

FDA Food Safety Modernization Act (FSMA) introduces generic *E. coli* test requirements for agricultural water that may come into contact with produce or food surfaces

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Key Words

FSMA, Agricultural, Irrigation, Water, Generic, *E. coli*, Produce, Food surfaces, Water quality

Goal

One of the requirements for the FSMA Produce Safety rule is to test for generic *E. coli* in agricultural water. Agricultural water is defined as any water that may come into contact with produce or food surfaces during or after growing and harvesting. The recommended method to test for generic *E. coli* in agricultural water is the Environmental Protection Agency (EPA) method 1603: *Escherichia coli* in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC). This technical note provides an overview of this EPA method and describes the Thermo Fisher Scientific Microbiology products that conform to this method.

FSMA Overview

FSMA was signed into law by President Obama on January 4th 2011, the aim of which is to ensure that the United States of America has a safe food supply. To achieve this, the act shifts the focus for food safety from responsive to preventative by increasing inspections, tightening domestic standards and extending these standards to imported produce. These measures are in place to ultimately prevent outbreaks from pathogens such as *E. coli* O157:H7 and viruses such as Hepatitis A that spread via food due to contaminated agricultural water.

FSMA has tightened food safety standards by introducing seven rules. One of these is the Produce Safety rule which, in part, establishes minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables that are commonly consumed raw.

Testing for Generic *E. coli* in Agricultural Water

The Produce Safety rule includes two requirements that relate to the presence of generic *E. coli* in agricultural water. *E. coli* is an indicator of faecal and possible other pathogenic contamination. The first requirement prohibits the presence of any generic *E. coli* in waters in which there is a reasonable risk that pathogenic microbes could be transferred to any produce. Such water includes that used during and after harvest, and for washing of hands or food surfaces which may come into contact with the produce¹. The second of the two requirements is for agricultural water directly applied to growing produce (other than sprouts) and is determined by two metrics. The two metrics are the geometric mean (GM) and the statistical threshold (STV). The GM is an average of the amount of generic *E. coli* across various samples and may not exceed 126 CFU generic *E. coli* in 100 ml of water. The STV indicates the variability of generic *E. coli* levels in adverse conditions and may not exceed 410 CFU generic *E. coli* in 100 ml of water¹.

Testing Frequencies

Table 1. Required testing frequencies depending on the type of water and the way in which the water will be used in agriculture¹.

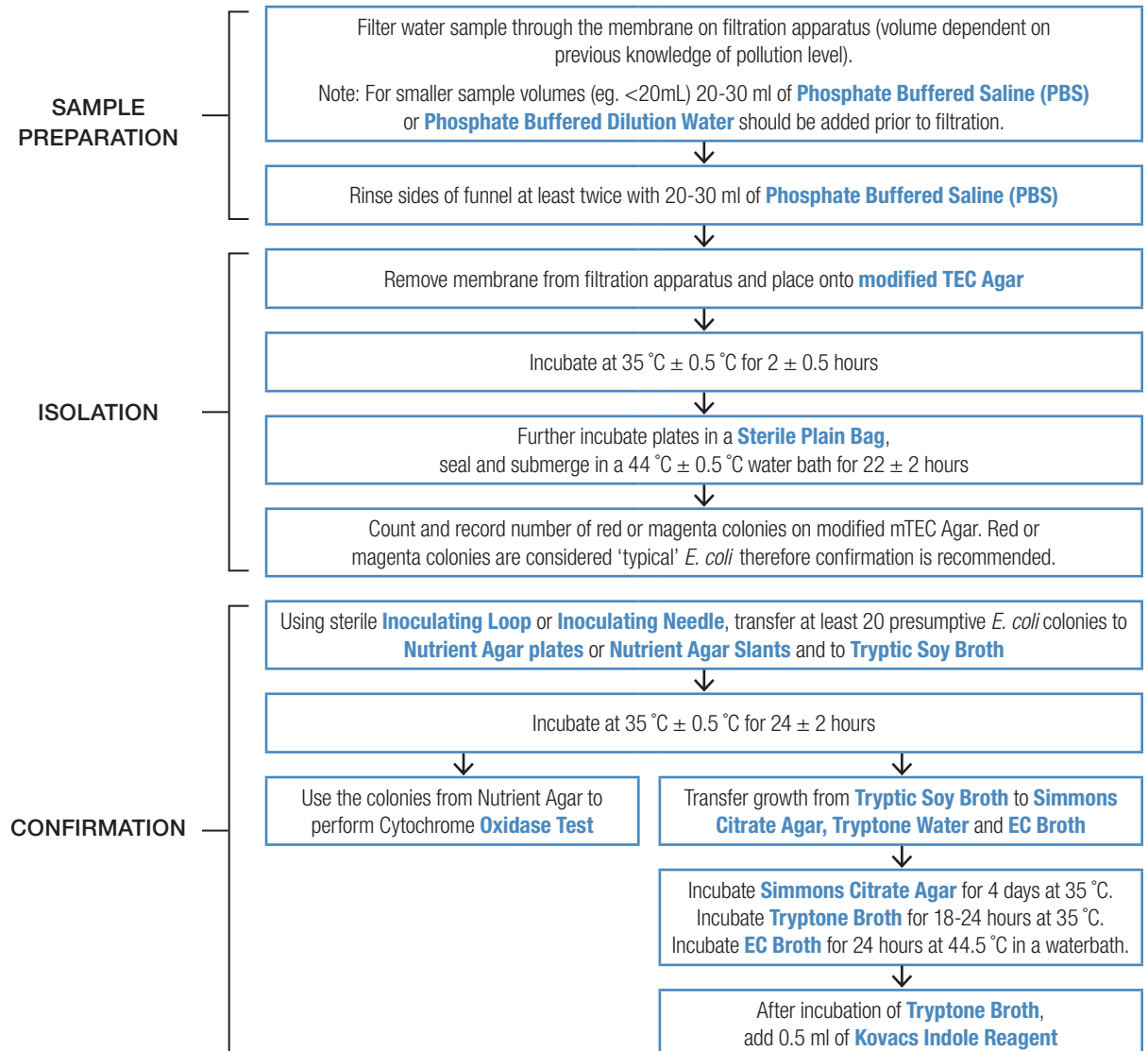
Water Type	Initial Test Number	Interval (Years)	Minimum Annual Test Number
Untreated Surface Water	20	2 - 4	5
Untreated Ground Water (Directly applied to produce other than sprouts)	4	1	1
Untreated Ground Water (for which no generic <i>E. coli</i> is allowed)	4	1 (during the growing season)	1

Methodology for the Testing of Agricultural Water for Generic *E. coli* Using Membrane Filtration

This EPA approved membrane filtration procedure for testing the presence of generic *E. coli* in agricultural water satisfies § 112.46 of the FSMA. The use of chromogenic media differentiates *E. coli* colonies due to the production of a red or magenta colour when the chromogen is metabolised by *E. coli*².

Summary of Method

A direct count of generic *E. coli* in agricultural water is achieved by the development of colonies on the surface of a membrane filter. Following filtration, the membrane is placed onto a modified mTEC agar plate, and incubated at 35 °C for 2 hours to allow for the recovery of any organisms on the filter. The plate and membrane are further incubated for 22 hours at 44 °C. Target *E. coli* can be differentiated from other organisms based on a red or magenta colouration of colonies². True *E. coli* are oxidase negative, citrate negative, EC broth growth and gas positive and indole positive.



Product	Product Codes	Format	Pack Size
SAMPLE PREPARATION			
Phosphate Buffered Saline (PBS)	R062582	5 ml Tube	20
	R062580	5 ml Tube	100
Phosphate Buffered Dilution Water	R07770	90 ml Borosilicate Septum Bottle	10
	R112531	20 ml Crimped Serum Bottle	10
	R118610	9 ml Tube	100
Sterile Plain Bag, BagLight™ 400	DB4013A	Bag	1000
ISOLATION			
Modified mTEC Agar	Fisher Catalogue #B14880	Dehydrated Powder	500 g
CONFIRMATION			
Inoculating Loop, Calibrated Disposable, 10µL	R501511	10 µl Loop	32
Inoculating Needle, Disposable	R501505	Needle	32
Nutrient Agar	R01640	Agar Plate	10
	R061570	Agar Slants	100
	R061572	Agar Slants	20
	R08622	1 ml Tube	20
	R09626	22 ml Pour Tube	20
Tryptic/Trypticase Soy Broth	R064880	1 ml Tube	100
	R064890	2 ml Tube	100
Simmons Citrate Broth	R454652	Dehydrated Powder	500 g
Tryptone Water	R455122	Dehydrated Powder	500 g
EC Broth	CM0853B	Dehydrated Powder	500 g
Oxidase Reagent	R21540	0.75 ml Thermo Scientific™ BactiDrop™ Stain	50
Kovacs Indole Reagent	R21522	0.75 ml BactiDrop Stain	50
QUALITY CONTROL			
Tryptic Soy Agar (TSA)	R01920	Agar Plate	10
	R01917	Agar Plate	100
Lauryl Tryptose Broth (LTB)	R453662	Dehydrated Powder	500 g
	R453664	Dehydrated Powder	10 kg
<i>Escherichia coli</i> (ATCC® 11775)	R4601989	Thermo Scientific™ Culti-Loops™ QC Organisms	5
<i>Enterococcus faecalis</i> (ATCC® 19433)	R4601990	Culti-Loops QC Organisms	5
<i>Enterobacter aerogenes</i> (ATCC® 13048)	R4607080	Culti-Loops QC Organisms	5

References

1. Nutrition C for FS and A. Food Safety Modernization Act (FSMA) – FSMA Final Rule on Produce Safety. Center for Food Safety and Applied Nutrition. Available from: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
2. Water USEPAO of, editor. Method 1603 [electronic resource] : *Escherichia coli* (*E. coli*) in water by membrane filtration using modified membrane-thermotolerant *Escherichia coli* agar (modified mTEC). [Washington, D.C.]: United States, Environmental Protection Agency, Office of Water; 2002.

Disclaimer: This technical note contains a summary of the FDA FSMA Produce Safety rule, in part, and EPA method 1603. Please refer to the references provided for more detailed information.

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993-132
LT2308A
October 2016

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