

Does the FDA – Food Safety Modernization Act (FSMA) Affect my Farm? Do I need to Comply?

Step 1

- Am I a farm as defined by FDA?

Step 2

- Do you grow/harvest/pack/hold covered produce?

Step 3

- Are you growing only for personnel consumption, have a kill step or under \$25K?

Step 4

- Do you have average annual FOOD sales <\$500K and >50% of FOOD sales to qualified end-users ((a) the consumer (b) a restaurant or retail food establishment located in the same state/same Indian reservation OR within 275 miles.

Step 5

- What are my compliance dates and "what do I need to do to be in compliance"?

Step 1

Am I a farm as defined by FDA?

Determining if activities you perform are within the “farm” definition is key in deciding if your business is exempt from registration as a facility. Does one of these farm operations describe your business?

A. Primary production farm is an operation:

- under one management in one general (but not necessarily contiguous) physical location
- devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.
- Pack or hold raw agricultural commodities;
- Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed
- Manufacture/process food, provided that:
 - (A) All food is consumed on that farm or another farm under the same management; or
 - (B) Any manufacturing/processing consists only of:
 - (1) Drying/dehydrating to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
 - (2) Treatment to manipulate the ripening of raw agricultural commodities (such as ethylene), and packaging and labeling, without additional manufacturing/processing; and
 - (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

B. Secondary activities farm is an operation:

- not located on a primary production farm
- devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities,
- provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.
- may also conduct those additional activities allowed on a primary production farm

C. Mixed-type facility means an operation:

- that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered.
- example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

If you answer “yes” to one of these operation types, Continue to Step 2

Step 2

Do you grow/harvest/pack/hold covered produce?

Produce Safety Rule “Covered” Produce Defined

A. First, check to see if your produce is one of the commodities that FDA has identified as rarely consumed raw (not a raw agricultural commodity (RAC)). This represents an exhaustive list of rarely consumed raw produce:

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 weeds); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

Continue to Step 3 as a non-RAC

B. Is your produce one of the “covered” products that FDA has identified as raw agricultural commodity (RACs)? The following are examples:

(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 (Boy 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 uniuq 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 artichoke, 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 belland 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).

Continue to Step 3 as a RAC

Step 3

Are you growing only for personnel consumption, have a kill step or under \$25K?

Are any of the following conditions “true” for your farm ?

- A. Does your farm on average (in the previous three years) have \$25k or less in annual produce sales?
- B. Have produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management;
- C. Have produce that is not a raw agricultural commodity (non – RAC);
- D . Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?

If yes to any of these questions, this produce is eligible for exemption if it:

- receives commercial processing that adequately reduces the presence of microorganisms of public health significance (kill step) and
- must annually obtain written assurance from either the customer performing the commercial processing or from your customer that an entity in the distribution chain subsequent to customer will perform commercial processing

Or

- discloses in documents accompanying the produce that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”

If none are “true”, Continue to Step 4

Step 4

Do you have average annual FOOD sales <\$500K and >50% of FOOD sales to qualified end-users ((a) the consumer (b) a restaurant or retail food establishment located in the same state/same Indian reservation OR within 275 miles.

Does this apply to your farm?

- Does your farm on average (in the previous three years) have < \$500k annual food sales, AND
- a majority of the food (by value) sold directly to “qualified end-users” defined as:
 - the consumer of the food OR
 - a restaurant or retail food establishment that is located in the same State OR not more than 275 miles from the farm.

If yes to all of the above, a qualified exemption allows farmers to comply with modified requirements of labeling and retention of some records.

A. Modified Requirements of labeling and retention of records

- Disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. Labeling requirement (if applicable) has a compliance date of January 1, 2020.
- Farms are also required to establish and keep certain documentation. Retention of records supporting eligibility for a qualified exemption has a compliance date of the effective date of the final rule, or January 26, 2016.

B. Withdrawal of Qualified Exemptions

- If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, OR
- If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm’s produce that would be covered by the rule.
- There is a procedure for reinstating an exemption that was withdrawn

If no, Continue to Step 5

Step 5

What are my compliance dates and "what do I need to do to be in compliance"?

If you have made it to this step, your farming operation is covered by the Produce Safety Rule; other FSMA rules may apply.

FDA created tiered-compliance deadlines for farms based on annual gross produce sales (3 yr. average):

- All other businesses: >\$500,000 have 2 yrs. * (January 26, 2018)
- Small businesses: > \$250,000 and < \$500,000 have 3 yrs. * (January 28, 2019)
- Very small businesses: > \$25,000 but < \$250,000 have 4 yrs.* (January 27, 2020)

* An additional two years beyond each of these compliance dates for the rest of the rule to comply with certain aspects of the water quality standards and related testing and recordkeeping provisions.

Dates for covered activities involving sprouts:

- All other businesses: >\$500,000 have 1 yrs. * (January 26, 2017)
- Small businesses: > \$250,000 and < \$500,000 have 2 yrs. * (January 26, 2018)
- Very small businesses: > \$25,000 but < \$250,000 have 3 yrs.* (January 26, 2019)

The final rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms focusing the provisions of this rule on five major routes of contamination and includes Sprouts as a separate category:

- Worker Training and Health and Hygiene
- Agricultural Water
- Biological Soil Amendments
- Domesticated and Wild Animals
- Equipment, Tools, and Buildings
- Sprouts

Additionally, the FSMA Produce Safety Rule requires that at least one supervisor or responsible party for your farm successfully completed food safety training on a standardized curriculum before the compliance date.

Need More Information? Visit our website: <http://ncfreshproducesafety.ces.ncsu.edu>