



FOOD SAFETY MODERNIZATION ACT PRODUCE SAFETY RULE ADD-ON

Guideline for Fruit and Vegetables

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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 (FSMA) Produce Safety Rule (PSR) of the United States Food and Drug Administration (FDA) refers to agricultural water. Effective 5 July 2024, the final rule on agricultural water revises preharvest agricultural water provisions (subpart E), and replaces the previous microbial quality criteria and testing requirements with requirements for a systems-based preharvest agricultural water assessment for hazard identification and risk management decision-making purposes (agricultural water risk assessment). The revised rule aligns with version 6.0 of IFA and the IFA guideline for fruit and vegetables; however, producers shall include all relevant criteria appearing in this document.

1.2 Definitions

The water requirements established by the PSR apply only to agricultural water.

- Agricultural water means water that is intended to, or is likely to, contact produce or food contact surfaces. Such water includes irrigation water applied using direct water application methods and water used for preparing crop sprays. If a specific use of water does not fit within the definition of agricultural water, then the requirements in subpart E do not apply.
- Agricultural water assessment (agricultural water risk assessment) means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors related to growing activities.
- Agricultural water system means a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system, and any equipment used for application of agricultural water.

1.3 Agricultural water risk assessment

As part of their preharvest agricultural water risk assessments, producers are required to evaluate certain factors that could impact produce safety as a result of the use of preharvest agricultural water. Below is an overview of factors.

Table 1 Summary of factors evaluated as part of a preharvest agricultural water risk assessment

| Factor | Description |
|------------------------------|--|
| Agricultural water system(s) | <ul style="list-style-type: none"> • The location and nature of the water source (for example, whether it is ground water or surface water) • The type of water distribution system (for example, whether it is open or closed to the environment) • The degree to which the system is protected from possible sources of contamination, including: |

| Factor | Description |
|------------------------------|--|
| | <ul style="list-style-type: none"> ○ Other users of the water system ○ Animal impacts (such as from grazing animals, working animals, and animal intrusion) ○ Adjacent and nearby land uses related to animal activity, the application of biological soil amendments of animal origin (BSAAOs), or the presence of untreated or improperly treated human waste |
| Agricultural water practices | <ul style="list-style-type: none"> • The type of application method (such as overhead sprinkler or spray, drip, furrow, flood, and seepage irrigation) • The time interval between the last direct application of agricultural water and harvest of the covered produce (other than sprouts) |
| Crop characteristics | <ul style="list-style-type: none"> • Susceptibility of the covered produce to surface adhesion or internalization of hazards |
| Environmental conditions | <ul style="list-style-type: none"> • Frequency of heavy rain or extreme weather events that may impact the agricultural water system (such as by stirring sediments that may contain human pathogens) or that may impact or damage produce. Damage can increase the susceptibility of produce to contamination. • Air temperatures • Sun (UV) exposure |
| Other relevant factors | <ul style="list-style-type: none"> • Including, if applicable, results of testing to inform the assessment |

[Expanded table on factors to consider for agricultural water risk assessments](#)

1.4 Outcomes and mitigation procedures

Based on the findings of the agricultural water risk assessment, producers are required to determine whether corrective measures or mitigation measures are necessary to reduce the potential for contamination. Below is a summary of actions.

Table 2 Outcomes and mitigation procedures

| If you determine: | Then you must: |
|---|--|
| That your agricultural water is not safe or is not of adequate sanitary quality for intended use(s) | <ul style="list-style-type: none"> • Immediately discontinue use(s) <p>AND</p> <ul style="list-style-type: none"> • Take corrective measures before resuming use of the water for preharvest activities |

| If you determine: | Then you must: |
|---|---|
| There is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land and for which mitigation is reasonably necessary | <ul style="list-style-type: none"> Implement mitigation measures promptly, and no later than the same growing season |
| There is one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land and for which mitigation is reasonably necessary | <ul style="list-style-type: none"> Implement mitigation measures as soon as practicable and no later than the following year <p>OR</p> <ul style="list-style-type: none"> Test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment |
| There are not any known or reasonably foreseeable hazards for which mitigation is reasonably necessary | <ul style="list-style-type: none"> Regularly (at least once each year) inspect and adequately maintain the water system(s) |

[Expanded table on corrective and mitigation measures for preharvest agricultural water](#)

1.5 Accepted testing methods for agricultural water

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® Broth PourRite ampules.

- IDEXX Colilert® test kit, but only if using IDEXX Quanti-Tray/2000 for quantification.
- IDEXX Colilert-18® test kit, but only if using IDEXX Quanti-Tray/2000 for quantification.

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.

| Examples of composting processes mentioned in the PSR (§ 112.54) | |
|--|---|
| 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> |

VERSION/EDITION UPDATE REGISTER

| New document | Replaced document | Date of publication | Description of modifications |
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| 250107_GG_FSMA_PSR_add-on_guideline_for_FV_v2_1_Jan25_en | 230727_GG_FSMA_PSR_add-on_guideline_for_FV_v2_0_Jul23_en | 7 January 2025 | 1.1 – explanation of changes 1.2 – new definitions 1.3 – added agricultural water risk assessment table 1.4 – added outcomes and mitigation procedures table 1.5 – changed title of section |

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