



# FOOD SAFETY MODERNIZATION ACT PRODUCE SAFETY RULE ADD-ON

## Guideline for Fruit and Vegetables

ENGLISH VERSION 2.0\_JUL23

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## TABLE OF CONTENTS

<b>1</b>	<b>AGRICULTURAL WATER .....</b>	<b>3</b>
1.1	Introduction to agricultural water .....	3
1.2	Definitions .....	3
<b>2</b>	<b>SOIL AMENDMENTS.....</b>	<b>4</b>
2.1	Treatment process for biological soil amendments .....	4
2.2	Stabilized compost .....	5

## 1 AGRICULTURAL WATER

### 1.1 Introduction to agricultural water

The Integrated Farm Assurance (IFA) standard for fruit and vegetables requires that producers develop a risk-based assessment to cover production-specific factors such as crop, water source, contact of water with crop, etc. A program for testing microbiological water quality and a defined sampling frequency are required, both based on this assessment. The GLOBALG.A.P. Secretariat accepts *E. coli* as an indicator of fecal contamination. Corrective actions shall be taken and proven to be effective if test results indicate microbial water quality does not meet required thresholds.

Subpart E of the Food Safety Modernization Act's (FSMA) Produce Safety Rule (PSR) refers to agricultural water. Previously, the United States Food and Drug Administration (FDA) had [extended the compliance dates](#) for the preharvest agricultural water provision, while the FDA chose to use enforcement discretion. The FDA has since published a [proposed agricultural water rule](#) in December 2021. A statement on the FDA's website reads: "The agency [FDA] intends to exercise enforcement discretion for the agricultural water requirements for covered produce while proposing to extend the compliance dates for all subpart E provisions applicable to such produce, with the goal of completing the compliance date rulemaking as quickly as possible." Therefore, regarding agricultural water, principles and criteria (P&Cs) in section 6 are scored as Recommendations until the FDA enforces the original requirements or the P&Cs are updated to reflect the finalized revised requirements. All testing, sampling, or records on microbial water quality as related to PSR requirements are not scored.

### 1.2 Definitions

The water requirements established by the PSR apply only to agricultural water, which is defined as the water that comes into contact with the produce and food contact surfaces.

- **Surface water:** Any water open to the atmosphere such as rivers, lakes, reservoirs (natural or man-made), streams, etc. If groundwater (such as wells, springs, etc.) is collected or maintained open to the atmosphere, it shall be considered surface water.
- **Groundwater:** Supply of water from beneath the earth's surface, such as aquifers which supply wells, springs, etc. This water shall be extracted in a properly constructed and closed system if it is used directly from the source. If it is stored on the farm, it should be maintained or transported in closed tanks/systems. If stored in pools, tanks, or reservoirs that are open, it will be considered surface water.

The producer shall build a microbial water quality profile of the agricultural water. The microbial count shall be lower than 126 colony-forming units (CFU) of *E. coli* per 100ml of water in any group of samples.

§ 112.46 (b)(1)(ii) requires that the sampling of water shall be representative of the use and that samples shall be taken before the harvest, but at the nearest practicable time to harvest possible.

The FDA has determined that the following methods are "scientifically valid" and "at least equivalent to the method of analysis in § 112.151 (a) in accuracy, precision, and sensitivity [1]":

- Method 1103.1 – "*Escherichia coli* (*E. coli*) in water by membrane filtration using membrane-thermo-tolerant *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.

- 9213 D – “Natural bathing beaches” (2007). In: “Standard methods for the examination of water and wastewater,” 22nd edition (Rice E.W., et al., eds.), 9-46 – 9-48. Washington, DC: American Public Health Association. (2012).
- 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., eds.), 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).
- (6) Hach method 10029 for coliforms – Total and *E. coli*, using m-ColiBlue24<sup>®</sup> Broth PourRite ampules.
- IDEXX Colilert<sup>®</sup> test kit, but only if using IDEXX Quanti-Tray/2000 for quantification.
- IDEXX Colilert-18<sup>®</sup> test kit, but only if using IDEXX Quanti-Tray/2000 for quantification.

Additional requirements for § 112.45, if agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44 (b), are given below. If the producer applies a time interval and/or a log reduction, the following apply.

1) A time interval (in days) and/or a (calculated) log reduction by one or both of the following:

- Applying a time interval between last irrigation and harvest using either: (A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of the geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44 (b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of four consecutive days; or (B) an alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49
- Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44 (b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided that adequate supporting scientific data and information is available

## 2 SOIL AMENDMENTS

### 2.1 Treatment process for biological soil amendments

The following treatment processes are acceptable for a biological soil amendment of animal origin that is applied in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

- A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical, and/or biological processes that has been validated to satisfy the microbial standard in § 112.55 (a) for *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7

- A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55 (b) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55 (b) are given below.

## 2.2 Stabilized compost

In the PSR, microbial standards that set limits on detectable amounts of bacteria (including *L. monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* O157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods shall be applied in a manner that minimizes the potential for contact with produce during and after application.

<b>Examples of composting processes mentioned in the PSR (§ 112.54)</b>	
Static composting:	Must maintain aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing
Turned composting:	Must maintain aerobic conditions at a minimum of 131°F (55°C) for 15 days (which do not have to be consecutive), with a minimum of 5 turnings, and is followed by adequate curing
Microbial standard (§ 112.55 (b)):	<p><i>L. monocytogenes</i> – not detected using a method that can detect 1 colony-forming unit (CFU)/5 grams (or milliliters, if liquid is being sampled) analytical portion</p> <p><i>Salmonella</i> species – not detected using a method that can detect 3 most probable numbers (MPN)/4 grams (or milliliters, if liquid is being sampled) of total solids</p> <p><i>E. coli</i> O157:H7 – not detected using a method that can detect 0.3 MPN/1 gram (or milliliter, if liquid is being sampled) analytical portion</p> <p>Or for dry weight basis:</p> <p><i>Salmonella</i> species – not detected using a method that can detect 3 MPN <i>Salmonella</i> species/4 grams of total solids</p> <p>Fecal coliforms – less than 1,000 MPN/gram of total solids</p>

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