

Frequently Asked Questions about the Produce Safety Rule (PSR)

The following document attempts to clarify questions frequently encountered by Program personnel during outreach activities. Further clarification of the definitions can be found here: Title 21 → Chapter I → Subchapter A → Part 1 → Subpart H → §1.227

https://www.ecfr.gov/cgi-bin/text-dx?SID=de8299fc4422abb94cf2590bb2fa0d91&mc=true&node=se21.1.1_1227&rgn=div8

DEFINITIONS:

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).

Food is defined under section 201(f) of the Federal Food, Drug, and Cosmetic Act as;

- (1) Except for purposes of this subpart, it does not include:
 - (i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or
 - (ii) Pesticides as defined in 7 U.S.C. 136(u).
- (2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

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.

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 FSMA rules such as the Preventative Controls for Human Food or Preventative Controls for Animal Food.

QUESTIONS:

1. Q – What is the Food Safety Modernization Act?

A – The Food Safety Modernization Act (FSMA) was passed in 2011 by President Obama and is the most sweeping reform of our food safety laws in more than 70 years (since the Food Drug and Cosmetic Act of 1938). The act aims to ensure the US food supply is safe by shifting the focus from responding to contamination to preventing it. The Food and Drug Administration has developed seven different regulations that encompass FSMA including (1) Produce Safety Rule, (2) Preventive Controls for Human Food Rule, (3) Preventive Controls for Animal Food Rule, (4) Mitigation Strategies to Protect Food Against Intentional Adulteration Rule, (5) Sanitary Transportation of Human and Animal Food Rule, (6) Foreign Supplier Verification Programs Rule, and (7) Accredited Third-Party Certification Rule.

2. Q – What is the Produce Safety Rule?

A – The Produce Safety Rule (PSR) is one of the seven food safety regulations that are part of the Food Safety Modernization Act (FSMA). The PSR sets a series of standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption: 21 Code of Federal Regulations Part 112. Similar to the other FSMA rules, the PSR aims to be proactive rather than reactive by focusing on high-risk practices and identification of hazards within individual operations. For example, there are no requirements for uncontrollable factors, such as number of wildlife allowed in fields. Instead, the PSR mandates covered produce not be harvested when contaminated by feces (e.g., bird dropping on a tomato intended for fresh market). Standards are set for: agricultural water; biological soil amendments; sprouts; wildlife and domesticated animals; worker health, hygiene, and training; equipment, tools, and buildings; among others.

3. Q – Who will be regulating the PSR in Virginia?

A – The Virginia Department of Agriculture and Consumer Services (VDACS) received federal grant funding in 2016 to establish a Produce Safety Program within the Office of Dairy and Foods. This new regulatory program will work to address the growing, packing, holding and dissemination of produce grown on farms and will encourage the safe production of fresh fruits and vegetables and promote understanding and compliance with the FDA Produce Safety Rule and state legislation.

4. Q – Is the Produce Safety Rule the same as GAP certification?

A – No, the Produce Safety Rule (PSR) is a regulation that establishes science-based *minimum* standards for safe production and harvesting of fresh fruits and vegetables. These standards are based on a foundation of Good Agricultural Practices (GAPs). However, while the PSR is based on a solid framework of understanding

on-farm risks and GAPs, it is not the same as GAP certification. Whereas the PSR is regulatory and mandatory for growers who are covered under the PSR, GAP certification is a voluntary program often required by industry and buyers.

5. Q – If I am already GAP certified do I also need to comply with FSMA PSR?

A – Some farms that are GAP certified may not necessarily grow covered produce under the PSR and may therefore be exempt. If your farm is covered under the PSR, then you must still adhere to and comply with the requirements of the PSR regulation.

6. Q – How do I know if I am covered or exempt?

A – Click on the “Coverage and Exemption Flow Chart” on this site, under Covered Farms. If you still are not sure, please contact us. A qualtrics survey has also been created by Virginia Cooperative Extension that will walk you through the questionnaire and it is posted on our website or can be accessed here:

https://vce.az1.qualtrics.com/jfe/form/SV_emnhR0UpFpiVvIrl

7. Q – When will compliance dates become effective?

A – See both links under Compliance Dates on this site. Regulatory compliance inspection will likely begin in the summer of 2019 and all inspections will be scheduled with farm management. VDACS will begin conducting on-farm readiness reviews (OFRRs) with Virginia Cooperative Extension after April 2018 at farms once they have completed the Produce Safety Alliance grower training course. To take part in an OFRR, please contact our office.

8. Q – When will VDACS begin regulatory inspections?

A – Large Farm inspections (greater than \$500,000 in annual produce sales for a 3-year average) will begin May 1, 2019. Small Farm inspections (greater than \$250,000 up to \$500,000 in annual produce sales for a 3-year average) will begin early 2020. Very Small Farm inspections (\$250,000 or less in annual produce sales for 3-year average) will begin early 2021.

9. Q - If a farm sells produce to only one restaurant, nearby, do they fall under the PSR?

A – If their produce sales are less than \$25,000, they are exempt from the PSR.

They might be qualified exempt if “nearby” means they are selling to a qualified end-user¹. In addition to selling to a qualified end-user, if the average annual monetary value of all *food* the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000 and more than 50% of their sales are to qualified end-users, then they are qualified exempt from the PSR. You must keep records to show your qualified exemption and you must follow label requirements.²

10. Q – If a farm sells produce and owns a restaurant, how do they fall under the PSR?

A – If their produce sales are less than \$25,000, they are exempt from the PSR.

If their average monetary value of all *food* this farm/restaurant sold during the 3-year period preceding the applicable calendar year was **less** than \$500,000; and more than 50% of their sales are to qualified end-users², then they are qualified exempt from the PSR. You must keep records to show your qualified exemption and you must follow label requirements.²

If the farm/restaurant’s average annual monetary value of all *food* sold during the 3-year period preceding the applicable calendar year was **more** than \$500,000, then they fall under the PSR.

11. Q – If one day my sales go over \$25,000, is my farm automatically under the PSR that day?

A – The sales are a 3-year average, so as your sales continue to go over the mark, you should be aware that your average will eventually go over the limit too. Even going over the \$25,000 average, if you sell to qualified end-users, you might be qualified exempt^{1, 2}.

12. Q – If a farm has fields in Virginia and North Carolina, does each farm fall under its own 275 mile radius?

A – Yes, the rule says not more than 275 miles from the farm that produced the food.

13. Q – If I have pick-your-own strawberries and pumpkins and have an agri-tourism business with hayrides, etc., does the agri-tourism part count towards the \$500,000 for qualified exemption?

A – No, the \$500,000 qualified exemption is the average annual monetary value of all *food* the farm sold during the 3-year period preceding the applicable calendar year.

14. Q -- A farm sells \$19,000 in produce average over a 3-year period at a local farmer's market and through a CSA. Is this farm covered by the FSMA Produce Safety Rule?

A -- This farm would NOT be covered by the PSR since <\$25,000 in produce is sold.

15. Q -- A farm sells \$35,600 in produce, and also sells \$650,000 in other food products, including sauerkraut and jam (3-year rolling average). Do they satisfy the 'qualified exemption' requirements?

A -- No. Since the farm has more than \$25,000 in average annual produce sales (calculated over the previous 3-year period), they would be covered by the PSR. They also do not qualify for the qualified exemption since they sell over \$500,000 of food products.

16. Q -- A farm sells \$475,000 in produce (3-year rolling avg) as follows: \$200,000 wholesaler out-of-state/more than 275 miles, \$200,000 to a local restaurant, and \$75,000 to a local grocery store. Do they satisfy the requirements for a qualified exemption?

A -- Yes. The farm is likely to be eligible for a qualified exemption because the sales to qualified end users exceed the sales to other buyers, and the sales are below \$500,000.

17. Q -- I am a grower and I sell \$30,000 in pumpkins and \$5,000 in tomatoes at my road side stand - what FSMA Produce Safety Rule status am I?

A -- Qualified exempt. You make more than \$25,000 in total produce sales. Total food sales are under \$500,000 and all sales are to direct end users. You still need to keep records and follow labeling requirements.

18. I am a grower and I sell \$30,000 in pumpkins, \$5,000 in tomatoes and \$600,000 milk/eggs at my local stand/market - what FSMA Produce Safety Rule status am I?

A -- Covered. You would not qualify for an exemption since total produce sales are over \$25,000. The pumpkins are exempt, the tomatoes are covered. Nothing is processed and you are not using for only personal-family consumption. Also, you do NOT qualify for a qualified exemption because total food sales are over the \$500,000 limit (even though it is all direct to end user).

19. Q -- I am a grower and I sell \$40,000 worth of tomatoes to special high end restaurants in New York City - what FSMA Produce Safety Rule status am I?

A -- Covered. You are over the \$25,000 total produce sales. Tomatoes are a covered commodity. No processing or kill step (all fresh market). Not for personal-family on-farm consumption. Sales to direct end users (100%) are more than 275 miles away so you do not qualify for a qualified exemption.

20. Q -- I am a grower and I sell \$40,000 worth of tomatoes to special high end restaurants in Virginia - what FSMA Produce Safety Rule status am I?

A – Covered but eligible for a qualified exemption. You are over the \$25,000 total produce sales. Tomatoes are a covered commodity. No processing or kill step (all fresh market). Not for personal-family

on-farm consumption. You do qualify for a qualified exemption since sales to direct end users (100%) are in same state, Indian reservation, or within 275 miles; and total food sales are less than \$500,000.

21. Q -- I am a grower and I only sell \$40,000 worth of pumpkins to a wholesaler - what FSMA Produce Safety Rule status am I?

A -- Exempt. This commodity is exempt (there is a list of 34 commodities not covered by the PSR due to the fact that they are rarely consumed raw, or without a kill step (like cooking). Therefore, it does not matter that you are over the \$25,000 in total produce sales.

22. Q – I am a produce farmer and also raise livestock and poultry – should that be included in the monetary calculation of food?

A – Please review the definition of food above. Live animals that are sold with the intention of later being processed to human or animal food should be considered as food according to the FD&C Act. Animal feed, ingredients and additives should also be included in the monetary calculation of “food.”

¹ Qualified end-user means the consumer of the food, or a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm that produced the food; or not more than 275 miles from such farm.

² You must keep dated sales receipts. You must keep adequate records to demonstrate that your farm satisfies the criteria for a qualified exemption (sales amount and to qualified end-users), including written record showing you performed an annual review and verification of your farm’s eligibility of the qualified exemption. The name and complete business address of the farm where the produce was grown must be clearly displayed at the point of purchase (on a label or on a sign).