

Exemptions

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 sunflower seed)
- Produce that is used for personal or on-farm consumption
- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 (adjusted for inflation) or less

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.

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

- To be eligible for a qualified exemption, the farm must meet two requirements:
 - The farm must have food sales averaging less than \$500,000 (adjusted for inflation) per year during the previous three years; and
 - The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) 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.
- 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- A farm's qualified exemption may be withdrawn as follows: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.
- 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, 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.
- 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.



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1. Requirements for Basic Exemption

If applying for a Basic Exemption, select which one of the following requirements you meet:

- A. Only grow produce that is rarely consumed raw, specifically the produce on the following exhaustive list: 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; ginger; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.
- B. Produce grown is used only for personal consumption or produced for consumption on the farm or another farm under the same management.
- C. Produce grown receives commercial processing that adequately reduces the presence of microorganisms of public health significance.
- D. During the previous 3-year period your annual average of all produce sales was less than \$25,000 (on a rolling basis) adjusted for inflation using 2011 as the baseline year for calculating the adjustment.

2. Requirements for Qualified Exemption:

If applying for a Qualified Exemption, both of the following requirements must be met:

A. During the previous 3-year period, annual average of food* sales are less than \$500,000 adjusted for inflation.
**The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.*

AND

B. You sell more than 50% of your annual food sales to qualified end-users (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).

- I meet both requirements for a Qualified Exemption.

3. Business Information:

Business name: _____ Owner/Manager: _____

Business physical address: _____

Business mailing address: _____

Primary phone number: _____ Secondary phone number: _____

Farm size based on 3-year average of annual produce sales:

- Large farm >\$500,000
- Small farm >\$250,000 to \$500,000
- Very small farm \$250,000 or less

I hereby certify that according to 21 C.F.R. §112.7, I have performed an annual review and verification of my farm's continued eligibility for a qualified exemption.

Owner/Manager signature: _____ Date: _____

Owner/Manager title: _____

Qualified Exemption Review Template

Name and address of farm: _____ Date: _____

Total food sales (in addition to produce, these sales include all other food for humans, feed for animals, and sales of live food animals)

Year 1 (Sales year: _____) \$ _____

Year 2 (Sales year: _____) \$ _____

Year 3 (Sales year: _____) \$ _____

Average total food sales \$ _____ **A**

Inflation adjusted¹ threshold for (range) \$ _____ **B**

(for example, B is \$539,982 for 2015-2017)

A must be smaller than B for eligibility

Sales to qualified end users (QEUs) (e.g. consumers anywhere, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation)

Year 1 (Sales year: _____) \$ _____

Year 2 (Sales year: _____) \$ _____

Year 3 (Sales year: _____) \$ _____

Average food sales to QEUs \$ _____ **C**

Sales to non-QEUs (e.g. wholesale buyers)

Year 1 (Sales year: _____) \$ _____

Year 2 (Sales year: _____) \$ _____

Year 3 (Sales year: _____) \$ _____

Average food sales to non-QEUs \$ _____ **D**

C must be larger than D for eligibility

Based on this information, this farm meets the criteria for a qualified exemption.

Reviewed by: _____ Title: _____ Date: _____

Sales receipts must also be retained to support this record.

¹FDA updates the inflation adjusted value (B) yearly:

<https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>