



Information for Farms that are Exempt or fall under the Modified Requirements of the Food Safety Modernization Act's Produce Safety Rule

Many Iowa produce farms* that are affected by the FDA's Food Safety Modernization Act's (FSMA) Produce Safety Rule will either be **exempt** or fall under the FDA's **modified requirements** portion of the Rule. However, all produce growers are encouraged to assess whether undertaking the requirements for full compliance may be beneficial for their farm operations (information on full compliance can be found below under "C) Full Compliance"). It is also important to remember that all produce farms, exempt or otherwise, must take appropriate measures to minimize the risk of serious adverse health consequences from use of, or exposure to, covered produce and to provide reasonable assurance that the produce is not adulterated as detailed in section 402 of the Food, Drug, and Cosmetic Act. The complete Produce Safety Rule can be found at the FDA's website:

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

A) Exempt Status: The Produce Safety Rule provides for four exemptions. These include farms that 1) grow, harvest, pack or hold **only** agricultural commodities that are not typically consumed raw including food grains**, 2) grow, harvest, pack or hold produce that is **only** used for personal or on-farm consumption, 3) sell produce (grown or acquired for re-selling) with an average annual value during the previous three-year period of \$25,000 or less. The rule also provides a fourth (4) exemption for produce that receives commercial processing (for example, distilling and commercial canning) that adequately reduces the presence of microorganisms of public health significance. Farms that sell covered produce that will undergo such treatments (for example, wine grapes, canning tomatoes, and green beans) must a) disclose in documents accompanying the produce that the food is "not processed to adequately reduce the presence of microorganisms of public health significance," and b) 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).

While the Produce Safety Rule does not apply to exempt farms (§ Part 112.2), records should be kept to show proof of which exemptions apply.

B) Modified requirements are applicable to "**qualified exempt**" farms. These are farms that average over the last three years less than \$500,000 in sales of all food and sell more than half of what is grown directly to "**qualified end users**" (§ 112.5). It is important to note that the rule distinguishes between food and produce. "Food" is defined by the Federal Food, Drug, and Cosmetic Act to mean "articles used for food or drink for man or other animals [and]....articles used for components of any such article" (US Code: Title 21, Subchapter II – Definitions). Please note the reference to "food" in the modified requirements description.

A qualified end user is the consumer of the food (an individual, not a business), or a restaurant, or a retail food establishment, 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 grocery store warehouses are not considered qualified end users.

C) Full Compliance: If you believe your farm does not fall within A) or B) above - that is, your farm on a three year rolling average has equal to or greater than \$500,000 in annual **food** sales and the majority of your sales are not to qualified end-users, you may fall under the “fully covered” portion of this Rule. Visit <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm> for more information.

Some farm examples can help “visualize” exempt status, qualified exempt status, and full compliance:

- A farm sells \$19,000 in produce averaged over a 3 year period at a local market and through a CSA.
 - This farm is under the \$25,000 threshold and is thus exempt from the Produce Safety Rule (see “A” above).
- A farm sells \$30,000 in food averaged over a 3 year period at a local farmers market and through a CSA. The farm grows \$23,000 worth of produce and purchases \$5,000 in produce and \$5,000 other value-added food for re-sale along with produce grown.
 - This farm would fall under the modified requirements (see “B” above): it sells on average over \$25,000 in produce (note this is regardless of whether the produce is grown on the farm or is a mix of purchased and farm-grown produce) so it is not exempt; most if not all of the **food** (produce plus value added) is sold to qualified end users.
- A farm sells \$35,600 in produce, and also sells \$650,000 in other food products, including sauerkraut and jam (3-year rolling average).
 - Because this produce farm sells more than \$500,000 in food, it falls under full compliance: Any produce sold from this farm that is typically consumed raw would fall under full compliance requirements (see “C” above).
- A farm sells \$475,000 in produce (3-year rolling average) with these details: \$200,000 sold to a wholesaler out-of-state/more than 275 miles, \$200,000 to a local restaurant, and \$75,000 to a local grocery store. The farm does not grow, harvest, pack or hold any other food.
 - Because the farm sells the majority of the food to “qualified end users” and sales are under the \$500,000 threshold, the farm would be qualified exempt (see “B” above).
- A farm sells all of their \$27,000 in produce annually 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 sells more than \$25,000 in produce so the farm would **not** fall under exempt status (“A” above); the produce grown that is typically consumed raw – the raspberries and strawberries – **falls under full compliance** (“C” above) since it is **not** sold to qualified end users (“B” above).

The remainder of this document applies only to producers that fall under the modified requirements (see “B” above) of the Produce Safety Rule. Producers that fall under the Modified Requirements portion of the Produce Safety Rule must comply with some Produce Safety Rule measures: primarily 1) labeling and 2) records (see “Additional” for further requirements).

1. Modified Requirements – Labeling (§ Part 112.6)

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 where the produce was grown including the street address or P.O. Box, city, state, and zip code.
- For produce purchased for resale to “qualified end users” the label must also include both the farm and resellers complete business addresses.

Compliance timeline: If the packaging label is required, then the compliance date by which the proper label is required is January 1, 2020.

For produce that does not require a food packaging label (examples would include sales at a farmers’ market and to some restaurants)

- The name and complete business address of the farm including the street address or P.O. Box, city, state, and zip code where the produce was grown 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 any other farms or businesses from which you purchased produce for resale.

Compliance timeline: As opposed to the specific compliance timeline above for packaging labels, farms with produce that does not require a food packaging label have until their general compliance date to comply with these traceability requirements. Those general compliance dates vary by size of operation as follows:

- Farms grossing no more than \$250,000 in produce sales annually (based on a rolling three-year average) are considered very small businesses, and the general compliance date for very small businesses is four years from the effective date of the rule (so, four years from January 26, 2016): **January 26, 2020**
- Farms grossing no more than \$500,000 in produce sales annually (based on a rolling three-year average) are considered small businesses, and the general compliance date for small businesses is three years from the effective date of the rule (so, three years from January 26, 2016): **January 26, 2019**

2. Modified Requirements – Records (§ Part 112.7)

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 threshold.
- Selling more to qualified end users than not.
- That the purchaser is a qualified end user.

Compliance timeline: FDA expects farms that will be claiming the qualified exemption to begin keeping these records as of the effective date of the rule – 60 days after publication – or, starting January 26, 2016.

The farm must also keep a written record that reflects an annual review and verification of the farm’s continued eligibility for the qualified exemption.

Compliance timeline: Farms do not have to begin keeping this record until one year from the farm’s general compliance date. January 26, 2020 for very small businesses, and January 26, 2019 small businesses.

Records that document status and annual verification do not have to be submitted to FDA, but they must be retained and made available upon request.

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.

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.

For recordkeeping, collect invoices where practicable from qualified end-users that help document that the buyer of your produce is indeed a qualified end user.

Additional

Farms falling under the Modified Requirements **must also comply with FDA compliance/enforcement and, when applicable, withdrawal and reinstatement of a qualified exemption. For more details, visit <http://sustainableagriculture.net/blog/produce-rule-analysis-part-1/> and scroll down to the “Modified Requirements” section.**

GAP Certification: Many producers are GAP (Good Agricultural Practices) certified or undertaking training to achieve that goal. Producers are encouraged to undergo GAP training; the general guidelines provided through GAP training can be adapted and/or incorporated into any production system. GAP training through level 3 provides producers with essentially all of the tools and knowledge needed for full compliance under the Produce Safety Rule. More information on GAP training can be found at <http://www.safeproduce.cals.iastate.edu/iowa-gap-program>.

Contacts

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

*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.

**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).