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

Review the FDA Coverage Flowchart. The following are excluded from the rule: 1) produce that is on the FDA rarely consumed raw list; 2) produce used for personal consumption; 3) food grains; 4) produce intended for commercial processing; and 5) farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less. More details are available in an FDA Produce Safety Rule Fact Sheet.

To be eligible for a qualified exemption, your farm must meet two requirements: 1) total food and animal feed sales averaging less than $500,000 per year during the previous three years, AND 2) sales to qualified end-users must exceed food sales to all others combined during the previous three years.

The sales cut-off values of $25,000 and $500,000 are adjusted for inflation annually. The University of Minnesota Extension has a great video examining coverage and exemptions: https://www.youtube.com/watch?v=Pt4G1AH7bhA

What produce is covered under the Produce Safety Rule?

Produce that is a raw agricultural commodity (RAC) is covered by this part. 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 uniq 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, sourso, 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

What if I am selling less than $25,000 in annual produce sales?

1) Complete an annual sales review to determine if you are covered under the rule
2) Maintain supporting documentation to demonstrate status

What if I meet the criteria for a Qualified Exemption?

1) Complete an annual sales 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 are the modified requirements for labeling of the produce safety rule?

A. When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown

B. When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, 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 in the normal course of business, or, in the case of Internet sales, in an electronic notice (this requirement could be satisfied using a handwritten poster made with a marker and posted at the farm market stand or CSA pick up site if the grower direct markets - provides contact information for the farm in case there is an issue with the produce)

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

Last updated on 03/12/2020
STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of “farm” is subject to the produce rule.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Exemption/Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your farm grow, harvest, pack or hold produce?</td>
<td></td>
<td>X</td>
<td>NOT covered by rule</td>
</tr>
<tr>
<td>Does your farm on average (in the previous three years) have $25k or less in annual produce sales?</td>
<td></td>
<td>X</td>
<td>NOT covered by rule</td>
</tr>
<tr>
<td>Is your produce one of the commodities that FDA has identified as rarely consumed raw?</td>
<td></td>
<td>X</td>
<td>NOT covered by rule</td>
</tr>
<tr>
<td>Is your produce for personal/on-farm consumption?</td>
<td></td>
<td>X</td>
<td>NOT covered by rule</td>
</tr>
<tr>
<td>Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?</td>
<td></td>
<td>X</td>
<td>NOT covered by rule</td>
</tr>
<tr>
<td>Does your farm on average (in the previous three years) have &lt; $500k annual food sales, AND a majority of the food (by value) sold directly to “qualified end-users”?</td>
<td></td>
<td>X</td>
<td>exempted from rule</td>
</tr>
</tbody>
</table>

**YOU ARE COVERED BY THIS RULE.**

The term “qualified end-user” as defined in Section 112.3(c) means:
- the consumer of the food OR
- a restaurant or retail food establishment that is located—
  - (i) in the same State or the same Indian reservation as the farm that produced the food; OR
  - (ii) not more than 275 miles from such farm.

(The term “consumer” does not include a business.)