

# The FSMA Produce Safety Rule- What this Means for Minnesota Farmers

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October 4, 2018

# Talk Outline

- What is produce safety
  - Why does it matter?
- What is the Produce Safety Rule
  - Definition of farm, covered produce
  - Exclusion and exemptions
- How is Minnesota implementing Produce Safety Rule work
  - What does this mean for Minnesota farmers?
- Resources

# Produce Safety – What does that mean?

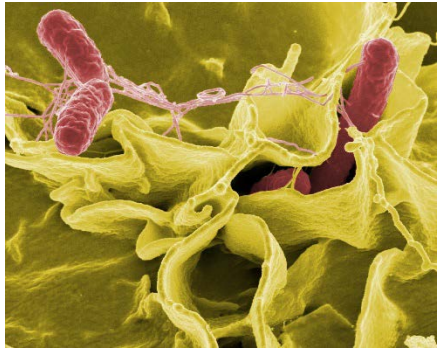
- Recent examples of produce related outbreaks
  - [Multistate outbreak of \*Salmonella\* Adelaide infections linked to pre-cut melon](#)
  - [Multistate outbreak of Cyclosporiasis linked to fresh express salad mix sold at McDonald's Restaurants- United States, 2018](#)
  - [Multistate outbreak of \*E. coli\* O157:H7 infections linked to romaine lettuce](#)
- Focus on practices that can reduce microbiological risks on farms

# Produce Safety – Why does it matter?

- Protects public health
  - At least one or two foodborne illness outbreaks are associated with produce each year
  - Consuming produce is considered good for health
- Protects farms, reputations, and the local food system
  - Makes businesses better
  - Good for overall farm efficiency and profitability



# Microorganisms of concern in fresh produce

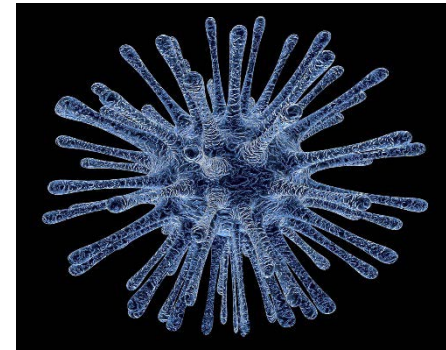


- **Bacteria**

- *Salmonella*, toxigenic *E. coli*, *Shigella*, *Listeria monocytogenes*

- **Viruses**

- Norovirus, Hepatitis A

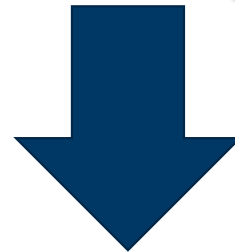


- **Parasites**

- *Giardia lamblia*, *Cryptosporidium parvum*, *Cyclospora cayetanensis*

# Potential sources of contamination

- People
- Soil
- Animals
- Water
- Buildings
- Equipment
- Tools



Produce

# Produce related biological hazards

- People often eat fresh produce raw (i.e., not cooked)
- If present on produce, microbial contamination is difficult to remove
  - Stem scars, rough surfaces, cracks and crevices
- Produce surfaces and wounds have the potential to provide the right conditions for bacterial growth



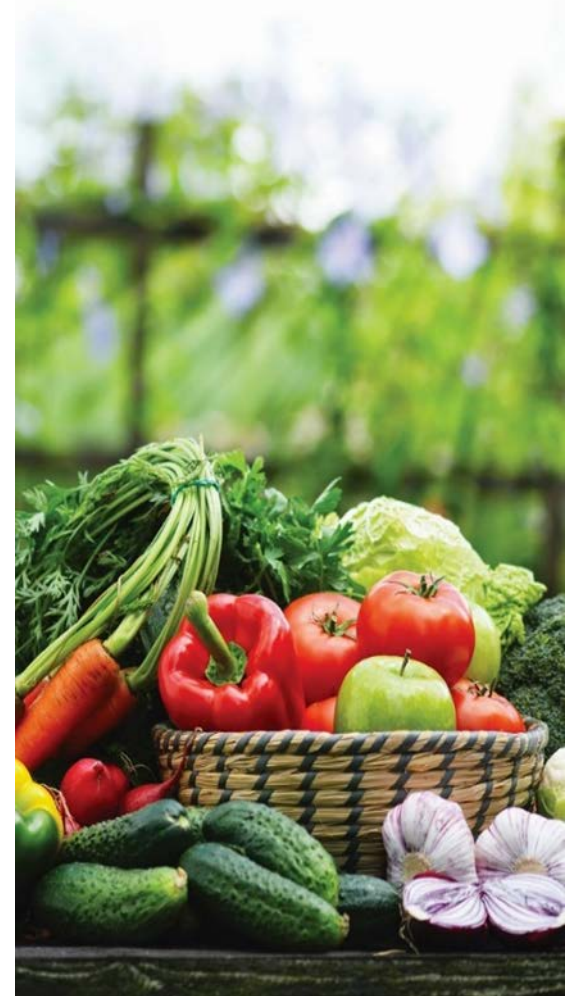
# Food Safety Modernization Act (FSMA)

- Signed into federal law in 2011
- Gave the FDA new authorities to regulate the way foods are grown, harvested, & processed
- Shifted focus from responding to foodborne illness to preventing
- Includes 7 major rules. Examples:
  - Preventive Controls for Human Food (for food facilities)
  - Foreign Supplier Verification Programs (for international imports)
  - **Produce Safety Rule (for farms)**



# The Produce Safety Rule – in brief

- Establishes standards for the growing, packing, harvesting, and / or holding of produce for human consumption
- Three ‘buckets’ that produce farmers can fall under:
  - Excluded
  - Qualified Exempt
  - Covered
- Depends on \$ sales, products, customer(s)



# The Produce Safety Rule – who falls under what?

- Excluded: less than \$25k in annual produce sales
- Qualified exempt: between \$25 - \$500k in annual FOOD sales AND
  - > 50% of those sales are to qualified end-users
    - Farm stands, grocery stores, restaurants...
    - Same state or Indian reservation or within 275 mile radius of the farm
- Of note:
  - Rarely consumed raw produce
  - Produce destined for a kill-step
  - Inflation



# Covered Commodities

- Definition of produce includes
  - Fruits and vegetables
  - Tree nuts
  - Mushrooms
  - Sprouts
  - Peanuts
  - Herbs
- Produce not covered includes: items not regularly consumed raw, items that are no longer raw agricultural commodities, and items grown for personal consumption



# Definition of Farms

- Two classifications
  - Primary production farm
  - Secondary activities farm
- Farm activities include:
  - Growing, harvesting, packing, holding, drying/dehydrating, packaging and labeling, or ripening
  - Growing only occurs on primary production farms
  - Secondary activities farm must be under same ownership



# Covered Farm Example

- Apple orchard owned by Joan Apple, separate storage location five miles down the road under same ownership
  - Apples wholesaled to 123 Produce Distribution in Saint Paul
  - Farm also sells sweet corn, pumpkins, and does pick your own raspberries
- Raspberries and apples are covered commodities
- Total sales are \$400,000 average/year
  - Sales of \$300,000 to 123 Produce
  - \$100,000 in sales on site at the farm






# Qualified Exempt Farm Example

- Diversified vegetable farm owned by three families
  - Grows lettuces, broccoli, carrots, kale, and swiss chard
  - 70 person consumer supported agriculture program
- Total sales are \$150,000 average/year
  - Wholesale of \$30,000 to a food hub
  - Direct sales are \$120,000



# Produce Safety Rule Compliance Dates

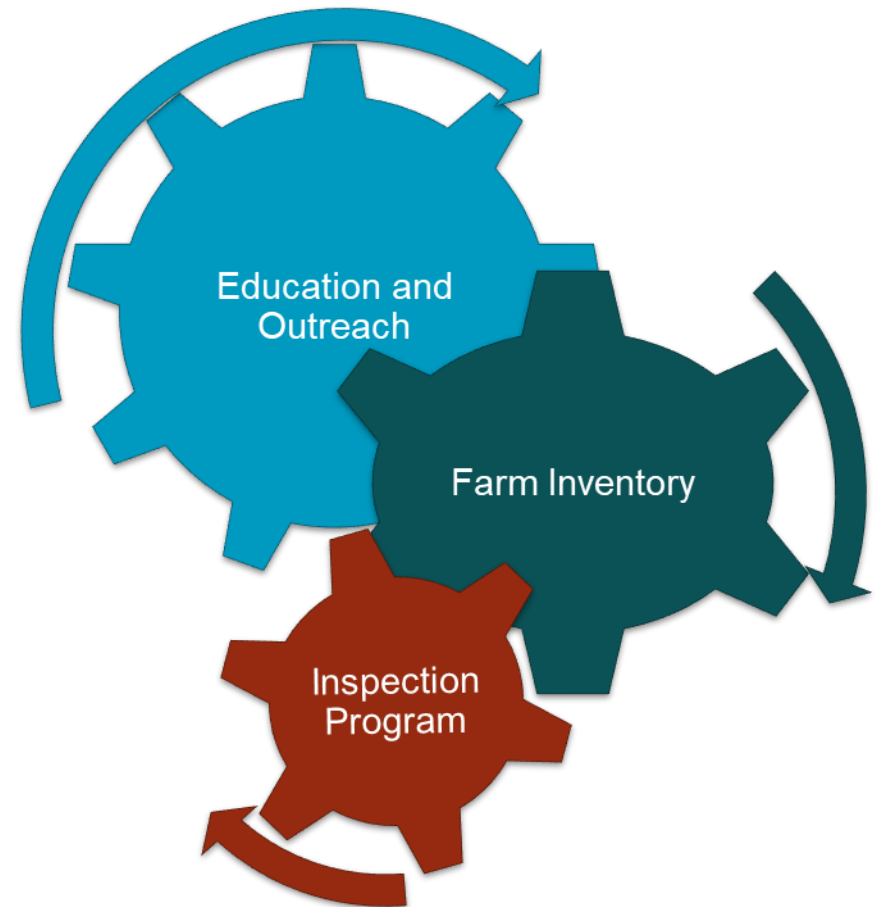
Business Size	 Compliance Dates for Sprouts	 Compliance Dates For Most Produce	 Water Related Compliance Dates <sup>1</sup>	Compliance Date for Qualified Exemption Labeling Requirement <sup>2</sup>	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>\$500K)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

# Minnesota Produce Safety Program

Outreach and Education

Farm Inventory

Inspection Program





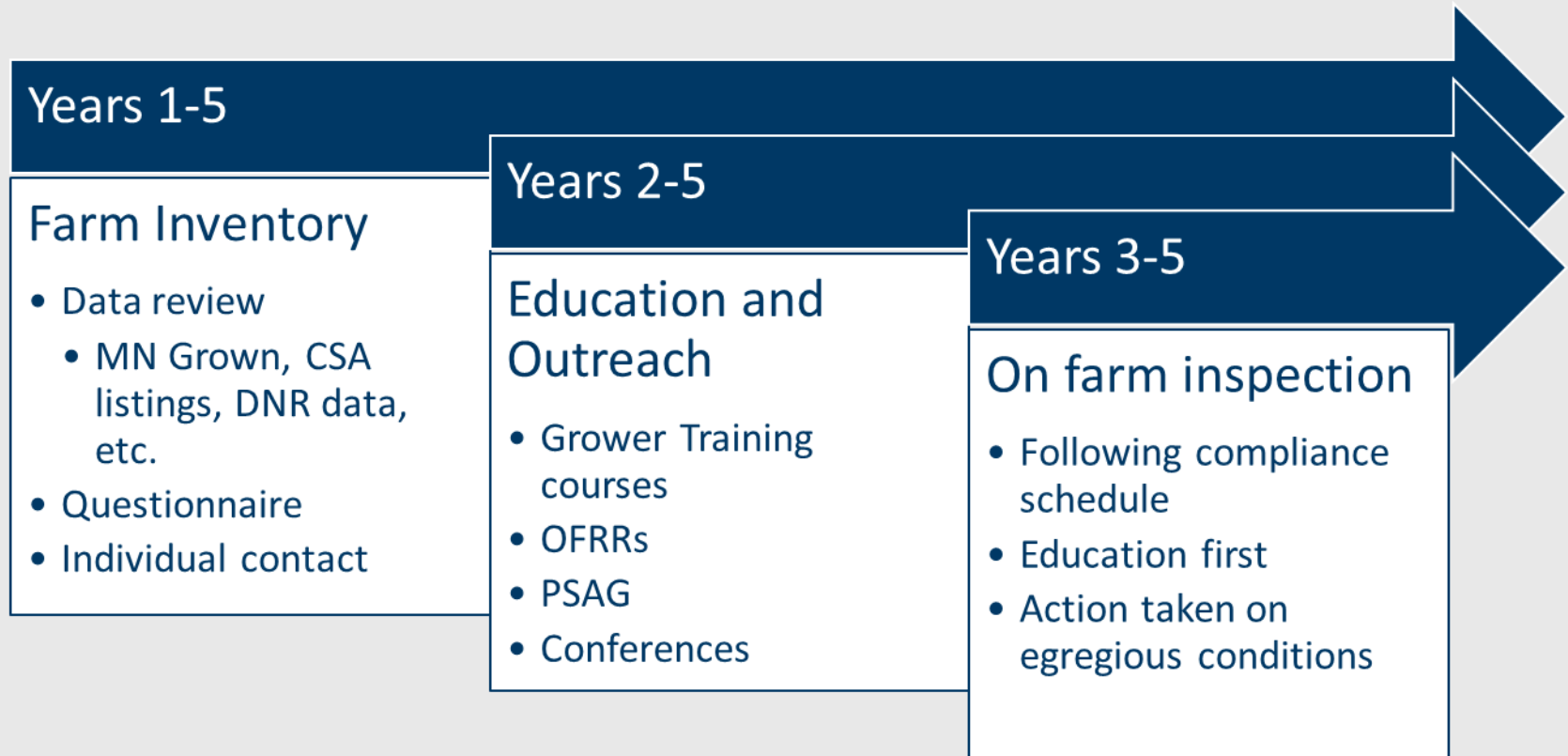
# The MDA Produce **Safety** Program

Focuses on the **safe production of fruits and vegetables** in order to reduce food borne illness factors for consumers of Minnesota produce.

Developing a program that provide Minnesota Produce Growers:

- **Outreach**, education, and food safety information
- **Culturally aware and respectful partnerships** that reflect the diversity of Minnesota's farming community
- Assistance **to address barriers and challenges** to growers in following the Produce Safety Rule
- Structured, **ongoing communication** with stakeholders about the rule and program development
- **Assistance and inspections** for farms covered by the Produce Safety Rule through education, outreach, and on-farm inspections

# MN Program Timeline



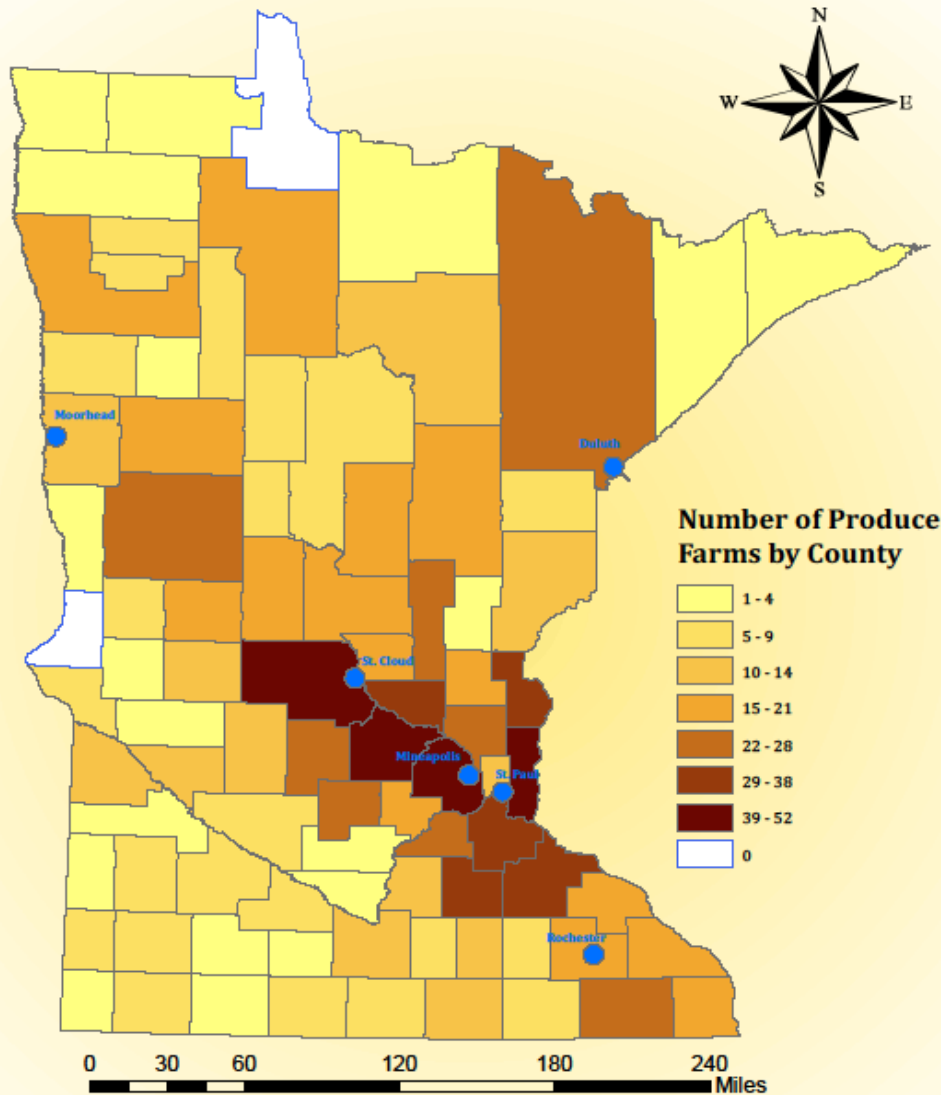
# Outreach and Education- Grower Trainings

Training Date	Training Location
11/09/2018	Bemidji, MN at Beltrami Electric Coop
11/14/2018	Windom, MN at Windom Community Center
11/28/2018	Morris, MN at University of Minnesota Regional Extension Office
12/05/2018	Hutchinson, MN at Days Inn and Suites
12/12/2018	Brooklyn Park, North Hennepin Community College
12/17/2018	St. Paul, MN at Minnesota Farmers Union
01/09/2019	St. Cloud, MN at Rivers Edge Convention Center
01/16/2019	St. Cloud, MN at Rivers Edge Convention Center
01/23/2019	Mankato, MN at Country Inn and Suites
01/25/2019	Cloquet, MN at Cloquet Forestry Center
02/06/2019	St. Charles, MN at St. Charles City Hall
02/20/2019	Andover, MN at Bunker Hills Activity Center
03/13/2019	Moorhead, MN at Hjemkomst Center
03/20/2019	Farmington, MN at University of Minnesota Regional Extension Office

# Outreach and Education- Produce Safety Advisory Group

- Quarterly meetings
- Active communication between program staff and interested/affected organizations
  - MN Farmer's Union
  - Hmong American Farmer's Association
  - MN Farmer's Association
  - MN Fruit and Vegetable Growers Association
  - Apple Growers Association
  - Project Sweetie Pie
  - Extension staff

## Produce Farms by County



Data is in process of being verified

Note: The counties, Traverse and Lake of the Woods contain NO produce farms

Sources: Designed through "ESRI ArcMap 10.4.1"

Shapefiles sourced from "gisdata.mn.gov"

September 17, 2018

Managed by the Minnesota Department of Agriculture: Produce Safety Program

# Farm Inventory

- Estimate of covered farms is 500-600 for the state
- Estimate of total produce farms is approximately 2,000

# Farm Inventory- Questionnaire

Exit



## Introduction

We're reaching out to you as a produce grower in Minnesota. You may have heard about [new laws for produce safety](#) under the federal Food Safety Modernization Act. The Minnesota Department of Agriculture (MDA) is collaborating with produce growers to implement the new Produce Safety Rule (PSR) in Minnesota. We are learning that some farms want more help understanding what the PSR means for them. This questionnaire will **help us help you** determine how the PSR applies to your produce operation.

The PSR requirements differ depending on the type of produce grown, sales, and end users (i.e., customers). Some farms will need to comply with the rule's requirements and be inspected; some farms are exempt from parts of the rule's requirements; and some farms are excluded from the rule entirely. However the rule applies to your farm, the MDA wants to make sure you have access to resources you need to understand produce safety.

By completing this questionnaire, you will:

- Provide information to help determine how the rule applies to your operation - whether you are covered, exempt, or excluded from the PSR.
- Get the latest updates, resources, and information about the PSR.
- Be notified about PSR-related training in Minnesota.

Please note, participation in this questionnaire is voluntary, you are not required to supply the data to the Minnesota Department of Agriculture. If you choose not to complete the questionnaire, MDA may not be able to reach you with information and resources regarding the Produce Safety Rule.

The information you provide is considered private and nonpublic data under Minnesota Statutes Section 13.643. You are being asked to supply the data for the purpose of completing a produce farm inventory database as part of a cooperative agreement with the U.S. Food and Drug Administration (FDA) for the implementation of the Produce Safety Rule under the Food Safety Modernization Act. Only state and federal agriculture department personnel whose job it is to use the data according to the law will have access to this data.

Please call the MDA's Produce Safety Program at 651-539-3648, or email [ProduceSafety.mda@state.mn.us](mailto:ProduceSafety.mda@state.mn.us) with questions or comments about this questionnaire or any issue related to produce safety. You can also find current information on our [Produce Safety Program website](#).

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651/201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

Next

# Inspection Program- Documents

- What to expect during an inspection handout
- Inspection procedure
  - Equipment list
  - Prioritization/inspection scheduling
- Field compliance and enforcement procedures
- Triggers for compliance and enforcement unit review
  - Prohibited acts/egregious conditions
- Water lab work- UMN Extension



# Additional Resources- UMN Extension



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## Growing safe food

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Food safety on the farm is good business!

< [Managing a farm](#)

- <https://extension.umn.edu/safety/growing-safe-food>



# Additional Resources- UMN Extension Water Project



Water Laboratories in MN that offer approved methods for testing agricultural water for growers

FSMA Produce Safety...

- ▼ The Food Safety Modernization Act (FSMA) Produce Safety Rule is new food safety legislation that applies to some fruit and 69 views  
[SHARE](#)
- Quantitative + P/A test labs
- All MN labs
  - ▼ Water Laboratories, Inc.
  - Pace Analytical Services, LLC - Duluth, MN
  - Instrumental Research, Inc
  - Interpoll Laboratories, Inc.
  - ... 24 more

## STANDARDS FOR PRODUCE SAFETY Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.

Does your farm grow, harvest, pack or hold produce?  
Sections 112.1 and 112.3(e)  
We define "produce" in section 112.3(e).

NO



Your farm is NOT covered by this rule.

YES

Does your farm on average (in the previous three years) have \$25k or less in annual produce sales?  
Section 112.4(a)

YES



Your farm is NOT covered by this rule.

NO

Is your produce one of the commodities that FDA has identified as rarely consumed raw?  
Section 112.2(a)(1)

If you grow, harvest, pack or hold more than one produce commodity, you must ask this question separately for each one to determine whether that particular produce commodity is covered by this rule.

YES



This product is NOT covered by this rule.

NO

Is your produce for personal/on-farm consumption?  
Section 112.2(a)(2)

YES



This produce is NOT covered by this rule.

NO

Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?

YES



This produce is eligible for exemption from the rule, provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.2(b)(2) through (b)(6).

NO

Does your farm on average (in the previous three years) as per Section 112.5: have < \$500k annual food sales, AND a majority of the food (by value) sold directly to "qualified end-users"?

Section 112.3(c)  
"Qualified End-User" as defined in Section 112.3(c) means:  
- the consumer of the food OR  
- a restaurant or retail food establishment that is located—  
(i) in the same State or the same Indian reservation as the farm that produced the food; OR  
(ii) not more than 275 miles from such farm.  
(The term "consumer" does not include a business.)

YES



Your farm is eligible for a qualified exemption from this rule, which means that you must comply with certain modified requirements and keep certain documentation, as per Sections 112.5 and 112.7.

NO

YOU ARE COVERED BY THIS RULE.

# Additional Resources- FDA



## KEY REQUIREMENTS: Final Rule on Produce Safety



The FDA Food Safety Modernization Act (FSMA) Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule (see "Compliance Dates" below). The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

This rule was first proposed in January 2012. In response to input received during the comment period and during numerous public engagements that included public meetings, webinars, listening sessions, and visits to farms across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective.

The final rule is a combination of the original proposal and revisions outlined in the supplemental proposal, with additional changes as appropriate. The definition of "farm" and related terms were revised in the final Preventive Controls for Human Food rule, and the same definitions of those terms are used in this rule to establish produce safety standards. Operations whose only activities are within the farm definition are not required to register with FDA as food facilities and thus are not subject to the preventive controls regulations.

Below are summaries of some key requirements, compliance dates, and other information.

### 1. AGRICULTURAL WATER:

**Water quality:** The final rule adopts the general approach to water quality proposed in the supplemental rule, with some changes. The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination.

- No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. The rule establishes that such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic *E. coli* is detected. The rule prohibits use of untreated surface water for any of these purposes.

- The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV). The GM of samples is 126 or less CFU of generic *E. coli* per 100 mL of water and the STV of samples is 410 CFU or less of generic *E. coli* in 100 mL of water.
  - The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic *E. coli* in a water source).
  - STV reflects the amount of variability in the water quality (indicating *E. coli* levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an oversimplification, it can be described as the level at which 90 percent of the samples are below the value.

# Additional Resources- Produce Safety Alliance



## Produce Safety Alliance

### Training

- [Train-the-Trainer Course](#)
- [Grower Training Course](#)
- [Trainer Resources](#)
- [Trainer Directory](#)



[Home / Training](#)

### Produce Safety Alliance Training Courses

The Produce Safety Alliance (PSA) has been tasked with developing the standardized national produce safety training program to prepare fresh produce growers to meet the regulatory requirements in the U.S. Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA) Produce Safety Rule. The PSA has developed two types of training courses: Grower Training Course and Train-the-Trainer Course.

The PSA Grower Training Curriculum was created through a four-year nationwide development process. In 2011,



Deer Run

WELCOME TO THE PRODUCE SAFETY ALLIANCE WEBSITE!

STAY UP-TO-DATE!

- Read our latest newsletter: March 2017
- March 2017 PSA Factsheet



Providing fundamental, science-based, on-farm food safety knowledge to fresh fruit and vegetable farmers, packers, regulatory personnel and others interested in the safety of fresh produce.

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

# Who else is involved?

- Lots of collaboration taking place to advance produce safety across the State



## PRODUCE SAFETY PROGRAM

[Home](#) > [Food, Feed](#) > [Food Safety](#) > [Produce Safety Program](#)

[Produce Safety Program](#)

[Resources](#)

[Wild Mushroom Foraging](#)

[FSMA Grower Training Courses](#)

### Program Overview

The Minnesota Department of Agriculture (MDA), under an agreement with the United States Food and Drug Administration (FDA), is currently building a Produce Safety Program to promote understanding of the new [Produce Safety Rule](#). The FDA established these new minimum standards for safe growing, harvesting, packing and holding of produce grown for human consumption as part of the [Food Safety Modernization Act](#) (FSMA).

#### EXTERNAL LINKS

- > [Produce Safety Alliance](#)
- > [University of Minnesota Extension](#)

[MDA Produce Safety Program](#)

651-539-3648

[ProduceSafety.MDA@state.mn.us](mailto:ProduceSafety.MDA@state.mn.us)