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 2020 are $28,075 and $561,494.

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 unig 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, plums, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, sour sop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as pattie 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.