

Not Covered Activities

1. The rule does not apply to:

- Produce that is not a raw agricultural commodity. (A raw agricultural commodity is any food in its raw or natural state)
- The following produce commodities that FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts
- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflowerseed)
- Produce that is used for personal or on-farm consumption
- Farms that have an average annual value of produce sold during the previous three (3) year period of \$25,000 or less

The final rule applies to both domestic and imported produce. The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

2. The rule also provides a qualified exemption and modified requirements for certain farms:

- Farms with greater than \$25K in average annual produce sales may be eligible for the qualified exemption based on the following requirements:
 - The farm must have food sales averaging less than \$500,000 per year during the previous three years; **and**
 - The farm's food sales to qualified end-users must exceed sales to all others combined during the previous three years.
- A farm with the qualified exemption must still meet certain modified requirements, including 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. These farms are also required to establish and keep certain documentation.

A qualified end-user is either:

- The consumer of the food **or**
- *A restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm or not more than 275 miles away.*

3. A farm’s qualified exemption may be withdrawn as follows:

- 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

4. Before FDA issues an order to withdraw a qualified exemption, the agency:

- May consider one or more other actions to protect public health including a warning letter, recall, and administrative detention, refusal of food offered for import, seizure and injunction.
- Must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency.

5. A withdrawn exemption may be reinstated if (as applicable):

- The FDA determines that the outbreak was not directly linked to the farm, **AND/OR**
- The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.
- Farm must request reinstatement of qualified exemption in accordance to subpart R
- Farms need to comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption once the farm’s general compliance date arrives. §112.2(b) (3).

Compliance Dates

(The table below does not include the Subpart E compliance dates (water requirements))

Size of covered farm*	Farms* eligible for a qualified exemption (if applicable)			Farms* eligible for a commercial processing exemption (if applicable)	
	Compliance date for retention of records supporting eligibility in §112.7(b)	Compliance date for modified requirement in §112.6(b)(1)	Compliance date for all other requirements in §112.6 and §112.7	Compliance date for requirements in §112.2(b)(3) –Customer written assurances	Compliance date for all other requirements in §112.2(b)

All other business	N/A			January 27, 2020	January 26, 2018
Small business	January 26, 2016	January 1, 2020	January 28, 2019	January 26, 2021	January 28, 2019
Very small business			January 27, 2020	January 26, 2022	January 27, 2020

**Other than sprouts*

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