

# THE FOOD SAFETY MODERNIZATION ACT (FSMA) AND THE PRODUCE SAFETY RULE (PSR)

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Fruits and vegetables are a vital component of a healthy diet and it's important that these key sources of nutrition are safe to eat. The [Food Safety Modernization Act \(FSMA\)](#) was signed into law in 2011 and is implemented by the **U.S. Food and Drug Administration (FDA)**.<sup>1</sup> The 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 happen.

The 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 \(PSR\)](#).<sup>2</sup> The rule went into effect in January 2016 and aims to reduce foodborne illnesses 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 2008.<sup>3</sup>

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. Produce items that the FDA has identified as being [rarely consumed raw](#) are not subject to the rule - these items are typically consumed after being cooked, which significantly reduces the levels of harmful microorganisms that may be present in the food.<sup>4</sup>

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 requirements.<sup>2</sup>

Keep in mind, however, that there are some farms and businesses that may be eligible for exemptions. This [FDA flowchart](#) can help you learn more about your farm's status, including if the PSR is applicable or if your farm may be eligible for a full or qualified exemption.<sup>5</sup>

PSR exemptions that may apply to a farm business are generally based on:

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

## 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





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

- Produce that is rarely consumed raw<sup>4</sup>
- Produce for personal or on-farm consumption
- Produce intended for commercial processing (e.g., cooking), which is covered by a [different FSMA rule](#)<sup>7</sup>
- 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.

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

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](#)).<sup>8</sup> 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](#)).<sup>9</sup>



- 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.

As a producer, the PSR should not impact your ability to sell to child nutrition programs. There is no Federal requirement for child nutrition programs to buy from farms that are covered by the PSR. Farms should always follow good food safety practices, whether covered by the PSR or a food safety certification, such as **Good Agricultural Practices (GAP)**.

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

In their solicitations, schools must ensure that vendors comply with all applicable Federal, State, Tribal, and local regulations. Be prepared to provide information about your farm's food safety practices that will help your child nutrition partners ensure that their school receives food that is safe.





## 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](http://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](http://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](http://www.cdc.gov/foodborneburden/attribution/attribution-1998-2008.html)
- (4) *FSMA Produce Safety Rule: "Rarely Consumed Raw" Produce*  
[www.fda.gov/media/107445/download](http://www.fda.gov/media/107445/download)
- (5) *Standards for Produce Safety: Coverage and Exemptions Exclusions for 21 Part 112*  
[www.fda.gov/media/94332/download](http://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](http://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](http://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](http://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](http://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112/subpart-A/section-112.3)





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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](http://www.fns.usda.gov/f2s/e-letter-archive).

Questions? Email us at [SM.FN.FarmToSchool@usda.gov](mailto:SM.FN.FarmToSchool@usda.gov).