



Produce Safety Rule Exemptions for Iowa Farms

The U.S. Food and Drug Administration's (FDA) Food Safety Modernization Act's (FSMA) Produce Safety Rule establishes standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. Many Iowa produce farms^a may qualify for an **Exemption** or **Qualified Exemption** from the Produce Safety Rule; others will not qualify for either exemption and will be **Fully Covered**. This document will outline the requirements a farm must meet to qualify for an **Exemption** or **Qualified Exemption**. The complete Produce Safety Rule can be found at the link below:

<http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>.

A. **Exempt:** If your farm meets any of the four requirements below, it qualifies for an exemption and is not covered by the Produce Safety Rule:

1. Farms that grow, harvest, pack or hold **only** agricultural commodities that are rarely consumed raw including food grains^b.
2. Farms that grow, harvest, pack or hold produce that is **only** used for personal or on-farm consumption.
3. Farms with average annual produce (grown or acquired for re-selling) sales less than \$25,000^c over the previous three years.
4. Produce that receives commercial processing (e.g. distilling, commercial canning). Farms that sell covered produce that will undergo such treatments (for example, canning tomatoes, and green beans) must:
 - Disclose in documents accompanying the produce that the food is "*processed to adequately reduce the presence of microorganisms of public health significance*".
 - Obtain an annual written assurance from the customer (buyer) that they have established and are following procedures, identified in the written assurance, that adequately reduce the presence of microorganisms of public health significance – or obtain from the customer (buyer) that a business entity in the distribution chain subsequent to the customer will do likewise (§ Part 112.2). Farms claiming exemption (§ Part 112.2) should maintain records showing proof of exemption.

Examples of an Exempt farm:

A farm sells \$19,000 (three-year average) in produce. This farm is exempt because average annual produce sales over the previous three years are less than \$25,000.

A farm grows and sells \$24,000 (three-year average) in sweet corn. This farm is exempt because average annual produce sales over the previous three years are less than \$25,000, and the crop is rarely consumed raw.

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B. Qualified Exempt: These are farms with average annual *produce* sales greater than \$25,000^c, and average annual *food* sales of less than \$500,000^c over the previous three years **AND** the majority of food sales are directly to qualified end users (§112.5).

1. **Food vs. Produce** - It is important to note that the Produce Safety Rule distinguishes between *food* and *produce* for this calculation. All food sales must be counted when average produce sales exceed \$25,000^c. Food is defined by the Federal Food, Drug, and Cosmetic Act (US Code: Title 21, Subchapter II – Definitions) to include human and animal food. Example products to be included in annual food sales: produce, livestock, grain, corn, soybeans, hay, prepared food, beverages.
2. **Qualified End User** - The consumer of the *food* (an individual, not a business), or a restaurant, or a retail food establishment, or a grocery store, that is located either in the same State or same Indian reservation as the farm that produced the food, or not more than 275 miles from the farm. Wholesale food hubs, food distributors (i.e. the produce is purchased by the hub or distributor) and independent warehouses are not considered qualified end users. For instance, individual grocery stores are Qualified End Users while a grocery distribution center is not.

Examples of Qualified Exempt farms:

A farm grows \$23,000 worth of produce and purchases an additional \$7,000 in produce along with \$5,000 worth of other value-added food for resale. The farm sells this total \$35,000 worth of food (three-year average) at a local farmers market and through their CSA. This farm would be considered Qualified Exempt because its average annual food sales over the previous three years is less than \$500,000 and all of the food is sold to qualified end users.

A farm's total sales of produce is \$475,000 (three-year average). An average of \$200,000 worth of produce is sold to a wholesaler in Indianapolis, Indiana. An average of \$75,000 is sold to several local restaurants. An average of \$200,000 is sold to several local grocery stores. The farm does not grow, harvest, pack or hold any other food. This farm would be qualified exempt because the farm sells the majority of the food to qualified end users and total food sales are under \$500,000.

C. Fully Covered (no exemption): If your farm did not meet the requirements for an Exemption or Qualified Exemption you may be Fully Covered by the Produce Safety Rule.

Examples of Fully Covered farms:

A farm meets the requirements for an exemption or qualified exemption, but does not maintain sales records. This farm would be Fully Covered because farms claiming an exemption or qualified exemption must maintain applicable records.

A farm sells \$35,600 in produce and also sells \$650,000 in other food products, corn and soybeans (average of previous 3 years). Because this farm sells more than \$500,000 in food, it does not qualify as exempt or qualified exempt and is considered fully covered by the Produce Safety Rule.

*A farm sells \$35,000 (average of previous 3 years) in produce to a distributor located more than 275 miles away and not in the same state where the produce was grown. The farm grows potatoes, pumpkins, sweet corn, winter squash, and has 1 acre of raspberries and strawberries. This farm would be considered fully covered because their average annual produce sales over the previous three years is greater than \$25,000 and it is **not** sold to qualified end users. However, the potatoes, pumpkins, sweet corn, and winter squash are not covered crops and are exempt from the rule.*

Additional Information for Qualified Exempt Farms

Qualified Exempt farms must comply with Modified Requirements of the Produce Safety Rule, which are listed below. Qualified Exempt farms must also comply with FDA compliance, enforcement and, when applicable, withdrawal and reinstatement of a Qualified Exemption. For more details, visit the link below and scroll down to the “Modified Requirements” section.

<http://sustainableagriculture.net/blog/produce-rule-analysis-part-1/>

A. Labeling (§112.6)

1. For produce requiring a food packaging label (for example, many grocery stores require labeling)
 - The label must “prominently and conspicuously” include on the food packaging label the name and the complete business address of the farm including the street address or P.O. Box, city, state, and zip code.
 - For produce purchased for resale to “qualified end users” you must also declare on a label, poster, sign, placard, or other documents the name and complete business address including the street address or P.O. Box, city, state, and zip code of the farm that is selling the produce to the qualified end user.

2. For produce that does not require a food packaging label (e.g. farmers market and restaurants):
 - The name and complete business address of the farm including the street address or P.O. Box, city, state, and zip code must be “prominently and conspicuously” displayed on a, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business. In the case of Internet sales, this could include an electronic notice.
 - For produce purchased for resale to “qualified end users” you must also declare on a label, poster, sign, placard, or other documents the name and complete business address of the farm including the street address or P.O. Box, city, state, and zip code.

B. Records (§112.7)

1. A Qualified Exempt farm must keep adequate records necessary to demonstrate that the farm satisfies the criteria for the qualified exemption including:
 - Records that show the farm is below the sales cutoffs.
 - Records that show the farm is selling the majority of food to Qualified End Users.
 - Records or documentation verifying that the purchaser is a Qualified End User.

2. The farm must also keep a written record of an annual review and verification of the farm’s eligibility for the qualified exemption. Records that document status and annual verification do not have to be submitted to FDA, but must be retained and made available upon request.

3. These records are subject to the same general requirements for all records kept under the Produce Rule: they must be detailed, accurate, legible, dated and signed or initialed by the person performing the documented activity; they can be stored offsite as long as they can be retrieved within 24 hours of request for official review; they can be written or electronic; they must be original or true copies; they can be based on existing records.

4. Sales receipts retained to document the \$500,000 threshold for qualified exempt farms do not need to be initialed, but they should be retained long enough to document the qualified exempt status for the applicable year, based on the rolling three-year average.

Additional Resources and Contact Information

GAP Certification: ISU Extension and Outreach offers online GAP (Good Agricultural Practices) training videos. The food safety topics covered in this three-part training provides fruit and vegetable producers with tools and knowledge to help with the Produce Safety Rule compliance. More information on GAP training can be found at <http://www.safeproduce.cals.iastate.edu/iowa-gap-program>

On-Farm Readiness Reviews (OFRR): Iowa State University Extension and Outreach has been conducting voluntary on-farm assessments to help Iowa growers prepare for FDA farm inspections.

The purpose of the OFRR process is to:

- Prepare Iowa farmers for implementation of the Produce Safety Rule
- Help growers better understand how to translate the Produce Safety Rule on their farm
- Help growers assess their readiness for implementation of the Produce Safety Rule
- Provide guidance on how to get individual farms into compliance with the Produce Safety Rule

The OFRRs are free, voluntary, and take less than 2 hours to complete. It is required that at least one person on the farm must have received the Produce Safety Alliance Grower Training certificate; and OFRRs must be conducted during the growing season. To learn more about OFRRs or to sign up contact iowafsma@iastate.edu or 515-294-6773

Contacts

ISU: Dr. Angela Shaw - angelaml@iastate.edu

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FDA: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

^a FDA defines a farm as either 1) a primary farm: an operation under one management in one general, but not necessarily contiguous, location and devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities; or 2) a secondary farm: an operation not located on a primary production farm that is also devoted to farming activities, like harvesting, packing and/or holding raw agricultural commodities (RACs) and where the primary production farm(s) that grows, harvests, and/or raises the majority of those RACs must own or jointly own a majority interest in the secondary activities farm. For more information see the FDA link under the “Contacts” section.

^b Rarely consumed raw produce commodities include: 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. Also 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).

^c Average sales cut offs are annually adjusted for inflation. Visit this site below and click on “Produce Safety” for current inflation-adjusted cutoff. <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>