



The FSMA Produce Safety Rule: Does it apply to my farm?

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 first article in the series is designed to help farmers understand whether or not the rule applies to them. Subsequent articles will help farmers understand how to comply with the law.

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

This article includes the following:

- Brief background on FSMA
- Brief background on the Produce Safety Rule
- Compliance dates
- Exemptions

Brief Background on FSMA

The Food Safety Modernization Act (FSMA) was signed into law in January 2011. It authorizes the U.S. Food and Drug Administration (FDA) to take a preventive approach to ensuring a safe food supply. FSMA contains seven major rules dealing with all aspects of the food supply chain.

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

Brief Background on the Produce Safety Rule

The Produce Safety Rule (hereafter, “the rule”) sets food safety standards for farms to follow to reduce the risk of microbiological contamination that can occur during the growing, harvesting, packing, and holding of fresh produce. The rule sets forth requirements for:

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).

Some farms might not be subject to the rule, or may not be subject to all provisions of the rule. This document will help you understand whether or not you must comply. Subsequent articles will explain how to comply, and how to access additional resources and support.

Note: farms not subject to these rules in whole or in part are still responsible for producing safe food as outlined in a different federal law: The Food, Drug and Cosmetic Act (FD&C) and related regulations. Thus FDA retains the authority to take enforcement action against adulterated food and/ or farmers producing adulterated food regardless of a farm or farmer’s FSMA responsibilities.

All farmers should implement appropriate on farm food safety practices to assure compliance with the FD&C.

When will requirements take effect?

The rule took effect on January 26, 2016. There is a staggered schedule by which farms must comply with most requirements.

- **Large farms** (annual sales over \$500,000): the compliance date is two years after the effective date (January 26, 2018);
- **Small farms** (annual sales between \$250,000 and \$500,000): the compliance date is three years after the effective date (January 26, 2019); and
- **Very small farms** (annual sales under \$250,000): the compliance date is four years after the effective date (January 26, 2020).

“Annual sales” are based on an average of sales of *all produce* over the previous three years. *All produce* refers to produce grown on the farm *and* produce purchased from another farm for resale.

FDA has provided more time for farms to come into compliance with the *water quality provisions* of the rule. Specifically, farms in each size category have two additional years relative to each compliance date stated above.

- **Large farms** must comply by January 26, 2020;
- **Small farms** must comply by January 26, 2021; and
- **Very small farms** must comply by January 26, 2022.

Exemptions from the Produce Safety Rule

Not all farms and/or produce will be subject to the rule. The following information explains how to determine eligibility for exemption from the rule.

What is a “full exemption”?

Generally, the only farms that are *fully exempt* from the rule are those farms with sales of produce under \$25,000 annually (3-year average), regardless of whether the specific types of produce being sold are covered under the rule.

Note: the dollar value for the full exemption is based on sales of *produce* only. The produce counted includes all produce, including produce purchased by a farm for resale.

What is a “qualified exemption”?

Certain producers will have a revocable exemption based on a farm’s average monetary value of *all food* sold and the percentage of food sold as direct sales.

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.

Note: unlike for the full exemption, the qualified exemption is based on sales of *all food*, not just produce. For example, if a farm sells a value added item produced on the farm and/or sells an item purchased from another farm or vendor, this sale would be included in the total sales relevant to a qualified exemption determination.

Additionally, the qualified exemption:

- Has special labeling requirements; and
- FDA retains the right to revoke the exemption.

“Covered” Produce versus Produce “Not Covered” by the rule

In addition to the exemptions stated above, some produce is covered by the rule and other produce is not. If you are not a fully exempt farm, it is important to know if you are growing produce subject to the rule (this is known as “covered produce”).

FDA has provided lists of produce covered, and not covered, under the rule. In the case of *covered* produce, there is a *non-exhaustive list*. In the case of produce *not covered*, there is an *exhaustive list*.

Covered Produce: The non-exhaustive list of covered produce only applies to the listed items if they are considered “raw agricultural commodities” (a food in its natural or raw state). There are some exemptions for raw agricultural commodities ultimately destined for commercial processing that adequately reduce the presence of microorganisms of public health significance.

The following is a list of fruits and vegetables commonly grown in Connecticut covered by the rule. Please note that this list is necessarily incomplete. A more complete, but still non-exhaustive list can be found under section 112.1 of the final rule in the [Federal Register](#).

Apples, blackberries, blueberries, broccoli, Brussels sprouts, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carrots, cauliflower, celeriac, celery, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, gooseberries, green beans, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, kale, kohlrabi, leek, lettuce, mushrooms, mustard greens, nectarines, onions, parsnips, peaches, pears, peas, peppers (such as bell and hot), plums, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), Swiss chard, tomatoes, turnips (roots and tops), and watermelons.

Produce Not Covered: The exhaustive list of produce not covered under the rule includes produce items rarely consumed raw. These items are not subject to the rule. Some of these items are unlikely to be produced in Connecticut, but the entire list is provided here for reference:

Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

Note: grains are generally not covered under the rule. Examples of food grains not covered include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (*e.g.*, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

In a few cases produce is not subject to the rule even if categorized as “covered” produce:

- Any produce specifically grown for *personal and/or on-farm consumption* is *not* subject to the rule; and
- Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (“kill step”) is eligible for exemption.

*** Exemptions from the Produce Safety Rule and other FSMA regulations do not exempt farmers from ensuring food safety.**

It is important for producers to remember that fully exempt and qualified exempt farms are still responsible for producing safe food as outlined in the Food, Drug and Cosmetic Act and related regulations.

Furthermore, some buyers of produce may require farms, regardless of whether such farms are subject to or exempt from FSMA regulations, to demonstrate compliance with a different food safety standard, such as USDA Good Agricultural Practices (GAP).