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FAQs About the Produce Safety Rules (PSR)

The Produce Safety Rule imposes new requirements on farms to ensure the safety of produce intended to be consumed by humans. New England farms tend to be smaller, have lower revenue, and sell more directly to consumers than the national average. Therefore, New England farms are more likely to be exempt from the Produce Safety Rule or eligible for a Qualified Exemption, which limits the requirements imposed on the farm when the farm is covered by the Produce Safety Rule. This legal guide looks at some common questions about these aspects of the Produce Safety Rule.

General

1. What is the Produce Safety Rule?

The Produce Safety Rule is part of Federal Drug Administration's (FDA) implementation of the Food Safety Modernization Act (FSMA). The Produce Safety Rule establishes minimum standards for the safe growing, harvesting, packing, and holding of produce for food intended to be consumed by humans. Farms are required to implement procedures and controls to minimize the risk of serious adverse health consequences. Serious adverse health consequences include death and long-term or serious illness or injury. Even if a farm is not covered by the Produce Safety Rule, food safety is the responsibility of all farms that produce food for human consumption.

2. I have heard about Good Agricultural Practices (GAP) audits. What is the difference between inspections conducted under PSR and GAP audits?

GAP audits are a voluntary program that assess the food safety processes of an agricultural producer. The audits verify that fresh fruits and vegetables are produced, packed, handled, and stored according to food safety practices that minimize the risks of microbial food safety hazards. While voluntary, many retail purchasers contractually require satisfactory GAP audits from its farmers.

The Produce Safety Rule is a federal law that requires farmers to develop programs and processes to ensure the safety of their produce. If a farm is covered by the Produce Safety Rule, as discussed below, compliance with the requirements of the Produce Safety Rule is mandatory. The requirements of the Produce Safety Rule are comparable to what is typically assessed in a GAP audit.



Though the requirements to pass a GAP audit are similar to what is required under the Produce Safety Rule, covered farmers must separately ensure that they comply with the Produce Safety Rule regardless of prior or current GAP audits.

3. Who is overseeing the training and enforcement of PSR in the New England states?

FDA is responsible for enforcement of the Produce Safety Rule, but has agreements with many states to support its implementation, training, and enforcement. In-person trainings are available through trainers certified by the Produce Safety Alliance: <https://producesafetyalliance.cornell.edu/>.

The FDA also has created a FSMA Technical Assistance Network (TAN), which is an interactive website supported by information specialists who can answer specific questions you may have. TAN is available at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>

Additionally, several New England states offer trainings. State agencies offering assistance with PSR are listed below.

Maine	Maine Department of Agriculture, Conservation, and Forestry, Bureau of Agriculture, Quality Assurance & Regulations 207-287-3841 https://www.maine.gov/dacf/qar/fsma/index.shtml
Massachusetts	Massachusetts Department of Agricultural Resources Contacts by Region, available at: https://ag.umass.edu/sites/ag.umass.edu/files/pdf-doc-ppt/mdar_food_safety_team_0.pdf
Rhode Island	Rhode Island Department of Environmental Management, Division of Agriculture 401-222-2781 http://www.dem.ri.gov/programs/agriculture/fsma.php
Connecticut	Connecticut Department of Agriculture ProduceSafety@ct.gov 860-713-2522 www.ctgrown.gov/producesafety
Vermont	Vermont Agency of Agriculture, Food & Markets Produce Program AGR.FSMA@vermont.gov 801-828-2433 https://agriculture.vermont.gov/produceprogram
New Hampshire	New Hampshire Department of Agriculture, Markets & Food – FSMA Program Coordinator Vickie Smith, Victoria.smith@agr.nh.gov 603-848-4781

https://www.agriculture.nh.gov/divisions/commissioner/food-safety.htm

Who is covered under PSR

1. Is my farm covered by the produce safety rules?

The Produce Safety Rule does not apply to farms that:

- Have averaged **annual produce sales** of \$25,000 or less over the last three years (when adjusted for inflation)
 - The FDA has created a guide to determining annual produce sales, available here: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>
- Only produce food for personal or on-farm consumption
- Grow, harvest, pack or hold produce that is “rarely consumed raw”, namely, fruits and vegetables that are almost always cooked before eaten
 - This analysis is done for every produce item the farm produces – it is possible that only a portion of a farm’s products will be exempt from the Produce Safety Rule
 - The FDA has provided an exhaustive list of produce that is rarely consumed raw, available here: <https://www.fda.gov/media/107445/download>
- Are eligible for a Qualified Exemption (discussed in Question #2)
 - Certain modified requirements of the Produce Safety Rule still apply to farms with a Qualified Exemption, which is addressed below.

All other farms that grow, harvest, pack, or hold produce for human food are covered by the requirements of the Produce Safety Rule.

FDA has provided a flow chart outlining the coverage and exemptions of the Produce Safety Rule, available here: <https://www.fda.gov/media/94332/download>

2. What is Qualified Exemption and how do I determine whether my farm qualifies?

Qualified Exemption relieves a farm of many of the requirements of the Produce Safety Rule, though the farm is still responsible for ensuring the safety of their food. The Qualified Exemption applies to farms with relatively small sales and a tightly connected supply chain to end consumers.

A Qualified Exemption is available to certain farms that meet two requirements:

- The average annual value of food sold to qualified end-users is greater than the annual monetary value of food sold to all other buyers

- The average annual value of all food sold during the last three years is less than \$500,000 (as adjusted for inflation)
 - See FDA's guide to calculating sales adjusted for inflation here:
<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

The Qualified Exemption requirements are based on the **total food sales** by a farm, not just produce sales. Food is any item used for food or drink for humans or animals, and includes: livestock, meat, dairy products, hay, and grains, processed foods such as jams, preserves, and breads, as well as produce.

Qualified end-users are either:

- The consumer of the food, excluding businesses
- A restaurant or retail food establishment that is located in the same state or Indian reservation as the farm OR no more than 275 miles from the farm
 - A restaurant is a location that prepares and sells food to consumers for immediate consumption
 - A retail food establishment is a location that primarily sells food directly to consumers – grocery stores and convenience stores are examples of these types of establishments

Eligibility for a Qualified Exemption must be determined every year based on an analysis of sales.

If a farm is eligible for a Qualified Exemption, the farm is not required to comply with many of the PSR rules. However, portions of the Produce Safety Rule still apply. Subparts A (General Provisions), O (Records), Q (Compliance and Enforcement), and R (Withdrawal of Qualified Exemption) apply to farm eligible for a Qualified Exemption. Additionally, specific labeling requirements are in place for farms with a Qualified Exemption.

Labeling:

The labeling requirements for farms with a Qualified Exemption are intended to ensure that the consumer is informed about the source of the produce.

- If a label is used on a food item, the label must include the name and complete business address of the farm where the food was grown
- If a label is not used on a food item, the name and complete business address of the farm where the food was grown must be posted conspicuously at the point of purchase or otherwise provided contemporaneously with purchase

Subpart O - Records:

The Records requirements are used to demonstrate to regulatory agencies that the farm is eligible for a Qualified Exemption.

- Records must be kept that demonstrate that the farm is eligible for a Qualified Exemption
 - Must include a record that reflects the completion of an annual review and verification of eligibility
 - Records could include:
 - Receipts or ledgers of sales showing the value of the sale and the location of the customer

Subpart Q – Compliance and Enforcement

This subpart outlines FDA's authority for education and enforcement of the Produce Safety Rule and does not impose additional requirements on the farm.

Subpart R – Withdrawal of Qualified Exemption

Subpart R outlines when and how a Qualified Exemption may be withdrawn, including the process for appealing a withdrawal of a Qualified Exemption. This subpart is discussed in greater detail below.

3. Can the Qualified Exemption be withdrawn?

The FDA may withdraw a farm's Qualified Exemption when an active investigation of a foodborne illness outbreak is directly linked to that farm and if an enforcement agency determines that it is necessary to withdraw the Qualified Exemption to protect the public health and prevent or mitigate a foodborne illness. FDA may consider other actions, such as warning letters, recalls, and administrative detention, to protect the public health before withdrawing a Qualified Exemption. If the FDA withdraws a Qualified Exemption, the farm has 120 days from the order to comply with the Produce Safety Rule or appeal the withdrawal.

4. What if I have been farming for less than three years; how do I determine whether my farm is covered or qualifies for exemption when I don't have three years sales records?

If a farm does not have three years of sales records, a projected estimate of revenue or market value is acceptable to use. The projection would be evaluated by FDA for credibility based on a variety of factors. After the farm has sales records for one or two

years, the FDA will accept a farm calculating average annual sales based on the records that are available.

5. If I am covered by the PSR, what are the deadlines for complying with the rules?

Most of the compliance dates have passed, but very small businesses have until January 27, 2020 to comply.

- **January 26, 2018:** Covered farms with average annual produce sales of more than \$500,000
- **January 28, 2019:** Covered farms with average annual produce sales of more than \$250,000 but not more than \$500,000 (small businesses).
- **January 27, 2020:** Covered farms with average annual produce sales of more than \$25,000 but no more than \$250,000 (very small businesses).

Summary:

The Produce Safety Rule was passed as part of FDA's implementation of the Food Safety Modernization Act. Under the PSR, farms that are covered by the rule and are not eligible for a Qualified Exemption must implement controls to ensure the safety of the food produced there. Small farms are not covered by the PSR, and farms that sell regionally to consumers or retailers are typically eligible for a Qualified Exemption. When a farm is either not covered by the Rule or is Qualified Exempt, the farm does not need to comply with most of the PSR requirements. However, even if a farm does not need to comply with the requirements of the PSR, food safety is the responsibility of all producers of human food.

Recommended Resources:

- FDA's Produce Safety Page: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>
- National Sustainable Agriculture Coalition's Understanding FDA's FSMA Rule for Produce Farms: <http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-PRODUCE-RULE-FINAL.pdf>
- National Sustainable Agriculture Coalition's Food Safety Modernization Act Flowcharts: http://sustainableagriculture.net/wp-content/uploads/2016/02/2016_2-FSMA-Final-Rule-Flowchart-V3.pdf
- The Center for Agriculture, Food and the Environment's FSMA Produce Safety Rule Compliance Tool: <https://ag.umass.edu/resources/food-safety/for-farmers/fsma-produce-rule>
- Cornell CALS Produce Safety Alliance: <https://producesafetyalliance.cornell.edu/>

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Looking for legal help?

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