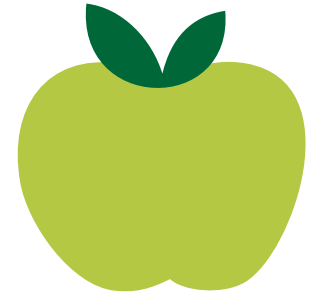




WHAT IS THE FOOD SAFETY MODERNIZATION ACT AND HOW DOES IT APPLY TO PRODUCE?



THE FOOD SAFETY MODERNIZATION ACT (FSMA) was signed into law in 2011 and enables the Food and Drug Administration (FDA) to better protect public health by strengthening the food safety system from the farm to the table. FSMA allows the FDA to focus on preventing food safety problems rather than reacting to problems. Those who grow, harvest, pack, process, transport, and store food for humans and animals (both foreign and domestic) will be required to implement these new food safety regulations, though there are specific exemptions that may apply to the regulations. Of course, there is no exemption from providing safe food!

FSMA is comprised of seven foundational rules, including the [Produce Safety Rule](#) (21 CFR 112).ⁱⁱ Fruits and vegetables are a vital component of a healthy diet. However, research shows that contaminated produce accounted for nearly half of all foodborne illnesses from 1998 to 2008.ⁱ The Produce Safety Ruleⁱⁱ (PSR) establishes, for the first time, minimum standards required for the safe growing, harvesting, packing, and holding of fruits and vegetables intended for human consumption.

Some produce items are not subject to the rule, such as foods that FDA has identified as being **rarely consumed raw**. These items are exempt from the requirements of the PSR because such fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that can be expected to adequately reduce the presence of microorganisms of public health concern.

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

Are farm to school sales exempt from the Produce Safety Rule?

Not exactly. FSMA's PSR applies to farms, not to individual sales. So it's not as simple as saying that all sales to schools are exempt. A farmer who sells to your school may be eligible for a full or qualified exemption based on the farmer's products grown and volume of sales. The FDA has a [flow-chart](#)ⁱⁱⁱ to assist with determining a farm's status.

- * **Full exemption.** Farms that have an *average annual value* of all produce sold during the previous 3-year period of \$25,000 or less (adjusted for inflation)^{iv} are not covered by the PSR, but need to keep records showing their sales figures.

It is more likely that farms that sell produce to schools in significant volumes are either covered by the PSR (meaning they need to be in compliance with the PSR), or they fall under a partial *qualified exemption*.

- * **Qualified exemption.** In order to be eligible for a qualified exemption, the farm must meet two requirements:
 - o It must have food sales averaging less than \$500,000 per year during the previous 3 years (this is all food for humans and animals, not just fruits and vegetables).
 - o Farm sales to qualified end users must be more than the combined sales to all other users, as an average over the previous 3 years. 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 the same Indian reservation as the farm or not more than 275 miles away. ***School nutrition programs would be considered retail food establishments and, therefore, qualified end-users under the PSR.***
 - o A farm with the qualified exemption must still meet certain 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 establish and keep certain records.

A small farm has average annual produce sales during the previous 3-year period between \$250,000 - \$500,000.

A very small farm has average annual produce sales during the previous 3-year period between \$25,000 - \$250,000.

A farm that has average annual produce sales of less than \$25,000 is not covered by the Rule.



*** Here's an example:**

A farmer has an average annual monetary value of food sold during the previous 3 years of less than \$500,000 and one-third of the monetary value of its sales comes from sales to farmers markets and local restaurants. One-third of the monetary value of its sales comes from sales to local school cafeterias, and one-third of the monetary value of its sales comes from sales to wholesalers. If those farmers markets, local restaurants, and local school cafeterias are within the same State, within the same Indian reservation, or within 275 miles of the farm, then the farm would have sold two-thirds of its produce to qualified end-users and the qualified exemption and associated modified requirements would apply.

Does the Produce Safety Rule impact school gardens?

Most school gardens will fall below the \$25,000 monetary threshold for coverage under the PSR. Donated garden produce does not count toward the total sales revenue. While the PSR may not apply to your school garden, USDA recommends that schools implement good food safety practices for all gardens. Check out [Food Safety Tips for School Gardens](#)^v to get started.



How does the Produce Safety Rule affect child nutrition procurement practices?

1. The PSR should not impact a school's ability to buy local food or a farmer's ability to sell to schools. All Federal child nutrition procurement rules remain the same.
2. When buying direct from farms, don't assume they are exempt from the PSR. Schools are required in their solicitations to assure that vendors comply with all applicable Federal, State, and local regulations. Ask your farm partners if they are covered under the PSR. It is not a Federal requirement to buy from farms that are covered by the PSR.
3. Compliance dates for the PSR vary based on a 3-year average income from produce sales (which determines FDA's classification of farm size). The earliest compliance date (for large farms) was January 26, 2018. Small farms must comply by 2019, and very small farms have until 2020 to comply. Specific agricultural water requirements have later dates.
4. There is no certificate of compliance from FDA, nor is there a "master list" of PSR compliant farms. Federal law does not require schools to purchase from farms with a Good Agricultural Practices (GAP) certification or other third-party food safety certification. If your program or State law requires a food safety certification, there are several private options, as well as USDA's GAP certification. USDA's Harmonized GAP audit is now aligned with FDA's FSMA rules.

Who can answer my Produce Safety Rule questions?

Your first line of assistance will most likely come from your [State Department of Agriculture](#).^{vi} The FDA has [cooperative agreements](#)^{vii} with many States to implement the PSR. In States and U.S. Territories that do not currently have a cooperative agreement, you can contact the FDA [Produce Safety Network](#).^{viii} FDA's [PSR website](#)ⁱⁱ provides helpful information and links, related guidance, webinars, and supporting material. The FDA also hosts the FSMA [Technical Assistance Network](#)^{ix} (TAN), a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

For answers to questions about local foods or school gardens, contact your [USDA Farm to School Regional Lead](#).^x

For answers to questions about food safety in Child Nutrition Programs, contact the USDA FNS [Office of Food Safety](#).^{xi}



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ⁱ <https://www.cdc.gov/foodborneburden/attribution/attribution-1998-2008.html>

ⁱⁱ <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

ⁱⁱⁱ <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf>

^{iv} <https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>

^v <https://theicn.org/resources/652/produce-safety-best-practices-fact-sheets/107980/food-safety-tips-for-school-gardens.pdf>

^{vi} <https://www.foodsafety.gov/about/state/index.html>

^{vii} <https://www.fda.gov/ForFederalStateandLocalOfficials/FundingOpportunities/GrantsCoopAgrmts/ucm517991.htm>

^{viii} <https://www.fda.gov/food/guidanceregulation/fsma/ucm510261.htm>

^{ix} <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

^x <https://www.fns.usda.gov/farmtoschool/usda-farm-school-staff>

^{xi} <https://www.fns.usda.gov/ofs/food-safety>

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