

Food Safety Modernization Act — FDA Final Rules

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: 21 C.F.R. Part 112
- What exceptions apply?

Subpart A — General Provisions

What food is covered? — 112.1

- Produce¹ that is a raw agricultural commodity.²
- Subject to the exemptions and qualified exemptions, covered produce includes all of the following:
 - 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
 - Mixes of intact fruits and vegetables (such as fruit baskets).

¹ 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).

² Raw Agricultural Commodity 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.

What food is not covered? — 112.2(a)

- 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.
- Produce does not include food grains (see produce definition).
- Produce that is produced for personal consumption or produced for consumption on the farm.
- Produce that is not a raw agricultural commodity.

What food is eligible for exemption? — 112.2(b)

- Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance.
- Must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.”
- Must annually obtain written assurances from customer that performs the commercial processing that the customer has established and is following procedures (identified in written assurances) that adequately reduce the presence of microorganisms of public health significance; OR
- Must annually obtain written assurances from the customer that an entity in the distribution chain subsequent to the customer will perform commercial processing.
 - These assurances must be done at every step of the chain of custody.
- Must establish and maintain documentation of compliance.

What farms are subject? — 112.4

- Farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of more than \$25,000 dollars.

What farms are eligible for a qualified exemption? — 112.5

- During previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food sold directly to qualified end-users exceeded the average annual monetary value of the food sold to all other buyers; AND
- The average annual monetary value of all food sold during the 3-year period was less than \$500,000 dollars.
- Qualified End-User – means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment that is located in the same State or not more than 275 miles from such farm.
 - Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. Does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

- Retail food establishment means an establishment that sells food products directly to consumers as its primary function. Includes grocery stores, convenience stores, and vending machines locations.
- Qualified End-User does not include a business. Therefore, it does not include a situation where a farm sells to a separate business that runs a CSA rather than directly to individual customers.

Qualified exemption requirements? — 112.6

- Subject to the following:
 - General Provisions;
 - Subpart O (Records)
 - Subpart Q (Compliance and Enforcement)
 - Subpart R (Withdrawal of Qualified Exemption)
 - Must include prominently and conspicuously the name and business address of the farm on:
 - Food packing labels, when required.³
 - At point of purchase when food packing label is not required.
- Farm must establish and keep adequate records necessary to demonstrate that the farm satisfies the criteria for the qualified exemption, including a written record reflecting that the farm has performed an annual review and verification of the farm's continued eligibility for the qualified exemption.

Subpart O — Records

What are the general requirements? — 112.161

- Except as otherwise specified, all records must:
 - Include: (1) the name and location of the farm; (2) actual values and observations obtained during monitoring; (3) an adequate description of covered produce applicable to the record; (4) the location of the growing area or other area; (5) the date and time the activity was documented.
 - Be created at the time an activity is performed or observed.
 - Be accurate, legible, and indelible.
 - Be dated, and signed or initialed by the person who performed the activity documented.
 - Records demonstrating the qualified exemption must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

Other Requirements — 112.162–.167

- Can use existing records if they contain all of the required information and satisfy the requirements of this part. Existing records can be supplemented as necessary.
- Must keep records for at least 2 years past the date the record was created. Records the farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption must be retained as long as necessary to support the status during the applicable calendar year.
- Records must be original, true copies, or electronic.
- Must have all records readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except you have 24 hours to obtain records kept offsite.

³ When required on food that would otherwise be covered produce under the Food, Drug, and Cosmetic Act.

Subpart Q — Compliance and Enforcement

- Failure to comply with this part is a prohibited act under the Food, Drug, and Cosmetic Act.
- The criteria and definitions in this part apply in determining whether a food is adulterated within the meaning of the FDCA or in violation of the Public Health Service Act.

Subpart R — Withdrawal of Qualified Exemption

- This subpart discusses the situations where the FDA can revoke a qualified exemption and the process for doing so.

Notes

- Farms not subject to 112 continue to be covered under the adulteration and other applicable provisions of the FDCA and applicable regulations.
- FDA does not see a conflict or discouragement to farms following National Organic Program requirements.
- FSMA does not require or prohibit States from setting up food safety programs for farms eligible for qualified exemptions.
- Sales threshold – do not consider donation in which there is no payment of money or anything else of value in exchange for produce.
- Farms under the qualified exemption are not required to include a statement notifying customers that the farm is a under a qualified exemption.
- Date of compliance for retention of records under the qualified exemption is the effective date of the rules (January 26, 2016) – farm may not have the required 3–year records – may rely on the records available.

Definitions for Compliance Dates

- Very Small Business — rolling basis, average annual monetary value of produce sold during previous 3–year period is no more than \$250,000 dollars.
- Small Business —rolling basis, average annual monetary value of produce sold during the previous 3–year period is no more than \$500,000 dollars.