

# Food Safety Modernization Act (FSMA) Produce Safety Rule Coverage & Exemptions Interactive PDF



This interactive PDF will discuss how the new federal produce safety laws, regulated by the Food and Drug Administration, apply to farms that grow, harvest, pack or hold fresh produce. Simply [click on any purple link](#) and it will take you to the corresponding resource. FDA guidance and enforcement discretion policies can change *at any time* - be sure to check back for the most current version and supporting documentation before making important decisions. **Version April 28, 2021**

## Who is covered under the Produce Safety Rule? Are there exemptions to being covered under the rule?

It is recommended to first watch the University of Minnesota Extension [introductory video](#) that briefly examines the coverage and exemptions of the Produce Safety Rule. A [deep dive podcast](#) is available that goes into greater detail with examples and commonly asked questions.

The Produce Safety Rule applies to operations that fall under the [definition of a farm](#) and grow [produce](#). The following are **not covered** under the rule: 1) produce that is on the FDA [rarely consumed raw](#) list; 2) produce used for personal consumption; 3) produce that is not a [raw agricultural commodity \(RAC\)](#); and 4) farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less.

The following may be eligible for an exemption: 1) produce intended for [commercial processing](#); and 2) farms that meet the requirements for a [qualified exemption](#). To be eligible for a qualified exemption your farm must have an average annual value of [food](#) sold during the previous three-year period of \$500,000 or less, and sales to [qualified end-users](#) must exceed food sales to all other buyers.

These concepts are organized in the official [FDA Coverage and Exemptions Flowchart](#).

The sales cut-off values of \$25,000 (for covered farms) and \$500,000 (for qualified exemption) are [adjusted for inflation](#) annually – current average values for use in 2021 are \$28,561 and \$571,214.



## What produce is covered under the Produce Safety Rule?

Produce that is a RAC is covered. This includes, but is not limited to: (1) fruits and vegetables *such as* almonds, apples, apricots, apriums, artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and (2) Mixes of intact fruits and vegetables (such as fruit baskets).

## What produce is NOT covered under the Produce Safety Rule?

Produce that is **rarely consumed raw**, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

Hops, wine grapes, pulses, and almonds are currently under **an FDA policy of enforcement discretion**.

## What if I have less than \$25,000 in annual produce sales?

- 1) Complete an **Annual Exclusion Review** to determine if you are covered under the rule
- 2) Maintaining supporting documentation to support sales totals is highly encouraged

## What if I meet the criteria for a Qualified Exemption?

- 1) Complete an **Annual Qualified Exemption Review** to determine your eligibility for a qualified exemption
- 2) Follow the **modified requirements for labeling** outlined in § 112.6(b)
- 3) Maintain **supporting documentation** to demonstrate eligibility

## What do I need to complete for produce that is intended for commercial processing?

- 1) Include a **Farm Disclosure** statement with each shipment
- 2) Obtain an annual **Buyer Written Assurance** statement (currently under **an FDA policy of enforcement discretion**)

## What about my packinghouse? Am I required to be a food facility subject to registering and preventive controls?

**Farms and Facilities** are treated differently under FSMA. Operations like packinghouses might be farms, or they might be facilities. This is important because *farms* fall under the Produce Safety Rule and *facilities* fall under the Preventive Controls Rule for Human Foods. Food facilities are required to **register** with FDA.

Packinghouses can be either farms or facilities depending on where they are located and who owns them. If the packinghouse is on a farm and only doing the following it is not a food facility: grading, sorting, washing, packing, labeling, or holding produce. An off-farm packinghouse can be a **Secondary Activities Farms** if more than half the produce it handles comes from the primary production farm that owns the packinghouse. That primary production farm must have more than 50% ownership of the packinghouse.

If your packinghouse is not a secondary activities farm because of ownership, **an FDA policy of enforcement discretion** states you can choose to follow either the Produce Safety Rule or current Good Manufacturing Practices (CGMPs) included in the Preventive Controls Rule - they are very similar. You still meet the definition of a facility and must register as a facility under section 415 of the FD&C Act.



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