FOOD SAFETY

PRODUCE SAFETY RULE



The Produce Safety Rule is one of seven rules included in the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA). The Produce Safety Rule (PSR) establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. This rule covers aspects of worker health, hygiene, and training; agricultural water (for both production and post-production harvest uses); biological soil amendments; domesticated and wild animals; equipment, tools, buildings, and sanitation; and the production of sprouts. Many small farms will not be required to comply with all the federal food safety regulations in the Food Safety and Modernization Act (FSMA) Produce Safety Rule (PSR). How the rule will affect you and your farm will depend on what you grow, how much you sell, and who your customers are.

COVERED PRODUCE

Beets, sugar

Foods that are eaten raw are at increased risk of foodborne illnesses because cooking reduces the presence of microorganisms of public health significance. For that reason, the FSMA PSR is focused on produce that is commonly consumed raw. Check with the FDA for a final list on produce not subject

to the Produce Safety Rule. Any crops not specifically listed as not subject to PSR by the FDA are subject to the rule. Below was the list of not covered crops at the time of this guide's publication.

Value Added Products

What about value added fresh foods made from covered raw agricultural commodities? While the production of the fruits and vegetables would be subject to the Produce Safety Rule, products made from them, ready-to-eat or processed products like cut and washed salad mixes, peeled baby carrots, zucchini noodles, and salsas are not regulated under the Produce Safety Rule. These products are potentially subject to other food rules under the FSMA Preventative Controls for Human Food Rule or rules determined by your public health department. (See Fact Sheet 5.4 Preventative Controls for Human Food for more information).

Sprout Production

Unfortunately, many foodborne illnesses have resulted from the production of sprouts. Because of this, the FDA has developed specific and rigorous standards for sprout production that are separate

SOME CROPS NOT SUBJECT TO PSR

Okra

Asparagus Cashews Eggplants **Peanuts** Beans, black **Pecans** Cherries, sour Figs Beans, great northern Chickpeas Food grains **Peppermint** Cocoa beans Beans, kidney (such as wheat, **Potatoes** Coffee beans Beans, lima oats, or rice) **Pumpkins** Squash, winter Beans, navy Collards Ginger Beans, pinto Corn, sweet **Hazelnuts** Sweet potatoes Beets, garden (roots Cranberries Horseradish Water chestnuts and tops) Dates Lentils

Dill (seeds and weed)

from the Produce Safety Rule. For resources refer to the Sprout Safety Alliance (https://www.iit.edu/ssa).

Note: Microgreens are not considered sprouts and would be subject to the general requirements for covered produce.

Does the Produce Safety Rule Apply to Your Farm?

Any farm engaged in growing, harvesting, packing, or holding produce identified as a raw agricultural commodity (RAC) that is not on the rarely consumed raw list provided by FDA is potentially subject to the FSMA Produce Safety Rule. Documentation is required to establish whether your farm is subject to the rule or not, and if subject, whether you qualify for an exemption. It is helpful to start by assessing your operation and answering a few key questions about your operation. You may use the anonymous, self-guided decision tool created by University of Idaho Extension or view the flow-chart developed by the Food and Drug Administration. You may also wish to use an annual produce sales and qualified exempt worksheets developed by the Idaho State Department of Agriculture. These tools and the material in this Fact Sheet are intended for general information only. It is recommended that you verify any assumed coverage or exemptions with the Idaho State Department of Agriculture Produce Safety Program, who serves as the FSMA PSR regulator in the state of Idaho.

University of Idaho Extension has developed a step-by-step guide to recordkeeping for covered and qualified exempt farms that can be requested through their Food Safety for Produce Growers website (https://www.uidaho.edu/extension/foodsafety-for-produce-growers).

Legal Responsibility

Compliance with the rule is serious and federally mandated. If you violate the FSMA PSR, you can be prosecuted criminally. You, as the owner of your business, are strictly liable for your operation—you

cannot plead ignorance to FSMA's rules, or any conditions of your farm. Even if you qualify for an exemption from inspection or other requirements in the rule, you could forfeit your exemption if hazardous practices on your farm lead to a foodborne illness outbreak. Make sure you're aware of the food safety risks in your operation and how to mitigate them.

COVERAGE CLASSIFICATIONS

Farms can be classified as Not Covered, Qualified Exempt, or Covered. These classifications are determined by what activities are conducted on a farm, what crops they grow, whether the crop is consumed raw or processed, how the produce is sold, and by volume of sales. Documentation is required to establish whether a farm is subject to the rule or not, and whether they qualify for an exemption. Need to know how this affects your farm? Use the anonymous, self-guided decision tool created by University of Idaho Extension. Note: this section is intended as general information only, please verify any assumed coverage or exemptions with the Idaho State Department of Agriculture Produce Safety Program.

FARMS NOT COVERED BY THE PRODUCE SAFETY RULE

In general, your farm would not be likely to be subject to the rule if you:

- ✓ Do not grow, harvest, pack, or hold any produce on your farm.
- Do not grow, harvest, pack, or hold any produce covered by the rule.
- ✓ Grow covered produce that is processed in a way that adequately reduces the presence of microorganisms of public health significance (for example, you grow tomatoes that are sold and processed into a cooked sauce).
- Grow only for personal consumption, not sale.
- ✓ Sell less than \$25K worth of produce per year, on average, in the previous three years.

FARMS ELIGIBLE FOR A QUALIFIED EXEMPTION

Your farm may be eligible for a qualified exemption to inspection and some of the record-keeping requirements of the Produce Safety Rule if your farm sells less than \$500,000 (gross) per year of all food, adjusted for inflation. (Note, this is not just your sales of produce. The FDA defines food as any product that is intended for human or animal consumption), and more than 50% of your food is sold directly to either 1) an individual consumer (not a business), including those reached through direct marketing, or 2) a restaurant or retail establishment located in the same state or Indian reservation or within 275 miles of your location (direct marketing examples include CSA subscribers, Farmers' Market customers, etc. Retail establishments can include grocery stores, farmstands, convenience stores, and even vending machines).

Requirements of Qualified Exempt Farms

Exempt growers in Idaho will be asked to verify their exemption annually with the Idaho State Department of Agriculture. Qualified Exempt farms are required to establish and keep sales records and documentation that supports their exemption.

Qualified exempt farms are also required to comply with modified labeling requirements. You must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard or documents delivered contemporaneously with the produce. See example below:



Withdrawal of Exemption

If your farm's total food sales exceed \$500,000 per year, adjusted for inflation, over a three year period, or if you sell less than 50% of your products to a qualified end user as defined in the rule, you will cease to qualify for an exemption and will be subject to all parts of the rule and inspection.

Also, according to FDA, your farm's qualified exemption may be withdrawn if there is an active investigation of an outbreak of foodborne illness directly linked to your farm, or if the FDA determines it is necessary to protect public health and prevent or mitigate an outbreak based on conduct or conditions associated with your farm. All the more reason to make it a priority to increase your knowledge and application of on-farm food safety practices!

FARMS COVERED BY THE PRODUCE SAFETY RULE

Farms covered by the Produce Safety Rule must comply with the below requirements.

Inspections

Covered farms are subject to mandatory compliance inspections. In Idaho, these inspections on behalf of FDA are conducted by the Idaho State Department of Agriculture (ISDA). There is no charge for an inspection. ISDA has published a helpful factsheet outlining what to expect from an inspection, titled "What to Expect of a Regulatory Inspection - Informational Handout for Farmers." Refusing the inspection of your operation is prohibited and carries legal consequences for you as the owner and for your operation. If your farm is GAP certified and has gone through the audit process, you will notice similarities between an audit and an inspection. (See Fact Sheet 5.8 Good Agricultural Practices for more information). The primary difference is that a GAP audit is voluntary, and a FSMA PSR inspection of a covered farm is not. If you participate in the USDA Agricultural Marketing Service Harmonized GAPs Audit Program, your Harmonized GAP audit is aligned with a FSMA Produce Safety Inspection, but does not replace it.

Food Safety Training for a Designated Individual

If your farm is covered by the Produce Safety Rule, you are required to send a designated farm food safety individual from your farm to a produce safety training approved by the FDA. Currently, the Produce Safety Alliance Grower Training, developed by Cornell University, is the only approved training that meets this requirement. This training is available in Idaho thanks to a collaboration between the University of Idaho Extension and the Idaho State Department of Agriculture. They offer one day in-person trainings or two half-day live online trainings in the fall and winter of each year. These trainings are offered for free or a significantly reduced rate thanks to grant funding, and they are open and available to all Idaho growers, regardless of size or coverage by the rule. Attending this training is beneficial to you and your operation regardless of your farm's size and whether you are exempt from the PSR, and most growers consider it time well spent. Find the trainings here: https:// www.uidaho.edu/extension/food-safety-for-produce-growers.

Recordkeeping for Qualified Exampt & Covered Farms

Keeping records that document your food safety practices related to the growing, harvesting, packing, and holding of fruits and vegetables under the FSMA Produce Safety Rule may be the most challenging task facing a covered farm. University of Idaho Extension has developed a step-by-step guide to recordkeeping for covered and qualified exempt farms. This guide can be requested through the University of Idaho Extension's Food Safety for Produce Growers website. (https://www.uidaho.edu/extension/food-safety-for-produce-growers).