inspect and take corrective action (similar to § 112.42)
  - Treat the water (§ 112.43)

Things to Consider
- The option to re-inspect, identify risks, and address problems is similar to typical GAPs requirements. See description in § 112.42 for specific inspection requirements.
- The option to treat (as described in § 112.43) is similar to currently available corrective actions
- There is a new option, in the form of a 0.5-log per-day adjustment to the GM and STV for in-field die-off.
  - Also in this option are die-off during storage and log removal during processing steps such as washing
  - The calculators that calculate GM and STV generally also will calculate the 0.5 day die-off
- Some farms might choose to change to a different water source or change how they use their water instead

§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

Summary of § 112.46(b)
- Sampling is done to create a microbial water quality profile (MWQP)
  - For surface water, 20 or more samples over 2-4 years
  - For ground water, 4 or more samples over 4 years
    - In the first year, 4 samples are required instead of 1
  - For both, annual update samples (5 for surface, 1 for ground)
- Sampling location and timing must be representative of how the water is used; prioritize times close to, but before, harvest
- EVERY SOURCE of ag water needs its own MWQP

Things to Consider
- The requirement to test water, used during production, applies only to agricultural water; if the water is not used as agricultural water, the Produce Safety Rule does not require testing
- The sample frequency for surface water (5 or more per year) generally is different from the sample frequency in other regulatory and voluntary programs
- Sample timing
The requirement to prioritize sampling of water used close to harvest is different from most other regulatory and voluntary programs.

Samples are taken during water use, instead of distributed throughout the year or the growing season.

§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?

Summary

- Samples need to be analyzed for generic E. coli concentration – not presence/absence
- Samples need to be collected properly using aseptic (sterile) technique
- This section includes reference to § 112.151, which says that analysis has to be done using Method 1603 or an equivalent method
  - Method 1603 is a membrane-filtration-based method that uses modified mTEC agar to grow and detect colonies of generic E. coli

Things to Consider

- Many farms already have their water sources tested for generic E. coli
- Because of the method requirement, it will become more important to know what method the lab uses. The method must be Method 1603 or an equivalent to Method 1603.
- Most farms will rely on the laboratory to help understand the sampling, delivery, and analysis requirements.

§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

Things to Consider

- These requirements apply to ag water used during and after harvest. They do not apply to agricultural water used during production.

§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

Summary

- There is a process for using alternatives to some rule requirements
  - Alternative to generic E. coli and the numerical criteria
  - Alternative die-off rates
  - Alternative number of samples in the initial surface water microbial water quality profile, and update samples
- § 112.12 requires adequate scientific data or information to support the alternative

Things to Consider

- Scientific data supporting these alternatives may not be readily available

§ 112.50 Under this subpart, what requirements apply regarding records?

Summary

- Record of annual inspection
- Results of all analytical tests (e.g., generic E. coli)
- Support for selected treatment option, if used
- Documentation of treatment monitoring
- Support for die-off or removal rate, if used as a Corrective Measure
• Documentation and calculation of any Corrective Measure applied
• Certificate of compliance for municipal water, if used
• Documentation to support alternatives, if used
• Record of analytical method used, if not Method 1603

Things to Consider

• The required records are often kept among the records needed for GAPs audits
• Specific record-keeping requirements are in Subpart O of the Produce Safety Rule