

FSMA's Produce Safety Rule

Do you have to comply with the Produce Safety Rule?

By: Elena Rogers, Area Specialized Agent, Food Safety- Fresh Produce- Western NC
NC State Cooperative Extension/ Department of Horticultural Sciences
Elena_rogers@ncsu.edu

In order to understand the Produce Safety (PS) Rule and what parts of the Rule apply to your farm it is important to first define if a farm grows covered produce (produce that is targeted by the PS Rule and that may be subject to inspection) or not and the second step, is to determine if the farm may be eligible for a qualified exemption or may not be covered at all by this Rule. If the farm does not meet the requirements set for qualified exempt farms, it is covered by the PS rule.

Important definitions

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (*e.g.*, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Raw agricultural commodity (RAC) means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

1. What produce is covered by the Produce Safety Rule?

a. All produce (fruits and vegetables) that is a raw agricultural commodity is considered "covered produce" under the Rule.

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, sweet cherries, 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), honeydews, 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, pigeon peas, 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.

This list of covered produce is not intended to be an exhaustive, exclusive nor a complete list and serves only as examples of produce covered by the rule.

These crops will be inspected under the PS Rule unless the farm meets the conditions for a qualified exemption or is not covered by the Rule.

b. “Not covered” produce:

1. Fruits and vegetables that are usually not eaten raw included in this list: Asparagus, beans (black, great Northern, kidney, lima, navy, pinto), garden beets (roots and tops), sugar beets, cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill (seeds and weeds), eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, winter squash, sweet potatoes, and water chestnuts.

2. Produce that is grown at a farm for personal consumption.

3. Produce that is not a raw agricultural commodity. Examples: lentils.

If the commodity is listed as “not covered” it will not be inspected under the PS Rule.

c. Exempt produce. This is produce that is intended for commercial processing that adequately reduces the presence of microorganisms to an extent sufficient to prevent illness.

If the produce grown, held or packed is destined to be commercially processed then the farm can get a written assurance from either the processor or customer performing the commercial processing or from the customer that an entity in the distribution chain subsequent to customer will perform commercial processing. Examples of processing activities include: refining, distilling, manufacturing/processing produce into sugar, oil, spirits, wine, beer or similar products. Examples of possible products: Produce that is used in the production of spices, ingredients of dietary supplements,

or food additives. The farm must disclose in documents accompanying the produce in accordance with the practice of trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” and document compliance with required disclosures and written assurances.

If taking advantage of this exemption, the grower is required to get the letter of assurance annually. The compliance date for this exemption is January 2020, but the farm can obtain the letter before that to have proof of the “exempt” status.

Produce for which the grower has a written assurance that will be commercially processed with a kill step is exempt from the PS Rule. The written assurance must be kept on file at the farm.

2. Farms under the Produce Safety Rule can be classified as:

a) Farms not covered by the PS Rule.

- ✓ Farms whose average annual produce sales is \$26,632* or less for the previous 3-year period are not covered by the Rule.

To determine annual produce sales = add the value of all produce sales (Covered produce + not covered produce + exempt produce).

These farms may be required to have financial records to prove they are “not covered” by the Rule but other than that they are not subject to the requirements for qualified exempt or covered farms.

b) Eligible for a qualified exemption and modified requirements.

For a farm to be eligible for a qualified exemption, it must meet the conditions in both numerals (1) and (2).

(1) The farm must sell the majority of the **food**** to qualified end users. Qualified end users are consumers, restaurants or retail establishments*** within NC or not more than 275 miles of the farm or via internet sales. Total annual food sales to businesses (i.e. brokers) must be 49% or less.

AND

(2) The average monetary value of **food*** sales for the past three years must be less than \$532,645* annually.

Qualified Exemptions require farms to keep financial records (dated sales receipts) to prove food sales starting on 1/26/2016 and comply with labeling requirements.

The labeling requirement consists of including the name and complete business address of the farm where the produce was grown either on the label of the produce or to display the same information at the point-of-purchase. The labeling requirement will be effective on 1/20/2020. **As long as a farm satisfies these requirements and FDA has not withdrawn a qualified exemption then the farm is compliant with the Produce Safety Rule.** Nonetheless it is important for produce growers to understand

the importance of following food safety practices and the conditions under which a qualified exemption can be withdrawn.

For more information about this category in the PS Rule read Understanding Qualified Exemptions and Modified Requirements.

* This value has been adjusted for inflation. FSMA's Inflation adjusted cut offs can be found at : <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

****“Food” means articles used for food or drink for human or animal consumption**, or articles used to make components of it. Includes seeds and beans used to grow sprouts.

Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods. Livestock and meat are both food within this definition. FDA may interpret the term “food” to “include live animals raised for food”. There are instances when live animals are sold for purposes other than for food, such as being sold as pets (e.g., dogs), pets are not considered food.

FDA notes that only the value of food “sold” during the year should be counted to determine the eligibility for the qualified exemption. As farms calculate food sales take into account that cotton, tobacco and timber are not considered food.

*****A “retail food establishment”** is an establishment that sells food products directly to consumers as its primary function and includes grocery stores, convenience stores, and vending machine locations.

A “retail food establishment” also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a **farm** or by a **farm-operated business** includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmer’s markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

For the purposes of this definition, **“farm-operated business”** means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

c) “Covered farms”.

These farms did not meet the conditions set for a qualified exemption and have to comply with the provisions for covered farms in the Produce Safety Rule. Covered farms must follow the standards set for worker health and hygiene, agricultural water, biological soil amendments, domesticated and wild animals, equipment, tools, sanitation and growing, harvesting, packing and holding activities. Covered farms need to have at least one representative attend a **Produce Safety Alliance (PSA) Grower training** by the respective compliance date. The PSA Training is an all-day training that goes over the 7 modules and outlines the practices that farms must comply with. Covered farms will be subject to unannounced inspections by the North Carolina Department of Agriculture and Consumer Services after the compliance dates.

Compliance dates for “Covered Farms”.

Covering	All other businesses (Sales over \$500K)	Small businesses (\$250K-\$500K Produce sales)	Very small Businesses (\$25K-\$250K Produce sales)
Most provisions in the Rule	1/26/2018	1/28/2019	1/27/2020
For water related regulations outlined in the Rule (UNDER REVISION)	1/27/2020	1/26/2021	1/26/2022
Sprouts	1/26/2017	1/26/2018	1/28/2019

For more information about FSMA’s Produce Safety Rule and to register for classes in NC visit: <https://ncfreshproducesafety.ces.ncsu.edu>

This document is not to be considered legal advice. This is a summary of the published guidelines by FDA for FSMA’s Produce Safety Rule (9/6/2017).