



## The FSMA Produce Safety Rule: How to comply

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In partnership with the Connecticut Department of Agriculture, New England Farmers Union (NEFU) is pleased to offer a series of articles explaining the Food Safety Modernization Act (FSMA) Produce Safety Rule.

This article is designed to help farmers who are covered by the rule, in whole or in part, understand how to comply. A broad overview of the rule's requirements are provided, followed by information about key resources and training opportunities.

The previous article in the series helped farmers figure out whether the rule applies to them. If you're not sure whether this rule applies to you, see our previous article: "The FSMA Produce Safety Rule: Does it apply to my farm?"

All of the articles in the series will be compiled into a guidebook and updated as new information becomes available from the entities charged with implementing the rule.

*Note: This article is primarily concerned with just one major rule: The Produce Safety Rule. However, it is possible that other FSMA rules apply to your farm business operation as well. Future fact sheets and a guidebook will address other FSMA rules potentially applicable to Connecticut farmers.*

# Key aspects of the Produce Safety Rule

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There are several key aspects of the Produce Safety Rule (hereafter, “the rule”) farmers should be aware of. If you are covered by the rule, you may be subject to a series of requirements concerning:

1. Worker Training and Health and Hygiene;
2. Agricultural Water (including water quality testing);
3. Biological Soil Amendments (such as raw manure and compost);
4. Domesticated and Wild Animals;
5. Equipment, Tools, and Buildings; and
6. Sprouts (for which there are special requirements that differ from the fruits and vegetables covered by the rule).

You are also subject to a number of recordkeeping requirements, which are outlined in this document.

In addition to the specific standards that pertain to the areas mentioned above, the rule generally requires farmers to:

“Take appropriate measures to minimize the risk of serious adverse health consequences or death... to prevent the introduction of known or reasonably foreseeable hazards into covered produce” and to provide “reasonable assurances” the produce is not adulterated because of those hazards.

The “hazards” in question are solely “biological hazards” (i.e. pathogens). Chemical, physical, and radiological hazards are covered under a different law, the Food, Drug, and Cosmetic (FD&C) Act. Nevertheless, most food safety plans address not only biological hazards but chemical, physical, and radiological hazards as well.

*Many of the standards set forth in the rule are very specific and in some cases complex. The purpose of this document is not to detail the rule in its entirety. Instead, it outlines basic requirements and subsequently directs farmers toward resources and guidance documents that can help them comply.*

# Brief explanations of Produce Rule requirements

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## 1. Worker Training and Health and Hygiene

The rule requires at least one supervisor on each farm to successfully complete food safety training under a standardized curriculum recognized by the Food and Drug Administration (FDA). Furthermore, producers must establish training requirements for all farm personnel (including temporary workers) who come in contact with covered produce or food-contact surfaces, and requires documentation of this training. Also, the rule sets forth required hygienic practices for all personnel and visitors to a farm operation.

## 2. Agricultural Water

Agricultural water, as defined by the rule, is water intended to, or likely to, come in contact with the harvestable portion of covered produce or food-contact surfaces and in harvesting, packing, and holding activities.

The rule:

- Requires such water be of safe and sanitary quality for its intended use;
- Establishes standards for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with covered produce;
- Requires treatment, and monitoring of the treatment of, unsafe or unsanitary water;
- Sets specific standards for water quality in certain cases, including periodic analytical testing of this water; and
- Requires maintenance of records for several of the above stated requirements.

## 3. Biological Soil Amendments of animal origin

This portion of the rule pertains to use, treatment, and recordkeeping primarily concerning manure and compost. The rule:

- Sets a numerical standard for the amount of certain microorganisms that can be found in biological soil amendments of animal origin;
- Establishes a minimum amount of time between application and harvest for untreated and treated biological soil amendments of animal origin;
- Requires records be kept regarding application and harvest dates, documentation from suppliers of biological soil amendments of animal origin, and periodic test results; and
- Prohibits the use of human waste for growing covered produce, except in accordance with specific regulations.

## 4. Domesticated and Wild Animals

The rule requires a waiting period before harvest if animals are allowed to graze, or are used as working animals, in fields where covered produce is grown. The rule also requires monitoring of fields where covered produce is grown throughout the season, and prior to harvest, to determine if animals (including wild animals) were present. Under certain circumstances, such as if covered produce is visibly contaminated with manure or other animal excrement, the rule sets forth processes for evaluating whether the produce can be harvested or not.

## 5. Equipment, Tools, and Buildings

The rule:

- Establishes requirements for equipment and tools that contact covered produce;
- Requires the maintenance of certain records regarding the date and method of cleaning/sanitizing equipment used in growing operations for sprouts, and in harvesting, packing, and/or holding activities for covered produce; and
- Sets specific requirements for toilet and hand washing facilities.

The rule outlines the types of equipment and tools subject to the rule, and how requirements differ depending on the design and construction of buildings (for example, fully enclosed, partially enclosed, etc.).

## 6. Sprouts

The rule sets forth special requirements for sprouts that differ from the fruits and vegetables covered by the rule. You can learn more from the [Sprout Safety Alliance \(SSA\)](#).

## What are the recordkeeping requirements?

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A key aspect of complying with the rule is keeping appropriate records. The rule clearly outlines the following recordkeeping requirements:

- That records be readily retrievable and made available to FDA within 24 hours of request; and
- That records are retained for two years after their creation, and that records about adequacy of equipment or processes being used by a farm are retained for at least 2 years after such equipment or processes are no longer used by the farm.

The rule requires the following be included in all records:

- The name and location of the farm;
- Actual values and observations obtained during monitoring;
- A description of the covered produce applicable to the record (e.g. name of the commodity, specific variety of the commodity, and when possible a lot number or other specific identifier);
- The location of the growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and
- The date and time the activity was documented.

Furthermore, the rule requires all documents:

- Be created at the time an activity is performed or observed;
- Be accurate, legible, and indelible; and
- Be dated, and signed or initialed by the person who performed the activity documented.

## Do “qualified exempt” farms need to keep records?

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Yes. Farms with a qualified exemption are required to keep records documenting that they indeed qualify for the exemption.

The criteria for eligibility for a qualified exemption are explained more thoroughly in the previous article in this series. You may recall that the basic requirements are that if certain farms sell to consumers, restaurants, and retail food establishments that are either within the same state as the farm or within 275 miles of the farm, these farms may be eligible for a “qualified exemption.” For this qualified exemption to apply, the farm must sell an average of less than \$500,000 (3-year average) worth of food to *any and all buyers*, for which the dollar value of sales that are “direct sales” exceeds the dollar value of non-direct sales.

The types of records required to receive a qualified exemption include:

- A written annual review of sales (to demonstrate continued eligibility for the upcoming year); and
- Records of those sales.

Records of sales may include receipts of your sales to different buyers; the location of any buyers that are restaurants or retail food establishments; the monetary value of sales of all food, adjusted for inflation using 2011 as the baseline year; and any other documentation that FDA can use, as necessary, to verify eligibility.

FDA has also established the compliance date for records maintained by a farm to support eligibility for the qualified exemption as the effective date of the final rule (January 26, 2016). Though, farms do not need to comply with the requirement for a written record of performance of an annual review until the farm's general compliance date. General compliance dates are indicated in the previous article in this series.

FDA has also noted that it understands there will be circumstances where a farm will not be required to have three calendar years of records as of their general compliance date. In such cases, FDA will accept records for the preceding one or two years to support eligibility for the qualified exemption.

## Produce Rule Resources and Training Opportunities

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The FDA, U.S. Department of Agriculture (USDA), state departments of agriculture, the Produce Safety Alliance, and the Sprouts Safety Alliance, and other partners, have been working to develop resources for training, education, and technical assistance to help farmers implement the rule on their farms.

### *UConn Cooperative Extension*

As a farmer in the state of Connecticut, the University of Connecticut Cooperative Extension will generally serve as an important portal of information as you work to comply with the new regulations. Visit: [foodsafety.uconn.edu](https://foodsafety.uconn.edu)

### *The Produce Safety Alliance (PSA)*

The rule establishes under § 112.22(c), that “at least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by FDA.”

The Produce Safety Alliance (PSA) has developed a standardized curriculum approved by the FDA to satisfy the training requirements outlined in the rule. It is currently the only FDA recognized training, though more options are expected to emerge. Visit: [producesafetyalliance.cornell.edu](https://producesafetyalliance.cornell.edu)

For more information about training for other FSMA regulations and alternate training opportunities, visit the [FDA's training strategy](#) page.

## Produce Farm Inspections

The final rule requires the inspection of agricultural water, water sources, and water distribution systems on covered farms.

While many of the standards for these inspections were established during the rulemaking process (i.e. frequency of inspection, water quality standards, required follow-up actions, etc.), *how* these inspections will be implemented is still not clear.

This article will be updated if new information regarding farm inspections becomes available.

## Food Safety Plan

While a food safety plan is not specifically required by the rule, a well prepared plan helps fulfill many of the rule's requirements. A well prepared plan identifies the hazards on your farm and prescribes best practices to minimize risks. Having a food safety plan does not necessarily guarantee your compliance with FSMA rules and regulations, but will likely help you do so.

The following is a list of helpful food safety plan resources:

### *Cornell University's National Good Agricultural Practices (GAP) Program*

Cornell's GAP program offers both online and in-person trainings. Their website also offers educational materials and many helpful web links. Visit: [gaps.cornell.edu](http://gaps.cornell.edu)

### *FamilyFarmed*

The On-Farm Food Safety Project of FamilyFarmed.org provides small to mid-size fruit and vegetable farmers a free online tool that guides producers through the necessary steps to develop a food safety plan. Once implemented, this plan gives farmers the foundation to become GAP-certified, which is a key requirement of most wholesale buyers. Visit: [onfarmfoodsafety.org](http://onfarmfoodsafety.org).

### *Pennsylvania State University Extension*

Penn State's extension service provides guides that help prepare farmers for GAP audits. Learn more here: [extension.psu.edu/food/safety/farm/how-do-i-write-a-food-safety-plan](http://extension.psu.edu/food/safety/farm/how-do-i-write-a-food-safety-plan)

## Federal versus State Rules

This article outlines what we know about what the federal government requires of farmers under the rule. The federal standards are the minimum standards and it is possible that certain state governments (including the state of Connecticut) will have higher and/or additional requirements. We will provide ongoing updates as additional standards are established.

**Have questions related to the Produce Safety Rule or other FSMA rules and regulations?**

You can submit questions to the [FDA Food Safety Modernization Act \(FSMA\) Technical Assistance Network](#) or send a mail inquiry to the FDA at:

Food and Drug Administration  
5100 Paint Branch Pkwy  
Wiley Building, HFS-009  
Attn: FSMA Outreach  
College Park, MD 20740