Emerging Issue: Analysis of Agricultural Water and Spent Sprout Irrigation Water

Webinar with APHL
15 April 2019

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Thank you

• For taking the time to be with us today
• This information is confusing to many farms
• Laboratories have agricultural stakeholders who are affected by the FSMA Produce Safety Rule
  – Agricultural water requirements are different from other requirements (drinking water, rec water, etc)
  – Agricultural water compliance dates recently extended (other than sprouts)
  – Farms have responsibilities related to use of sanitary water
    • Laboratories help farms address these responsibilities
Many Multi-State Produce Outbreaks

**Impetus to establish produce safety standards**

<table>
<thead>
<tr>
<th>Year</th>
<th>Microorganism</th>
<th>Produce</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>E. coli O157</td>
<td>Spinach</td>
</tr>
<tr>
<td>2008</td>
<td>Salmonella</td>
<td>Produce</td>
</tr>
<tr>
<td>2008</td>
<td>Salmonella</td>
<td>Cantaloupe</td>
</tr>
<tr>
<td>2009</td>
<td>Salmonella</td>
<td>Alfalfa Sprouts</td>
</tr>
<tr>
<td>2010</td>
<td>Salmonella</td>
<td>Alfalfa Sprouts (1)</td>
</tr>
<tr>
<td></td>
<td>Salmonella</td>
<td>Alfalfa Sprouts (2)</td>
</tr>
<tr>
<td></td>
<td>Salmonella</td>
<td>Alfalfa Sprouts (3)</td>
</tr>
<tr>
<td>2011</td>
<td>E. coli O157</td>
<td>Romaine</td>
</tr>
<tr>
<td></td>
<td>Listeria monocytogenes</td>
<td>Cantaloupe</td>
</tr>
<tr>
<td></td>
<td>Salmonella</td>
<td>Alfalfa Sprouts</td>
</tr>
<tr>
<td>2012</td>
<td>E. coli</td>
<td>Spinach</td>
</tr>
<tr>
<td>2013</td>
<td>Cyclospora</td>
<td>Fresh Produce</td>
</tr>
<tr>
<td>2014</td>
<td>Salmonella, L. mono</td>
<td>Sprouts</td>
</tr>
<tr>
<td></td>
<td>Cyclospora</td>
<td>Cilantro</td>
</tr>
<tr>
<td></td>
<td>E. coli 021</td>
<td>Clover Sprouts</td>
</tr>
<tr>
<td>2016</td>
<td>Salmonella</td>
<td>Alfalfa Sprouts (1)</td>
</tr>
<tr>
<td></td>
<td>Salmonella</td>
<td>Alfalfa Sprouts (2)</td>
</tr>
<tr>
<td></td>
<td>Salmonella</td>
<td>Alfalfa Sprouts (3)</td>
</tr>
<tr>
<td>2017-18</td>
<td>E. coli O157</td>
<td>Romaine</td>
</tr>
</tbody>
</table>


- Produce is vulnerable to these microorganisms of public health significance
Assessment of Produce Contamination

• Called Qualitative Assessment of Risk (QAR); findings used to finalize FMSA Produce Rule

• 5 Major Routes of Contamination = provisions for this Rule
  – Agriculture water
    – Soil amendments
    – Animals
    – Workers health/hygiene
    – Equipment/buildings
  – Seeds, additional route of contamination for sprouts

• Benefits of Produce Rule
  – Prevent microbial contamination and reduce foodborne illness
  – Ultimately protect public health!
Water Testing Requirements for Sprout Growers

Kaiping Deng

Sprout Safety Alliance

April 15, 2019
The Sprout Industry

Geographic Distribution of Sprout Growers

IFSH - Institute for Food Safety and Health

Sprout Safety Alliance
Sprout Safety Alliance (SSA)

• A public-private alliance

• Goal - to enhance the sprout industry's understanding and implementation of best practices and the Produce Safety Rule
  - Develop a core curriculum
  - Establish training and outreach programs
## Compliance Dates for Sprout Operations

<table>
<thead>
<tr>
<th>Size of Operation</th>
<th>Average Annual Produce Sale</th>
<th>Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>&gt;$500k</td>
<td>January 26, 2017</td>
</tr>
<tr>
<td>Small</td>
<td>$250k-500k</td>
<td>January 26, 2018</td>
</tr>
<tr>
<td>Very Small</td>
<td>$25k-250k</td>
<td>January 28, 2019</td>
</tr>
</tbody>
</table>
Sprouting Conditions

Warm, humid and nutritious conditions

If 0.1% seed was contaminated (e.g., a few seeds in 1 kg)

The entire growing unit could be contaminated
Sprout Safety Concerns

- Seed can be contaminated on farm
- Sprout germination conditions also encourage the proliferation of pathogens
- Sprouts can be contaminated during production
- Outbreaks associated with sprouts have occurred
Multi-hurdle Strategies

• Sanitary production environment
• Good worker health and hygiene practices
• Safe seed and water
• Seed treatment
• Verification of control measures
  • Spent sprout irrigation water testing
  • Environmental monitoring
Produce Safety Requirements

• Develop and follow a written plan of spent sprout irrigation water sampling and testing
• Aseptically collect samples of spent sprout irrigation water (or in-process sprouts)
• Test for *E. coli* O157:H7 and *Salmonella*
• Hold product unless pathogen results are negative
• Maintain records
Preparation for Sampling

• Samples must be collected in an aseptic manner
• Equipment and tools for sample collection must be sterile
What to Sample

• Sample every production batch

“Production Batch of Sprouts”- “All sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).”
Growing Batch Examples

Two batches

Alfalfa sprouts
Growing Batch Examples

One batch

Two or three batches

Green Sprouts
Growing Batch Examples

Two batches

Mung bean sprouts
How Much Water to Sample

- Collect 1.5 L of spent sprout irrigation water from each batch
- FDA recommends testing more samples/batch for batches > 2400 lbs (1100 kg)
Sampling Sprouts instead of Water

• When sampling sprout irrigation water is not feasible, testing in-process sprouts is required.
• Collect 30 sub-samples (50 g each) from different locations throughout production batch to obtain a representative sample.
Testing Timeline

Day 0
- Start batch

Day 2
- Take samples, send to lab

Day 3
- Lab starts test
- Assumes 1 day for shipping

Day 4
- Presumptive results
- STOP if result is negative

Day 5-7
- Confirmed results
Criteria for a Testing Lab

• Qualified microbial pathogen testing
  o Examples of accredited labs for microbiological testing
    ▪ Meets ISO 17025 standards or
    ▪ Accredited by state or national authority

• Trained and experienced staff
Testing Timeline

Day 0
• Start batch

Day 2
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Day 3
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Day 4
• Presumptive results
• STOP if result is negative

Day 5-7
• Confirmed results
What to Test for

• The presence or absence of two major pathogens
  o *E. coli* O157:H7
  o *Salmonella* species
Testing Methods

• FDA reference methods:
  
  http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm

• Scientifically valid methods equivalent to the FDA methods in accuracy, precision, and sensitivity
FDA Reference Method for *E. coli* O157:H7

- 100 ml water sample or 25 g sprout sample for enrichment
- Presumptive screening - real-time PCR
- Confirmation – culture identification by serology (colony morphology/selective media/serological identification

[http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm](http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm)
FDA Reference Method for *Salmonella*

- 375 ml water sample or 375 g sprout sample for enrichment
- Presumptive screening- classic culture method with generic identification
- Confirmation testing- culture identification by serology

http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm
Equivalent Methods for Testing *Salmonella* in Sprout Water

- AOAC Official Method 999.08. Transia® AG *Salmonella* EIA
- AOAC Official Method 999.09. VIP
- AOAC Official Method 2011.03. VIDAS® *Salmonella* (SLM) Easy *Salmonella*
- AOAC Official Method 2016.01. 3M™ Molecular Detection Assay (MDA) 2

https://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM622917.pdf
Equivalent Methods for Testing *E. coli* O157:H7 in Sprout Water

- AOAC Official Method 996.09. VIP for EHEC Assay*
**Testing Timeline**

**Day 0**
- Start batch

**Day 2**
- Take samples, send to lab

**Day 3**
- Lab starts test
- Assumes 1 day for shipping

**Day 4**
- Presumptive results
- STOP if result is negative

**Day 5-7**
- Confirmed results
Testing Result Decision Tree

Was the screen result *presumptive* positive for a pathogen?

- **No**
  - Release product

- **Yes**
  - Must ask lab to run confirmatory tests on original enrichment
    - Continue growing cycle and **HOLD**
    - Stop growing, take *in-house* corrective action

Was the final result *confirmed* positive?

- **No**
  - Release product

- **Yes**
  - Complete corrective action
FDA Reference Method for *E. coli* O157:H7

- 100 ml water sample or 25 g sprout sample for enrichment
- Presumptive screening - real-time PCR
- Confirmation – culture identification by serology (colony morphology/selective media/serological identification)

http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm
FDA Reference Method for *Salmonella*

- 375 ml water sample or 375 g sprouts for enrichment
- Presumptive screening- classic culture method with generic identification
- Confirmation testing- culture identification by serology

http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm
Important Notes of Testing
Spent Sprout Irrigation Water

• Loaded microbial background
Important Notes of Testing
Spent Sprout Irrigation Water
(cont.)

• Confirmatory testing should be performed using the same enrichment from the original sample

• Screening test kits cannot be used for confirmation
Other Testing Requirements for Sprout Growers

• Environmental testing for *Listeria*
  o At least monthly

• Inspection of water system
  o Water testing if:
    ▪ Water problem is identified
    ▪ Well water is used
    ▪ Water treatment is done
Welcome to the Sprout Safety Alliance Technical Assistance Network (TAN)

The Sprout Safety Alliance (SSA) was created to develop a training curriculum and outreach programs for stakeholders in the sprout production community to enhance the industry’s understanding and implementation of the requirements in the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule, and best practices for improving sprout safety. Utilizing the resources on this webpage, you may submit a sprout safety related technical question to the SSA Food Safety Resource Team (FSRT) Members. For regulation and policy interpretation questions related to the Produce Safety Rule and sprout safety, please submit your inquiry to the FSMA TAN [here].

About Produce Safety Alliance

• Cooperative agreement between Cornell University, FDA, and USDA
• Established in 2010
• Focused on outreach and education
• Assist with meeting regulatory requirements
Labs Are One Source of Info

- Farms have many other sources for reliable information
  - Produce Safety Alliance at Cornell University
  - Produce Safety Network at FDA
  - Regional Coordination Centers
    - Northeast Center to Advance Food Safety (NECAFS) at University of Vermont
    - Western Regional Center to Enhance Food Safety (WRCEFS) (four sub-regions)
    - North Central Region (NCR) Center for FSMA Training, Extension, and Technical Assistance at Iowa State University
    - Southern Regional FSMA Training Center (SC) for Training, Education, Extension, Outreach and Technical Assistance to Enhance Produce Safety at Univ. Florida
  - The Native American Tribal Center for Food Safety Outreach, Education, Training and Technical Assistance with the Indigenous Food and Agricultural Initiative (IFAI) at University of Arkansas
  - The Local Food Safety Collaborative (LFSC) with National Farmer’s Union Foundation and National Young Farmers’ Coalition
Compliance Timeframe

• FSMA PSR compliance dates for water other than sprouts were extended until 2022 or later

The reason given for this extension is “to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to protect public health”

• The Produce Safety Alliance-hosted Water Summit was a forum to discuss concerns and needs

• What, if anything, will change by 2022?
  – FDA clarifies that the compliance date extension rule “... does not address the underlying requirements in subpart E, but only the compliance dates for those requirements (for covered produce other than sprouts).”
  – FDA’s documentation associated with the compliance date: the focus of FDA re-evaluation is on pre-harvest water testing requirements.
Other Considerations

• Farms still have water-related requirements
• FD&C Act: sale of adulterated food into interstate commerce, by anyone, is prohibited (since 1906)
• Produce Safety Rule, §112.11: covered farms must prevent introduction of hazards into covered produce (by general compliance date)

A helpful message for farms:

– No requirement to sample for water quality now
– Ongoing responsibility to avoid contamination of produce by avoiding, for example, non-sanitary water
Currently in the PSR: Core Requirements for Water

- Annual inspection of the agricultural water system
- Testing for generic *E. coli* as an indication of quality for agricultural water
- Maintenance of agricultural water quality during use
  - “maintain its safety and adequate sanitary quality”

The compliance dates for water rules (Subpart E except for sprouts) in the PSR are 2022 or later. Requirements may change.
Not All Water is Covered

• **Agricultural** water used with a direct water application method to covered produce
  - **Agricultural water** means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces.
  - **Direct water application method** means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.
  - **Covered produce** means produce that is subject to the Produce Safety Rule. The term “covered produce” refers to the harvestable or harvested part of the crop.
§ 112.44(b): When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49): (sub bullets deleted)

**Criteria for Production Water**

- Summary
  - For water used during production, two statistics based on long-term *E. coli* test results 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

The compliance dates for water rules (Subpart E except for sprouts) in the PSR are 2022 or later. Requirements may change.
More Information About Production Water Criteria

FDA is re-evaluating the criteria and other requirements

- There is no single-sample maximum in the Produce Rule
  - This is different from some audit standards, like LGMA
  - There is no actionable level other than the calculated statistics
- The grower, the lab, or somebody else will need to calculate the statistics (GM and STV) for the farm
  - The statistics are calculated similar to the EPA 2012 revised Recreational Water Quality Criteria but typically use a 4-year data set

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)
Other Information About Production Water Criteria

• The statistics (GM and STV) as used in the PSR are called a Microbial Water Quality Profile (MWQP)
  – Spreadsheets and extension documents are available

Publicly-Available Calculator Tools
• wcfs.ucdavis.edu/
• agwater.arizona.edu/
• agwater.arizona.edu/onlinecalc/

Produce Safety Alliance Fact Sheet
• producesafetyalliance.cornell.edu/resources/general-resource-listing/

<table>
<thead>
<tr>
<th>Difference between MWQP results and PSR criteria (generic E. coli log CFU/100ml).</th>
<th>Meets PSR criteria?</th>
<th>Is microbial die-off required?</th>
<th>How many days are necessary if using microbial die-off between last irrigation and harvest? Apply the greater number of days.</th>
</tr>
</thead>
<tbody>
<tr>
<td>GM</td>
<td>-0.02</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>STV</td>
<td>0.12</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Geometric Means, Statistical Threshold Values, and Microbial Die-Off Rates

This document outlines how to perform key mathematical steps necessary to develop a microbial water quality profile (MWQP) and then calculate microbial die-off if the MWQP values exceed numerical Geometric Mean (GM) and Statistical Threshold Value (STV) criteria outlined in the Food Safety Modernization Act (FSMA) Produce Safety Rule. There are tools to make the calculations easier, but for those who want to know how to do the math, it is covered here.
Criteria for Postharvest Water

§ 112.44(a): When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes (sub bullets deleted)

• Summary
  – For water used during postharvest, E. coli test is required:
    • No detectable E. coli in 100 mL water
  – Postharvest uses include washing and cooling produce, harvest bin and pack house sanitation (food contact surfaces), hand washing, and others
  – Untreated surface water cannot be used in postharvest even if the water is tested and meets the criterion

The compliance dates for water rules (Subpart E except for sprouts) in the PSR are 2022 or later. Requirements may change.
Test methods

§ 112.151: You must test the quality of water using (a) The method of analysis published by the U.S. Environmental Protection Agency (EPA), “Method 1603 ...” or (b) A scientifically valid method that is at least equivalent ... in accuracy, precision, and sensitivity; or (c) For any other indicator of fecal contamination ... a scientifically valid method

• FDA created a list of methods that are considered equivalent to modified mTEC (EPA Method 1603)
  – Similar to, but not the same as, EPA’s lists of approved methods for ambient, drinking, and ground water
  – Other methods may also be used if there is scientific information that supports equivalency
## FDA Fact Sheet: Equivalent Water Testing Methodologies (Quantitative)

www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM575255.pdf

### Membrane filtration methods (quantitative)

<table>
<thead>
<tr>
<th>Cited method in FDA Fact Sheet</th>
<th>Shorthand method name</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPA Method 1603</td>
<td>Modified mTEC agar</td>
</tr>
<tr>
<td>EPA Method 1103.1, Standard Methods 9213 D, ASTM method D5392-93</td>
<td>mTEC agar</td>
</tr>
<tr>
<td>EPA Method 1604</td>
<td>MI agar</td>
</tr>
<tr>
<td>Standard Methods 9222 B followed by 9222 G</td>
<td>m-Endo followed by NA-MUG agar</td>
</tr>
<tr>
<td>Hach method 10029</td>
<td>m-ColiBlue 24 ampules</td>
</tr>
</tbody>
</table>

### Most probable number methods (quantitative)

<table>
<thead>
<tr>
<th>Product/medium named in FDA Fact Sheet</th>
<th>Method notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDEXX Colilert test kit, only if using Quanti-Tray/2000</td>
<td>There are several formats for Colilert, be sure the lab uses the FDA-named quantitative format. One reference protocol for this product is Standard Methods 9223B.</td>
</tr>
<tr>
<td>IDEXX Colilert-18 test kit, only if using Quanti-Tray/2000</td>
<td></td>
</tr>
</tbody>
</table>
## FDA Fact Sheet: Equivalent Water Testing Methodologies (P/A)

[www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM575255.pdf](http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM575255.pdf)

<table>
<thead>
<tr>
<th>Presence/absence methods (in 100 mL)</th>
<th>Product/medium named in FDA Fact Sheet</th>
<th>Manufacturer/source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postharvest Water Only</td>
<td>TECTA™ EC/TC medium and instrument</td>
<td>Veolia Water Technologies</td>
</tr>
<tr>
<td></td>
<td>Modified Colitag, ATP D05-0035</td>
<td>CPI International</td>
</tr>
<tr>
<td></td>
<td>IDEXX Colilert test kit</td>
<td>IDEXX Laboratories, Inc.</td>
</tr>
<tr>
<td></td>
<td>IDEXX Colilert-18 test kit</td>
<td>IDEXX Laboratories, Inc.</td>
</tr>
<tr>
<td></td>
<td>IDEXX Colisure test kit</td>
<td>IDEXX Laboratories, Inc.</td>
</tr>
<tr>
<td></td>
<td>E*Colite Bag or Vial test</td>
<td>Charm Sciences</td>
</tr>
<tr>
<td></td>
<td>Readycult Coliforms 100</td>
<td>EMD Millipore, catalog 101298</td>
</tr>
</tbody>
</table>
Sampling Production Water

• Build a 4-year data set under current PSR system
  – For Ground water, 4 or more samples
    • Initial set of 4 or more samples over 1 year
    • 1 new sample added every year, 1 old sample may be dropped
  – For Surface water, 20 or more samples
    • Initial set of 20 or more samples over 2-4 years
    • Ongoing rolling data set includes 4 years’ prior data
    • At least 5 new samples added every year
  – Public water supply water: annual assurance from utility
• Compare this data set to the 5 samples over 30 days system often used for beaches

The compliance dates for water rules (Subpart E except for sprouts) in the PSR are 2022 or later. Requirements may change.
When Labs May See Samples

- Samples for compliance may begin arriving in 2022

<table>
<thead>
<tr>
<th>For Farms Over $500,000 Annual Produce Sales</th>
<th>Sampling Schedule, MWQP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance Date January 26, 2022</td>
<td></td>
</tr>
<tr>
<td>All water requirements (other than sprouts)</td>
<td></td>
</tr>
<tr>
<td>Water Source Type</td>
<td>Surface</td>
</tr>
<tr>
<td>Production Water</td>
<td>Begin Sampling</td>
</tr>
<tr>
<td>Typical growing season to meet requirements:</td>
<td>Complete Initial MWQP</td>
</tr>
<tr>
<td>Use MWQP to Make Decisions</td>
<td>2026</td>
</tr>
</tbody>
</table>

- Small businesses ($>250K – 500K)
  - Compliance and Sampling year = Table +1 year
- Very small businesses (up to $250K)
  - Compliance and Sampling year = Table +2 years

The compliance dates for water rules (Subpart E except for sprouts) in the PSR are 2022 or later. Requirements may change.
§ 112.47: You may meet the requirements related to agricultural water testing required under § 112.46 using: (sub bullets deleted)

• Summary
  – The covered farm is responsible for appropriate sampling
  – Samples need to be collected properly (aseptic technique)
  – Only certain lab testing methods are allowed
Sample Delivery

• FDA made no hold time specifications in the Produce Safety Rule
  – Hold time requirements listed in some methods
  – Consider reference to Standard Methods 9060B
    • Non-potable water for compliance purposes, quantitative test
      – Deliver within 6 hours of collection, sample analysis within 8 hours
    • Prior to compliance date, quantitative tests for non-compliance
      – Do not exceed 24 hours hold time
    • Drinking water, using presence/absence test, for compliance
      – Do not exceed 30 hours hold time
  – Future guidance from FDA may address hold time
Lab Mapping Effort

- Initiative to map available laboratories for farm contact
  - Aware of requirements
  - Offer analysis using FDA-acceptable methods

Maps or lists of labs for ag water testing
- Northeastern states map
- Colorado map
- Hawaii list
- Iowa map, list
- Kansas map
- Kentucky map
- Michigan fact sheet with map and list
- Minnesota map
- Missouri map
- New Hampshire list
- New Jersey map
- North Carolina list
- Virginia map, list
- Washington map
- Wisconsin map

Find the right water testing lab for Food Safety Modernization Act Produce Safety Rule compliance

Although the Food Safety Modernization Act has added new testing methods to the approval list, finding the right lab still isn’t easy. Use this map to find a lab near you.

April 6, 2018 - Author: Marissa Schuh, Benjamin Phillips and Phillip Tocco, Michigan State University Extension

While a majority of the Produce Safety Rule (PSR) is either in effect or coming into effect in the next two years, when it comes to agricultural water, growers have a little more time to get into their routine. This is because there have been changes to the types of tests allowed under the rule – but this expansion in available tests doesn’t mean finding the right lab will be easy.

The first consideration is finding a lab is figuring out what kind of water you are using on your farm. Water used for frost protection, overhead irrigation and crop sprays (among other things) is categorized as...
Record keeping

• The farm must keep results of all analytical tests in the farm records while used in a MWQP (4 years)

• Does the lab have to provide results to the state?
  – Each state can have its own inspectional system
  – Your state’s regulatory authority may have information about providing results related to compliance
    • FDA may conduct compliance inspections in lieu of the State
    • The State may conduct compliance inspections under FDA inspectional authority
    • The State may conduct compliance inspections under their own inspectional authority

The compliance dates for water rules (Subpart E except for sprouts) in the PSR are 2022 or later. Requirements may change.
Information for Farms

• Farms may ask labs for help with
  – Sample collection kits (sterile bottles)
  – Sampling instructions
  – Documentation (analytical results)
  – How to calculate MWQP statistics

• FDA recommends that farms
  – Are not expected to implement subpart E (including water sampling) until the extended compliance dates (2022-2024)
  – Should focus attention on good agricultural practices
    • Maintain water quality
    • Protect sources of water
  – Continue testing water programs, or opt to begin testing
Water-Specific Resources

- PSA Fact Sheet *The Water Analysis Method Requirement in the FSMA Produce Safety Rule* (rev 01/2018 [link here](#)) (being revised)
- PSA Fact Sheet *Geometric Means, Statistical Threshold Values, and Microbial Die-Off Rates (longhand calculations)* (02/17/2017 [link here](#))
- Western Center for Food Safety *Tools to calculate Geometric Mean and Statistical Threshold Value* (UC Davis and University of Arizona [link here](#))
- FDA Fact Sheet *Equivalent Testing Methodologies for Agricultural Water* (07/03/2018 [link here](#))
- FDA Question and Answer Sheet *FSMA Final Rule for Produce Safety: How Did FDA Establish Requirements for Water Quality and Testing of Irrigation Water?* (November 2015; [link here](#))
- FDA Rule *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E* (03/18/2019 [link here](#))
Suggestions to Laboratories

- Contact the FSMA regional centers in your area to see what impact this rule will have on your lab and how you can help
  - Iowa: 20 full compliance; 1000 qualified compliance with no water testing at this time but could change depending on year

- Understand water testing aspects of rule to guide farmers what test and how many tests are needed, esp PA or Quantitative (MPN or CFU)
  - Automatic bottle order program helpful

- Provide a test result endpoint for the GM and STV calculations; NOT > values!
  - Examples: Colilert QT 2000, perform 1:10 dilution for a range of 10-24000 MPN/100mL; for *E.coli* MF, use 10,1,0.1 mL sample for range of 10-60,000 CFU/100L

In Summary...
Suggestions to Labs (continued)

- Provide good collection instructions that includes aseptic techniques; poor collection can impact results

- If you have the capability to perform SSIW or sprout testing for *Salmonella*, need PCR method validations utilizing better enrichments to reduce the TAT and increase sensitivity
  - PCR will greatly shorten TAT (e.g. 7 to 4 days for neg)
  - For PCR and this challenging matrix, lactose broth does not appear to be ideal
  - Enrichment alternatives could be Universal Preenrichment Broth (FDA) and 2X Selenite broth (SHL)
Questions?

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