



**Produce Safety**  
ALLIANCE



# Produce Safety Rule Updates



Great Plains Growers Conference  
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Business Size	 Compliance Dates for Sprouts	 Compliance Dates For Most Produce	 Water Related Compliance Dates <sup>1</sup>	Compliance Date for Qualified Exemption Labeling Requirement <sup>2</sup>	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>\$500K)	1/26/17	1/26/18	1/26/22		
Small businesses (>\$250K-500K) <sup>3</sup>	1/26/18	1/28/19	1/26/23	1/1/2020	1/26/16
Very small businesses (>\$25K-250K) <sup>4</sup>	1/28/19	1/27/20	1/26/24		

<sup>1</sup> According to the [Proposed Rule](#) issued 9/13/17, Compliance dates for Subpart E, Agricultural Water, allow an additional four years.

<sup>2</sup> A farm eligible for a qualified exemption must notify consumers as to the complete business address of the farm where the food is grown, harvested, packed, and held. <sup>3</sup> A farm is a small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$500,000.

<sup>4</sup> A farm is a very small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000.

Before the compliance date, every covered farm that does not qualify for an exemption must have a supervisor (such as a farm owner/operator) complete a standardized food safety training program. You can find out more about food safety training from the Produce Safety Alliance. <https://producesafetyalliance.cornell.edu/training>

Revised 10/09/17



# Draft Guidance Published

- Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
  - Published in Federal Register on October 22, 2018
  - Comments can be submitted until April 22, 2019
  - At-a-glance overviews are available for each of the nine chapters



**FEDERAL REGISTER**  
The Daily Journal of the United States Government



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## Subpart A – General Provisions

- § 112.2(b)(2) and (3) – disclosures and written assurance for produce going to commercial processing
  - To qualify for the commercial processing exemption, you must disclose, in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” (21 CFR 112.2(b)(2)) – page 14 gives examples
  - (page 14) FDA intends to exercise **enforcement discretion regarding written assurance** from your customers



## Subpart C – Personnel Qualifications and Training

- Who **does** have to be qualified and trained in accordance with § 112.21(a) and (b)?
  - (Page 26) “All personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof”
  - (Page 39) “Personnel can include full-time, part-time, **contracted, and seasonal personnel; volunteers; and paid or unpaid interns** at your facility.”
- Who **does not** have to be qualified and trained in accordance with § 112.21(a) and (b)?
  - (Page 27) those with “duties that do not involve contact with covered produce or food contact surfaces (e.g., removing trash, sweeping floors, maintaining restrooms, maintaining or repairing non-food contact surfaces of equipment, **pest control, or operating forklifts and tractors**)”



## Subpart C – Personnel Qualifications and Training

- §§ 112.21(a) and (b) and 112.30
  - (Page 38) “If you employ contracted personnel, and you choose to rely on the training the contracted company (or a third-party service provider) provides, you should request training documentation from the contracted company or third-party service provider, and maintain the **records to demonstrate compliance with the training requirements.**”



## Subpart D – Health & Hygiene

- § 112.32(b)(6) – Eating, chewing gum, drinking
  - Personnel must not eat, chew gum, or use tobacco products in an area used for a covered activity; drinking beverages is permitted in designated areas.
  - (Page 54) “You should locate these designated areas at a sufficient distance from covered produce and food contact surfaces so as not to serve as potential sources of contamination to covered produce or food contact surfaces, such as by spillage of partially consumed beverages and by personnel drinking beverages (e.g., through **hand to mouth contact or spittle**).”



## Subpart D – Health & Hygiene

- § 112.33 – Visitors
  - (Page 54-55) “Visitors could include consumers, delivery personnel, vendors, or others who are touring, conducting business, or observing your farm.”
  - (Page 55-56): Examples of ways that farms can make visitors aware of policies and procedures to protect covered produce and food contact surfaces
    - Supervisor explains to visitors
    - Signage where visitors will be on the farm
    - Handouts provided to visitors



## Subpart F – BSAAOs and Human Waste

- § 112.56 – Application requirements and minimum application intervals that apply to BSAAOs
  - (Page 67-68) Examples 4a through 4e highlight ways to minimize contact with the crop during and after application of untreated soil amendments
  - (Page 69) “We do not object to growers’ use of a 90 or 120 day application interval for untreated BSAAOs subject to 21 CFR 112.56(a)(1)(i). **We believe adherence to a 90 or 120 day application interval to be a prudent step toward minimizing the likelihood of contamination** while the risk assessment and further research occur.”



## Subpart K – Growing, Harvesting, Packing and Holding Activities

- § 112.112 – Pre-Harvest Assessment
  - (page 85) **Signs that covered produce is reasonably likely to be contaminated** with a known or reasonably foreseeable hazard include:
    - Excreta observed on the covered produce;
    - Excreta observed in an area where it is reasonably likely that it has contacted or will contact nearby covered produce during harvest
    - Animal fur, hair, or feathers observed on the covered produce; and
    - Crop damage or destruction by animals (e.g., bite/gnaw marks; bent, uprooted, or trampled crops).



## Subpart K – Growing, Harvesting, Packing and Holding Activities

- § 112.111
  - (page 82-83) “Keep covered produce separate from excluded produce (except when placed in the same container for distribution)” and “Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.”
- § 112.22(a)(3)
  - (page 84) “Personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive training related to the separation of excluded and covered produce, as applicable.”



## Subpart L – Equipment, Tools, Buildings, and Sanitation

- § 112.127(b) – Guard and guide dogs in and around buildings
  - (page 119) “You should inform guard and guide dog handlers of the potential for dogs to carry contamination into your buildings and ensure that they minimize the likelihood of the dogs becoming contaminated (e.g., contact with animal excreta) before entering your buildings.”



## Subpart O – Records

- § 112.161 – general requirements for records
  - (page 134) Growers that use **dry erase boards** should be aware that these alone could not be used for required records
  - (page 135) Guidance suggests that **1 week** is an appropriate amount of time for supervisor to perform review
  - (page 135-136) For small growers, the **person signing the record can be the person originating the record**



# Equivalent Ag Water Tests



## 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).

1. 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.
2. 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.
3. 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).
6. 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.

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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™ EC/TC medium and the TECTA™ Instrument: A Presence/Absence Method for the Simultaneous Detection of Total Coliforms and *Escherichia coli* (*E. coli*) in Drinking Water. (2014).
2. Modified Colitag™ 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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# Produce Safety Alliance Resources



## General Resource Listing

[Home](#) / [Resources](#) / [General Resource Listing](#)

### Water

- [The Water Analysis Method Requirement in the FSMA Produce Safety Rule \(Updated August 2018 to reflect recent FDA announcements\)](#)
- [FSMA Produce Safety Rule Water Requirements: Insights to Get You Organized!](#)
- [MWQP Agricultural Water Calculators \(online tools\)](#)
- [Geometric Means, Statistical Threshold Values, and Microbial Die-Off Rates \(longhand calculations\)](#)

### Soil Amendments

- [Geneva Soil Summit Resources](#)
- [South Central Soil Summit Resources](#)
- [Southeastern Soil Summit Resources](#)

### Land Use Issues

- [Food Safety for Flooded Farms](#)

### Sanitation

- [Introduction to Selecting an EPA-Labeled Sanitizer](#)
- [Labeled Sanitizers for Produce - Excel Tool Version 2 updated 9/27/18](#)
  - [Video Tutorial: How to Use the Excel Tool Labeled Sanitizers for Produce](#)
- [United Fresh—Guidance on Environmental Monitoring and Control of Listeria for the Fresh Produce Industry](#)

### Recordkeeping

- [Records Required by the FSMA Produce Safety Rule](#)
  - [Template Records in Word format](#)



# NECAFS Clearinghouse

**NECAFS**

The Northeast Center to Advance Food Safety



Search Resources

## TYPE

- Guidance - Federal
- People
- Project
- National Curricula
- Add-on / Supplemental Educational Material
- Fact Sheets
- Published Plans & Statutes (State)
- Published Rules (Federal)
- Coverage Assessment Tools
- Videos
- Tools & Calculators
- Funding Source
- Informational Overview
- TAN Question/Answer

## TOPIC

- Preventive Controls for Human Foods (PCHF)**
  - General (PCHF)
  - Good Manufacturing Practices (GMP's)
  - Preventive Controls (PC's)
  - Food Safety Plan
- Produce Safety Rule (PSR)**
  - General (PSR)
  - Worker Health, Hygiene & Training
  - Soil Amendments
  - Wildlife, Domestic Animals & Land Use
  - Ag Water (Preharvest)
  - Ag Water (Postharvest)
  - Postharvest Handling & Sanitation
  - Food Safety Plans
  - Record Keeping

## STATE

- Any -

## KEYWORDS

SEARCH



# On-Farm Readiness Review





# Benefits of Participating in an On-Farm Readiness Review

- The OFRR is voluntary, free, and confidential
- Helps align what you're doing with what's required in the Produce Safety Rule
- Helps you determine what you're missing regarding on-farm produce safety
- Provides a personalized discussion of your farm food safety activities
- And will improve your readiness for a Produce Safety Rule inspection



# The PSA Website

<http://producesafetyalliance.cornell.edu/>

The screenshot shows the homepage of the Produce Safety Alliance website. At the top, the title "Produce Safety Alliance" is displayed in red. Below it is a navigation menu with links for Training, PSA Curriculum, Resources, News, Food Safety Modernization Act, The Alliance, and Contact Us. The main content area features a large photograph of a farmer operating a red tractor in a field with a center pivot irrigation system. Below the photo is a small "Produce Safety Alliance" logo. A red banner below the photo reads "WELCOME TO THE PRODUCE SAFETY ALLIANCE WEBSITE!". To the left of the banner is the Produce Safety Alliance logo, and to the right is a smaller photo of an irrigation system with the caption "Water Summit Meeting". Below the smaller photo, text states: "The Produce Safety Alliance hosted a Water Summit on February 27-28, 2018 at the".



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