

FOOD SAFETY FREQUENTLY ASKED QUESTIONS: THE FOOD SAFETY MODERNIZATION ACT AND ITS IMPACT ON FARM TO SCHOOL ACTIVITIES

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Child nutrition program operators may purchase fruits and vegetables from a variety of sources, including local produce growers and suppliers. All farms should follow good food safety practices and it is important to be aware of food safety requirements and regulations that help keep fresh produce safe, such as the [Food Safety Modernization Act \(FSMA\)](#)¹. Understanding produce safety best practices and requirements will help keep meals served in child nutrition programs safe.

What is FSMA and the Produce Safety Rule?

FSMA was signed into law in 2011 and is implemented by the **U.S. Food and Drug Administration (FDA)**. FSMA protects public health by taking a proactive approach to strengthening the nation's food safety system. It allows the FDA to focus on reducing and preventing food safety problems at each point of the supply chain, rather than responding after they occur.

FSMA has **seven rules**, including science-based **Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**, which is widely known as the [Produce Safety Rule \(PSR\)](#)². The rule went into effect in January 2016 and aims to reduce foodborne illness associated with consuming contaminated produce which, according to research by the **U.S. Centers for Disease Control and Prevention (CDC)**, accounted for nearly half of all foodborne illnesses from 1998 to 2008³.

Does the FSMA Produce Safety Rule apply to all fruits and vegetables?

Produce that the FDA has identified as being [rarely consumed raw](#) is not subject to the PSR^{2,4}. These items are typically consumed after being cooked, which significantly reduces the levels of harmful microorganisms that may be present in the food.

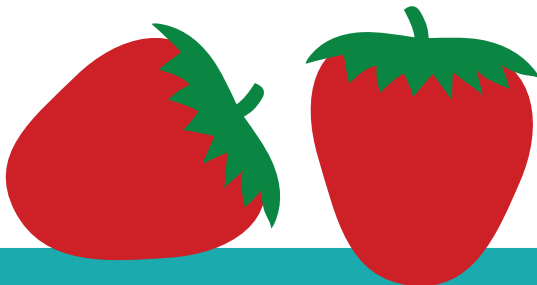
FDA List of Produce Rarely Consumed Raw:

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); eggplant; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts

When does the FSMA Produce Safety Rule apply to a farm business?

The PSR applies to commercial growers, harvesters, and packers of produce that the FDA has deemed likely to be eaten raw, and that is grown on farms with greater than \$25,000 in average annual produce sales. The PSR also applies to most farms that grow, harvest, and pack produce in one general location and under one general management.

The business category of covered farms and their PSR compliance dates are based on the farm size and the farm's annual average produce sales of the previous 3-year period. Visit the [FDA webpage](#) for more information about applicable PSR compliance dates and other key requirements².





Child nutrition professionals should keep in mind that produce growers and suppliers who sell to schools may fall into different categories and may be eligible for exemptions. The criteria information provided in this section and the [FDA flowchart](#) can help child nutrition professionals understand whether the PSR is applicable to a farm, or if a farm may be partially or fully exempt from the PSR⁵.

PSR exemptions are generally based on:

- The type of food grown
- Total annual sales of the food (adjusted each year to [account for inflation](#))⁶
- Where the food is sold
- To whom the food is sold

The following types of produce are typically not covered by the PSR:

- Produce that is rarely consumed raw^{2,4}
- Produce for personal or on-farm consumption
- Produce intended for commercial processing (e.g., cooking) which is covered by a [different FSMA rule](#)⁷
- Produce from farms with full exemptions or qualified exemptions

Full exemption: Farms with annual average produce sales of \$25,000 or less (adjusted for inflation) during the previous 3-year period are not covered by the PSR. These farms should keep records showing their sales information.

Qualified exemption: To be eligible for a qualified exemption, there are two requirements for farms.

- The farm must have food sales averaging less than \$500,000 per year (adjusted for inflation) during the previous 3-year period – these sales include all food for humans and animals, not just fruits and vegetables.
- During the 3-year period, farm sales to **qualified end-users** must be more than the combined sales to all other users ([21 CFR 112.5](#))⁸. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same State or Indian reservation as the farm, or not more than 275 miles away ([21 CFR 112.3](#))⁹.

School nutrition programs are considered retail food establishments and are qualified end-users under the PSR.

A farm with a qualified exemption must still meet some modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce, or at the point of purchase. These farms are also required to keep certain records.





Does the FSMA Produce Safety Rule impact procurement practices and farm to school activities in child nutrition programs?

The PSR should not impact a child nutrition program's ability to buy local food or a farmer's ability to sell to child nutrition programs. It is not a Federal requirement to buy from farms that are covered by the PSR. All Federal child nutrition procurement rules remain the same.

When buying directly from farms, you should ask your farm partners if they are covered under the PSR; don't assume that they may be exempt. There is no certificate of compliance from the FDA and there is no list of farms that are compliant with the PSR.

If your program or state law requires a food safety certification, there are several private options, as well as the **Good Agricultural Practices (GAP)** certification from the **United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS)**, which is aligned with the FDA's FSMA rules.

Federal law does not require schools to purchase from farms with a Good Agricultural Practices (GAP) certification or other third-party food safety certification.

Farms should always follow good food safety practices, whether covered by the PSR or a food safety certification such as GAP. It is your responsibility to ask questions about the farm's food safety practices to ensure that your school receives food that is safe.

In solicitations, schools must ensure that vendors comply with all applicable Federal, state, tribal, and local regulations. Review the [Verifying On-Farm Food Safety](#) fact sheet for more information on how to address and verify on-farm food safety of food sourced from local producers¹⁰.

Does the FSMA Produce Safety Rule impact school gardens?

Many school gardens fall below the \$25,000 threshold of annual average produce sales – the PSR does not apply to these gardens. Donated garden produce does not count toward the total sales revenue.

Many school nutrition programs use most of the produce grown in their school gardens; since school nutrition programs fall into the **qualified end-user** category, the PSR would not apply to these school gardens. Even if the PSR does not apply to your school garden, schools should implement good food safety practices for all gardens. Review the [School Gardens Fact Sheet](#) for more information¹¹.





References

- (1) *Full Text of the Food Safety Modernization Act (FSMA)*
www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma
- (2) *FSMA Final Rule on Produce Safety*
www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety
- (3) *CDC Attribution of Foodborne Illness: Findings*
www.cdc.gov/foodborneburden/attribution/attribution-1998-2008.html
- (4) *FSMA Produce Safety Rule: "Rarely Consumed Raw" Products*
www.fda.gov/media/107445/download
- (5) *FSMA Produce Safety Rule: Coverage and Exemptions/Exclusions*
www.fda.gov/media/94332/download
- (6) *FSMA Inflation Adjusted Cut Offs*
www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs
- (7) *FSMA Final Rule on Preventive Controls for Human Food*
www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food
- (8) *FSMA Produce Safety Rule (Final Rule): Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?*
www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112/subpart-A/section-112.5
- (9) *FSMA Produce Safety Rule (Final Rule): What definitions apply to this part?*
www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112/subpart-A/section-112.3
- (10) *USDA FNS Food Safety: Verifying On-Farm Food Safety Fact Sheet*
www.fns.usda.gov/fs/verifying-farm-food-safety
- (11) *USDA FNS Farm to School Program: School Gardens Fact Sheet*
www.fns.usda.gov/f2s/school-gardens



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For more information and to sign up for The Dirt, the e-newsletter from the Patrick Leahy Farm to School Program, visit

www.fns.usda.gov/f2s/e-letter-archive.

Questions? Email us at SM.FN.FarmToSchool@usda.gov.