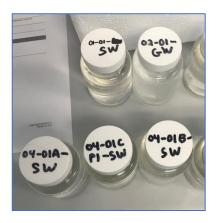
## Kentucky Agriculture Water **Testing Project**

Connecting Produce Growers with Local Water Testing Facilities





















# Kentucky Agriculture Water Testing Project

2019

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## Introduction and Project Background

The horticultural food production segment of Kentucky agriculture has an estimated market value of approximately \$48 million. According to the 2019 USDA Agriculture Census, Kentucky has over 3,680 farms growing produce for fresh market sales on more than 9,500 acres. The Kentucky Department of Agriculture estimates more than 3,500+ operations sell directly to customers at farmers markets across the state.



Kentucky operation using high tunnel and field production systems for growing produce.

In January 2016, the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) went into effect. These regulations developed by the US Food and Drug Administration (FDA) establish minimum standards for safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

Farm food safety plans are a critical tool for ensuring safe production of food crops and one component is managing the risk of transferring human health pathogens. Water management is a key component of an efficient and effective food safety plan. Testing agriculture water to assess risk associated with the water source is the first step of a water management plan.

Agricultural water is described as either *production water* or *postharvest water*. Production water is water used for activities during the growing cycle. Postharvest water is any water used during and after harvest, including washing, packing, and holding activities.





Examples of agriculture water used in Kentucky operations: production water from a farm pond used for irrigation (left) and post-harvest water used for washing lettuce (right).

Having access to convenient, affordable, reliable laboratories equipped to perform microbial detection in agriculture water samples is of high value to Kentucky's produce growers. Understanding levels of generic *E. coli*, an indicator of fecal contamination, helps produce growers determine source water quality. Test values – expressed as colony forming units (CFU)/100 mL or most probable number (MPN)/100 mL – that estimate bacterial concentration are used to calculate the geometric mean (GM) and statistical threshold value (STV) to quantify risk of a water source. This information is used as a basis for management decisions.



Simple paperwork and easy to understand reports of analysis are appreciated by growers.

In 2019, the Kentucky Horticulture Council (KHC) received a grant from the National Farmers Union (NFU) as part of the

Local Food Safety Collaborative (LFSC) to train Kentucky produce growers on food safety basics and sampling of agriculture water sources for production and post-harvest use. KHC and the project partners are committed to helping Kentucky growers increase farm revenue by building capacity, ensuring regulation compliance, managing farm risk, and enabling access to new markets.

This manual is intended to provide water testing laboratories in Kentucky with introductory food safety information and identifies key resources to reference as management and staff work with Kentucky produce growers. Copies of the manual with active hyperlinks and updates after publication can be found on the Kentucky Horticulture Council's webpage: <a href="www.kyhortcouncil.org">www.kyhortcouncil.org</a>. The manual does not substitute for training in analytical methodology, proficiency testing, or familiarity with relevant statutes, regulations, or other requirements. Mention of commercial products does not constitute an endorsement of product use by KHC. We encourage further reading as this resource alone cannot provide the full details on these topics.

On behalf of our local produce growers, we express appreciation of the commitment of laboratories across Kentucing in producing water quality data that are scientifically valid, precise, and accurate.

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## Kentucky Water Testing Laboratory Online Geographic Directory

To promote the use of local laboratories and to help growers identify facilities offering agriculture water testing, the Kentucky Horticulture Council (KHC) has partnered with the University of Kentucky Center for Crop Diversification (UK CCD) to provide an online, interactive map showing the geographic location of laboratories using FDA-approved analytical methods for microbial water quality testing (Fig. 1). Along with each lab's physical location, contact information is available to help growers communicate with and understand individual laboratory requirements.

This resource can be found online at: <a href="https://uk-horticulture.github.io/hort-directory/">https://uk-horticulture.github.io/hort-directory/</a>. The map includes many other resources important to Kentucky growers. Laboratories can be displayed alone by using the *Feature* filter in the top right corner of the map and selecting water testing labs.

At the time of this publication's development, 14 laboratory locations have been identified that offer FDA-approved analytical methods for microbial water quality testing. Each of these labs are listed on the resource. As new locations are identified, the map will be updated.

It is recommended that you review the information listed for your facility annually. Any updates or corrections to your listing can be submitted to:

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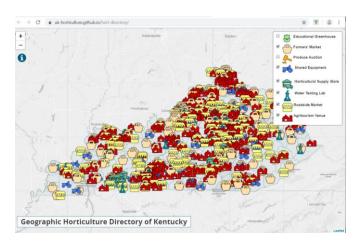
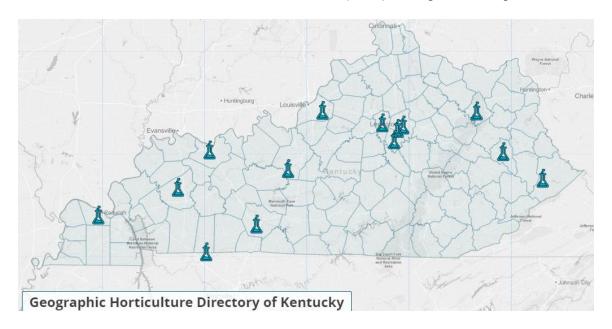


Fig. 1. The online Geographic Horticulture Directory of Kentucky (left) and filtered map (below) showing water testing laboratories.



## Agriculture Water Use

Agricultural water describes any water source used for production or postharvest activities. **Production water** is water used during the season for growing the crop. Production water uses include irrigation, fertigation, crop sprays, cooling, frost protection, and dust management.



Agriculture water supplied through irrigation lines under black plastic mulch lines is a common production practice in Kentucky. This is an example of production water.

**Post-harvest water** is any water used during and after harvest, including packing and holding activities. Uses of postharvest water include rinsing and washing, cooling, ice making, postharvest fungicide treatments, handwashing, cleaning and sanitizing.



Agriculture water used for post-harvest removal of field soil from carrots in a drum washer.

## **Agriculture Water Sources**

There are three categories of agriculture water sources that farmers use for growing produce crops: ground water; surface water; and municipal water.

#### **Ground Water Sources**

Ground water is typically held in aquifers made up of porous or fractured rock, gravel and sand. Wells drilled underground into aquifers are the primary method of accessing ground water used for agricultural operations. Precipitation and removal influence the water table and availability of groundwater for irrigation purposes. According to a 2015 report by the National Groundwater Association (NWGA), Kentucky had 427 wells serving 249 farms supplying irrigation water to 26,500 acres.





Technologies for installing, accessing, and pumping ground water can be simple or quite complex. At left, an airrotary drilling rig and at right, a properly constructed bored well head installation. Photos: Kentucky Well Education Program (www.water.ca.uky.edu).

#### **Surface Water Sources**

Sources of surface water used for agricultural purposes include rivers, streams, and impounded water such as ponds, reservoirs (including locally-collected water in cisterns and rain barrels), and lakes. Water is pumped from these sources for direct delivery to crops using various irrigation systems such as overhead sprinklers and drip systems.





A typical farm pond (left) and river (right) commonly used as surface water sources supplying irrigation water.

#### **Municipal Water Sources**

Many produce growers in Kentucky use public water systems for agricultural purposes. While this water may originate from wells, lakes, or reservoirs, the local water authority is responsible for treating and monitoring water quality according to drinking water standards. Growers using municipal water are required to obtain documentation establishing the system's compliance as to sampling and quality. Water from municipal sources used for irrigation purposes can get very expensive, contributing to overall production costs for produce growers. Therefore, having the ability to convert to or supplement with water from ground or surface water sources is of high value to produce growers. Understanding the quality of available water sources helps growers make critical management decisions.

## Agriculture Water Sampling Frequency

Sampling frequency guidelines have been established in the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) to help growers understand microbial quality of their agricultural water over time. Data are used as a management tool and to determine long-term strategies for water sources available to the farmer. Additional testing may be necessary if an incident suggests contamination of the water source.

#### **Ground Water Sources**

As the PSR currently stands, producers using a *ground water source* are required to sample 4 or more times during the growing season (or over a year) and at least once annually once a baseline is established.

#### **Surface Water Sources**

Producers using *surface water sources* must collect and test 20 samples over 2 to 4 years and 5 or more annually after the initial baseline is established.

#### **Municipal Water Sources**

At this time, there is no requirement to test agricultural water supplied by *municipal sources* or other public water systems that meet microbial water quality requirements established in the PSR. Growers should obtain a report of analysis from their water provider annually to document water quality used in their operation.

#### **Treated Water Sources**

There is no requirement to test agricultural water that is treated in accordance with FSMA Produce Safety Rule's compliance requirements.

<u>Note:</u> The PSR water requirements are under review and subject to change; however, produce growers are being encouraged to start building water quality profiles now to understand farm risk based on water source being used and for future compliance. It is recommended to check FDA's FSMA webpage to stay current on any changes to water testing requirements:

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety

## **Laboratory Test Methods**

In September 2017, FDA identified a list of methods determined to be scientifically valid and at least equivalent to the U.S. Environmental Protection Agency's method 1603. This list of methods can be found in Appendix A and online at: <a href="https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water">https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water</a>. If your laboratory uses one of the approved methods, growers can use the test results to ensure compliance with the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR).



Agriculture water sample preparation and analysis (www.idexx.com)

## Agriculture Water Standards

Agricultural water is water used during production or post-harvest that is likely to come into direct or indirect contact with produce. Standards are based on detection of non-specific *E. coli*, which is an indicator of fecal contamination in a water source. Direct contact can occur through washing produce and indirect exposure can occur from food contact surfaces. Several microbial test methods have been approved for use by the US Food and Drug Administration (FDA; Appendix A). Up-to-date methods can be found online at: <a href="https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water">https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water</a>.

Post-harvest Water Standards

No detectable generic *E. coli* is the standard for post-harvest water. This means a test value of 0 (zero) cfu per 100 mL sample.

**Production Water Standards** 

The acceptable profile characteristics for production water is 126 or fewer colony forming units (cfu) per 100 mL (geometric mean; GM) and 410 or fewer cfu per 100 mL (statistical threshold value; STV).

- GM is an average and represents the central tendency of the water quality. This is interpreted as the average amount of generic *E. coli* in the water source.
- STV describes the amount of variability in water quality test results. Simply, it is the level at which 90% of the samples would fall below the test value. This is important when interpreting *E. coli* levels when adverse conditions are present (heavy rainfall or flooding that impacts waterways, for example).
- Online tools are available to aid producers in calculating these values.
  - Downloadable Excel Format Ground Water Calculator:
     <a href="https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/files/page/239320.xl">https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/files/page/239320.xl</a>
     <a href="mailto:sx">sx</a> (University of California Davis)
  - Downloadable Excel Format Surface Water Calculator:
     https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/files/page/268306.xl
     sx (University of California Davis)
  - Online Agriculture Water Calculator: <a href="https://agwater.arizona.edu/onlinecalc/default.aspx">https://agwater.arizona.edu/onlinecalc/default.aspx</a> (University of Arizona)

The established criteria are a tool for understanding microbial quality. If standards are not met, corrective measures are necessary.

## Frequently Asked Questions

Below are several frequently asked questions about water quality testing as it relates to the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). This section is intended as a quick reference to provide basic information and links to additional resources. It is not an exhaustive list and laboratories are not expected to provide detailed information about FSMA, the PSR, or water quality testing requirements to growers. Please know and feel free to reassure growers that there are several resources and agencies available to help farmers understand and comply with the PSR. This information is subject to revision based on changes to the FSMA PSR by the FDA. Referencing FDA's online information is the best way to stay up-to-date with current regulations and rulings.

If you have questions that haven't been addressed in the following FAQ, feel free to submit those by email to info@kyhortcouncil.org.

How can I be sure our lab is included in the online geographic listing of laboratories?

Verify your lab is using one of the approved test methods (<a href="https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water">https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water</a>) then check the online geographic directory (<a href="https://uk-horticulture.github.io/hort-directory/">https://uk-horticulture.github.io/hort-directory/</a>). Reference the section in this manual for the update procedure if corrections are needed.

What if a farmer asks if they are required to test their water?

Currently, water testing will be required for produce growers who have annual food sales that exceed \$25,000, although there are some exceptions. Several resources are available to produce growers to help them determine their responsibilities under the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). The University of Kentucky Center for Crop Diversification (CCD) has a simple, confidential online quiz

(https://uky.az1.qualtrics.com/jfe/form/SV 9oQEXqziH1yYmdD) where growers answer a series of questions about their operation. The Kentucky Department of Agriculture (KDA; 502-573-0282) can also answer questions growers may have about ensuring their farm is in compliance with the PSR.

When will the FDA require farmers to have their water tested?

The current dates by which ag water testing is required is based on revenue tiers: >\$500,000 (January 2022); \$250,001 - \$500,000 (January 2023); and \$25,000 - \$250,000 (January 2024). Stay up-to-date on any changes to this by checking the FDA website: <a href="https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety">https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety</a>

#### What is a "covered" farm?

A covered farm is a produce grower who is subject to FSMA requirements. Growers producing crops under cover (i.e. in plastic high tunnels, glass greenhouses, or other passive or controlled environment structures) may be subject to FSMA depending on the crops under production and the grower's revenue level. Generally, any grower producing crops that are usually eaten raw and who has a 3-year average annual food sale figure that exceeds \$25,000, although there are some exceptions. Stay up-to-date by checking the FDA website: <a href="https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety">https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety</a>

#### Aren't FSMA compliance dates already in effect?

The primary parts of FSMA are currently being enforced, with farm inspections by the Kentucky Department of Agriculture happening now. It is only the water testing component that has been delayed. Stay up-to-date by checking the FDA website: <a href="https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety">https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety</a>

What if a producer's water quality profile exceeds the geometric mean (GM) and statistical threshold value (STV) standards?

A single test value cannot be compared to the standards as both GM and STV require a series of analyses to make the statistical calculations. Several corrective actions are recognized by the FDA as measures a grower can take to reduce the risk of using a water source that has tested positive for generic *E. coli*. Growers can consult with their local University of Kentucky Cooperative Extension Office (local office online tool: <a href="http://extension.ca.uky.edu/county">http://extension.ca.uky.edu/county</a>), the University of Kentucky Food Systems Innovation Center (FSIC; <a href="http://www.uky.edu/fsic/">http://www.uky.edu/fsic/</a>; 859-218-4387), or the Kentucky Department of Agriculture (KDA; <a href="https://www.kyagr.com/">https://www.kyagr.com/</a>; 502-573-0282) for guidance in selecting the most appropriate measures for their operation based on their microbial quality profile. Some strategies are very simple, like timing harvest after the last irrigation event to ensure natural microbial die-off. Corrective actions should be implemented as soon as practical.

#### What is a corrective action?

Corrective actions are measures taken by the grower when thresholds have been exceeded to ensure source water quality is in compliance with the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). Corrective actions are farm-specific based on the grower's needs and operation. Actions can be a change of management techniques (transitioning to a black plastic mulch system from a traditional open field production system, for example) or implementing a technology (installing a water treatment system, for example). After making the changes, the grower should re-test the agriculture water quality to verify the efficacy of the corrective action. Refer to additional online information prepared by the Produce Safety Alliance (PSA) <a href="https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/2017%20GM%20STV%20Worksheet%20v1.0.pdf">https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/2017%20GM%20STV%20Worksheet%20v1.0.pdf</a>

How are the geometric mean (GM) and statistical threshold value (STV) calculated?

Geometric mean (GM) is an average and represents the central tendency of the water quality. This is interpreted as the average amount of generic *E. coli* in the water source. Statistical Threshold Value (STV) describes the amount of variability in water quality. Simply, it is the level at which 90% of the samples would fall below the test value. Online tools can be used to calculate this value. An explanation and examples of the calculations can be found online:

https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/2017%20GM%20STV%20Worksheet%20v1.0.pdf

#### What about sprouts?

FDA's Food Safety Modernization Act (FSMA) has requirements to help prevent contamination of sprouts, which have been frequently associated with foodborne illness outbreaks. The warm, moist, and nutrient-rich conditions needed to grow sprouts creates an especially favorable environment for microbial growth. Requirements specific to farmers growing sprouts includes testing irrigation water or sprouts from each production batch for certain pathogens. The first compliance date for the largest sprout operations began on January 26, 2017. More details are available online: <a href="https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety">https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety</a>



Sprouts being grown for direct marketing to customers.

If a grower has tested agriculture water sources for Good Agricultural Practices (GAPs) or other third-party certification programs, does that mean they have met the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) requirements?

Not necessarily. FDA's Food Safety Modernization Act (FSMA) is a mandatory program while Good Agricultural Practices (GAPs) and other third-party certifications are elective. Since these programs are different, the requirements related to testing agriculture water are not identical. However, if growers plan well, their agricultural water testing strategy can satisfy the requirements for multiple programs. Cultivate Kentucky (<a href="https://foodconnection.ca.uky.edu/content/cultivate-kentucky">https://foodconnection.ca.uky.edu/content/cultivate-kentucky</a>) works with growers interested in GAPs certification and can consult on a comprehensive water testing strategy to ensure compliance with GAPs, FSMA, and other certification programs.

#### Resources

#### Cultivate Kentucky

The Cultivate Kentucky program at the University of Kentucky College of Agriculture, Food and the Environment's Food Connection provides on-farm assistance to growers across the Commonwealth interested in pursuing a third-party audit and entering wholesale markets. Bryan Brady, Cultivate KY Senior Extension Associate, helps growers understand requirements of a sound food safety program, assists them in creating a food safety plan for their operation, and helps them implement that plan in cost-effective ways. Beyond third party food safety audits, Cultivate Kentucky also helps farmers meet product quality demands of wholesale buyers by providing technical assistance in postharvest best practices. (https://foodconnection.ca.uky.edu/content/cultivate-kentucky)

#### Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR)

The US Food & Drug Administration (FDA) is responsible for the legislation regulating the nation's food safety system. The Produce Safety Rule (PSR) is one of seven major rules to implement the Food Safety Modernization Act (FSMA) designed to prevent foodborne illnesses and ensure the safety of the food supply is in the global supply chain for both human and animal food. (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety)

#### Kentucky Department of Agriculture Produce Safety Program

The Produce Safety Program at the Kentucky Department of Agriculture (KDA) helps Kentucky produce growers comply with the Food Safety Modernization Act (FSMA) and its Produce Safety Rule (PSR). Through a cooperative agreement with the US Food and Drug Administration (FDA), KDA is responsible for PSR implementation in Kentucky. (https://www.kyagr.com/marketing/produce-safety.html)

#### Kentucky Horticulture Council (KHC)

The Kentucky Horticulture Council (KHC) supports the state horticulture industry and is a resource for information and education for growers, business owners, and the public to promote a thriving industry. KHC assists produce growers in Kentucky by identifying research needs, organizing educational programming, and working to develop markets. (<a href="www.kyhortcouncil.org">www.kyhortcouncil.org</a>)

#### Produce Safety Alliance (PSA)

The Produce Safety Alliance (PSA) is a collaboration between Cornell University, FDA, and USDA to prepare fresh produce growers to meet the regulatory requirements included in the United States Food and Drug Administration's Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). Several resources are available on the PSA website: <a href="https://producesafetyalliance.cornell.edu/">https://producesafetyalliance.cornell.edu/</a>.

#### Produce Safety Network

The Produce Safety Network (PSN) supports the efforts of farmers, regulators, and other key stakeholders to implement the Produce Safety Rule (PSR) of the Food Safety Modernization Act (FSMA). The network consists of FDA produce safety experts, located in various locations throughout the country. Currently there are six produce safety experts, one team leader from the Center for Food Safety and Applied Nutrition (CFSAN), and 14 investigators and two branch chiefs from the Office of Regulatory Affairs (ORA). They work closely with stakeholders, such as state produce safety programs, to provide regulatory support and technical assistance. (https://www.fda.gov/food/food-safety-modernization-act-fsma/produce-safety-network)

#### University of Kentucky Center for Crop Diversification

The University of Kentucky Center for Crop Diversification (UK CCD) is a specialty crops-focused Cooperative Extension organization based out of the University of Kentucky College of Agriculture Food and the Environment (UK CAFE). The UK CCD partners with a wide variety of regional and national individuals to create and distribute production and marketing resources for Kentucky growers. (<a href="http://www.uky.edu/ccd/">http://www.uky.edu/ccd/</a>)

#### University of Kentucky Food Systems Innovation Center (FSIC)

The University of Kentucky Food Systems Innovation Center (FSIC) assists small and large processors, producers and entrepreneurs in maximizing their market capabilities. FSIC provides technical and business development services to facilitate the profitable production, processing and marketing of locally produced and processed food by Kentucky-based enterprises and entrepreneurs. (<a href="http://www.uky.edu/fsic/">http://www.uky.edu/fsic/</a>)

#### **Additional Resources**

- Understanding the U.S. Food Safety Regulatory System <a href="https://www.uky.edu/ccd/sites/www.uky.edu.ccd/files/Food Safety System.pdf">https://www.uky.edu/ccd/sites/www.uky.edu.ccd/files/Food Safety System.pdf</a>
- FDA at a Glance. Key Requirements: Final Rule on Produce Safety <a href="https://www.fda.gov/media/94738/download">https://www.fda.gov/media/94738/download</a>
- Food Safety Modernization Act (FSMA): Produce Safety Rule Agricultural Water, Introduction (CCD-PFS-2)
   <a href="https://www.uky.edu/ccd/sites/www.uky.edu.ccd/files/FSMA">https://www.uky.edu/ccd/sites/www.uky.edu.ccd/files/FSMA</a> Water Introduction Final update2.pdf
- Food Safety Modernization Act (FSMA): Produce Safety Rule Agricultural Water, Part 2 (CCD-PFS-4)
   https://www.uky.edu/ccd/sites/www.uky.edu.ccd/files/FSMA Water Part2 Final.pdf

## Appendix A. Equivalent Testing Methodology for Agriculture Water



## FDA FACT SHEET

Produce Safety Rule (21 CFR 112)

#### **EQUIVALENT TESTING METHODOLOGY FOR AGRICULTURAL WATER**

FDA has determined that the following quantification methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC)" (December 2009), in accuracy, precision, and sensitivity in quantifying generic Escherichia coli in agricultural water when used in connection with the criteria described in § 112.44(a) or § 112.44(b).

- Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC) (September 2014). U.S. Environmental Protection Agency. EPA-821-R-14-010.
- Method 1103.1: Escherichia coli (E. coli) in Water by Membrane Filtration Using membrane-Thermotolerant Escherichia coli Agar (mTEC) (March 2010). U.S. Environmental Protection Agency. EPA-821-R-10-002.
- Method 1604: Total Coliforms and Escherichia coli in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002). U.S. Environmental Protection Agency. EPA-821-R-02-024.
- 4. 9213 D Natural Bathing Beaches (2007). In: Standard Methods for the Examination of Water and Wastewater, 22nd Edition (Rice E.W., et al., Ed.), 9-46 9-48. Washington, DC: American Public Health Association. (2012).
- 5. 9222 B Standard Total Coliform Membrane Filter Procedure (1997), followed by 9222 G MF Partition Procedures (1997) using NA-MUG media. In: Standard Methods for the Examination of Water and Wastewater, 21st Edition (Eaton A.D., et al., Ed.), 9-60 9-65, and 9-70 9-71, respectively. Washington, DC: American Public Health Association. (2005).
- D 5392-93 Standard Test Method for Isolation and Enumeration of Escherichia coli in Water by the Two-Step Membrane Filter Procedure. In: Annual Book of ASTM Standards, Volume 11.02. ASTM International. (1996, 1999, 2000).
- 7. Hach Method 10029 for Coliforms Total and E. coli, using m-ColiBlue24 Broth PourRite Ampules.
- 8. IDEXX Colilert Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.
- 9. IDEXX Colilert-18 Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.

U.S. Food and Drug Administration 5001 Campus Drive College Park, MD, 20740 www.fda.gov



With regard to criteria described only in § 112.44(a), FDA has determined that the following presence/absence methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC)" (December 2009), in accuracy, precision, and sensitivity in detecting generic Escherichia coli in agricultural water.

- 1. TECTA<sup>TM</sup> EC/TC medium and the TECTA<sup>TM</sup> Instrument: A Presence/Absence Method for the Simultaneous Detection of Total Coliforms and Escherichia coli (E. coli) in Drinking Water. (2014).
- 2. Modified Colitag<sup>™</sup> Test Method for the Simultaneous Detection of *E. coli* and other Total Coliforms in Water. ATP D05-0035. (2009).
- 3. IDEXX Colilert Test Kit
- 4. IDEXX Colilert-18 Test Kit
- 5. IDEXX Colisure Test Kit
- 6. E\*Colite Bag or Vial Test for Total Coliforms and E. coli in Potable Water. Charm Sciences, Inc.
- 7. 101298 Readycult Coliforms 100. EMD Millipore (division of Merck KGaA, Darmstadt, Germany).

#### For more information:

FSMA Final Rule on Produce Safety. https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

Have you seen our Blog? FDA Voice











The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

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