



Does my Farm have to Comply with the Food Safety Modernization Act’s Produce Safety Rule? A Tool to Assist Producers

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Overview

In 2011, President Obama passed the Food Safety Modernization Act (FSMA). The new act will change food safety in the United States (US) across the entire food system; in fact, the food system has not seen a major overhaul in the food safety laws like this in more than 70 years. One of the seven laws that make up the FSMA is the Produce Safety Rule (PSR), which seeks to shift the food safety focus from responding to contamination and outbreaks to preventive measures in order to improve the food safety of produce grown in the US. The PSR seeks to achieve this by setting science-based standards for the growing, harvesting, packing and holding of produce. One of the largest challenges of the implementation of the PSR for producers, regulators and educators is effectively understanding and communicating if a produce operation is covered by the PSR and if so, to what extent. No two produce operations are alike and with the regulatory language of the PSR, it can be difficult to understand/know by simply reading of the PSR if a produce operation is covered, exempt or qualified exempt. The following survey was developed in order to assist produce operation owners or stakeholders in understanding if the PSR covers their operation and if so, what are they required to do for compliance.

FSMA PSR compliance dates listed in image to right. Please contact your local VCE agent or Virginia Department of Agriculture and Consumer Services Produce Safety Specialist for more information (contact information at end of document).

Business Size	Compliance Dates for Sprouts	Compliance Dates For Most Produce	Water Related Compliance Dates ¹	Compliance Date for Qualified Exemption Labeling Requirement ²	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) ³	1/26/18	1/28/19	1/26/23	1/1/2020	1/26/16
Very small businesses (>\$25K-250K) ⁴	1/28/19	1/27/20	1/26/24		

¹ According to the *Proposed Rule* issued 9/13/17, Compliance dates for Subpart E, Agricultural Water, allow an additional four years.
² 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.
³ 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.
⁴ 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>

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Question 1:

Is your business a farm based on being classified as one of the following FDA definitions?

A Primary Production Farm is an operation:

- in one general area, although it may include multiple non-contiguous parcels,
- with the principal focus of growing or harvesting crops and/or raising livestock, including seafood

In addition, a Primary Production Farm may

- pack and hold raw agricultural commodities (RACs, defined as a food crop in its raw or natural state), including RACs grown on that farm and RACs supplied from other farms;
- dry/dehydrate RACs to create a distinct product with no other processing (for example drying grapes to make raisins);
- artificially ripen RACs (for example tomatoes in controlled storage);
- manufacture/ process food provided that all food is consumed on that farm or another farm under the same management; III.

A Secondary Activities Farm is an operation:

- not located on a Primary Production Farm;
- majority-owned by the operator of a Primary Production Farm, or by multiple Primary Production Farm operators together;
- where the Primary Production Farms of the majority-owner or owners also provide the majority of the RACs handled by the Secondary Activities Farm; and
- that harvests, shells, hulls, washes, packs, holds, packages, and labels RACs, and/or artificially ripens RACs or dries RACs to create a distinct product with no other processing (such as grapes into raisins).

A mixed-type facility* is an establishment that:

- Engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to register with FDA under section 415 of the FD&C Act.

* Please note that if your business is classified as a mixed type facility, part of your operation may be covered by the Produce Safety Rule and other parts may be covered by other rules such as the Preventative Controls for Human Food or Preventative Controls for Animal Food. To verify coverage or exemption and to understand what requirements apply to your farm contact The Virginia Department of Agriculture & Consumer Services.

- Yes
- No

If you answered 'No' to this question, then your operation is NOT covered by this rule. To verify coverage or exemption contact The Virginia Department of Agriculture & Consumer Services

If you answered 'Yes' to this question, please continue to question 2.

Question 2:

Does your farm grow, harvest, pack or hold produce?

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains 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).

- Yes
- No

If you answered ‘No’ to this question, then your operation is NOT covered by this rule. To verify coverage or exemption contact The Virginia Department of Agriculture & Consumer Services

If you answered ‘Yes’ to this question, please continue to question 3.

Question 3.

Does your farm on average (in the previous three years) have more than \$25,000*(adjusted for inflation) in annual produce sales?

*This includes all produce sales regardless if the produce is rarely consumed raw or is specifically grown for commercial processing that adequately reduces pathogens. However, this does not include produce grown for personal/on-farm consumption, as it is not being sold.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains 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).

*The below image shows the inflation index for produce sales.

For the latest inflation index please go to

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

Baseline Value for Cut-offs (2011)	Value in 2012	Value in 2013	Value in 2014	Value in 2015	Value in 2016	Value in 2017	Average 3 Year Value for 2015 - 2017
\$25,000	\$25,460	\$25,871	\$26,332	\$26,608	\$26,956	\$27,433	\$26,999

- Yes
- No

If you answered ‘No’ to this question, then your operation is NOT covered by this rule. To verify coverage or exemption contact The Virginia Department of Agriculture & Consumer Services

If you answered ‘Yes’ to this question, please continue to question 4.

Question 4.

Do you grow, harvest, pack or hold produce that is considered rarely consumed raw?

The FDA has identified the following exhaustive (meaning that if your produce is not on this list, it cannot be considered rarely consumed raw) list of produce commodities that are rarely consumed raw and exempt from the rule:

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

Do you grow, harvest, pack or hold only this type of produce? (If you grow multiple types of produce or commodities not listed here then click “No”)

- Yes
- No

If you answered ‘Yes’ to this question, then your operation is NOT covered by this rule. To verify coverage or exemption contact The Virginia Department of Agriculture & Consumer Services

If you answered ‘No’ to this question, please continue to question 5.

Question 5.

Is your produce ONLY for personal/on-farm consumption?

- Yes
- No

If you answered 'Yes' to this question, then your operation is NOT covered by this rule. To verify coverage or exemption contact The Virginia Department of Agriculture & Consumer Services

If you answered 'No' to this question, please continue to question 6.

Question 6.

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

Examples of commercial processing include:

- Processing tomatoes to produce tomato paste or shelf-stable tomatoes.
- Processing apples to produce applesauce.
- Processing produce into products such as spirits, wine and beer.

- Yes
- No

If you answered 'Yes' to this question, your produce is eligible for exemption IF certain conditions are met and documentation and written assurance are obtained proving that the produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance at some point in the distribution chain. *To verify coverage or exemption and to understand what requirements apply to your farm contact The Virginia Department of Agriculture & Consumer Services.*

If you answered 'No' to this question, please continue to question 7.

Question 7.

Is your farm eligible for a qualified exemption?

- Does your farm on average (in the previous three years) have less than \$500,000* (adjusted for inflation) annual **food** sales

AND

- 50% or more of the **food** (by value) sold directly to "qualified end users" defined as: either (a) the consumer of the food or (b) a restaurant or retail food establishment (this does not include a grocery store chain distribution center) that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.

“Food” means articles used for food or drink for man or animals, or articles used to make components of it. Includes seeds and beans used to grow sprouts.

*The below image shows the inflation index for food sales.

For the latest inflation index please go to

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

Baseline Value for Cut-offs (2011)	Value in 2012	Value in 2013	Value in 2014	Value in 2015	Value in 2016	Value in 2017	Average 3 Year Value for 2015 - 2017
\$500,000	\$509,199	\$517,417	\$526,645	\$532,170	\$539,121	\$548,654	\$539,982

- Yes
- No

If you answered “Yes” to this question then 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 including:

- Annual record keeping: Your farm must establish and keep adequate records necessary to demonstrate that the farm satisfies the criteria for a qualified exemption, including a written record reflecting that an annual review has been performed and verification of the farm’s continued eligibility for the qualified exemption.
- Labeling requirements: Include their name and complete business address either on the label of the produce that would otherwise be covered (if a label is required under the FD&C Act and its implementing regulations) or to display the same information at the point-of-purchase for example a poster, sign, placard or documents delivered with the produce in the normal course of business, or in the case of Internet sales, in an electronic notice.

To verify coverage or exemption and to understand what requirements apply to your farm contact The Virginia Department of Agriculture & Consumer Services.

If you answered 'No' to this question then your farm is covered by this rule.

- As a result, at least one supervisor from your farm must have successfully completed a certified food safety training. In addition to this training, you will be required to comply with all aspects of the Produce Safety rule. *To verify coverage and for further assistance please contact The Virginia Department of Agriculture & Consumer Services or your local Virginia Cooperative Extension Office.*

Who do I contact for more information?

The Virginia Department of Agriculture & Consumer Services Produce Safety Program
P.O. Box 1163
Richmond, VA 23218
Phone - 804.786.4003
www.VAProduceSafety.com

For additional information on the Food Safety Modernization Act (FSMA) and the Produce Safety Rule, see the Virginia Produce Safety website at
<http://www.hort.vt.edu/producesafety/>

Alternatively, contact your local Virginia Cooperative Extension office.