

FSMA Produce Safety Rule

Full exemption and qualified exemption for small farms

Some farms are exempt from complying with part or all of the FSMA Produce Safety Rule. A farm can be fully exempt or have a qualified exemption. These exemptions are based on the size of the operation, its products, and/or its market channels. This document will help small and very small produce farms verify their exemption status based on sales and markets.

What do you need to do?

You do not need to apply for an exemption, but you must keep documentation that verifies your status, such as sales records. You may need to provide these documents to officials, such as a WSDA Produce Safety Program inspector, upon request. The template provided here will help you verify and prove your eligibility status for a *qualified* exemption. For a full exemption, all you need are sales receipts.

How to use this template

This template is to help you verify your qualified exemption status, which is dependent on both sales volume and market channels. Both requirements (a - sales) and (b - markets), discussed below, are based on three-year rolling averages compared against a threshold value. To fill out the template use information from the immediately preceding three calendar years. For example, to determine your eligibility for 2019, enter your data from 2018, 2017, and 2016. If you have been in business for less than three years, use the information for as many years as you have available.

Fill in the boxes shaded light green in both sections. Your rolling averages will automatically appear in the boxes shaded dark green. Compare this number to the threshold requirements (\$500,000 and 50%, as described below) to determine your eligibility status. Remember that you must meet BOTH requirements to be eligible for qualified exemption from the FSMA Produce Safety Rule.

Determine if your farm is fully exempt (excluded) from the FSMA Produce Safety Rule

Farms that gross less than \$25,000 in average annual produce sales (adjusted for inflation) are fully exempt (excluded) from having to comply with any part of the FSMA Produce Safety Rule. This sales threshold is for produce (fruits and vegetables) only. Fully exempt farms will not be inspected. The \$25,000 sales threshold is adjusted for inflation; see the table below.

| | |
|--|----------------|
| Threshold value of gross annual produce sales to meet full exemption, adjusted for inflation | Full Exemption |
| Baseline value for cut-offs (2011) | \$25,000 |
| Value in 2016 | \$26,956 |
| Value in 2017 | \$27,433 |

The value for years 2018 and beyond will be published online by the FDA when they become available at fda.gov/food/guidanceregulation/fsma/ucm554484.htm. Click the drop-down menu for Produce Safety to see the threshold value of food sales for a "not covered farm."

[Link here](#)

Determine if your farm is qualified exempt from the FSMA Produce Safety Rule

Farms that gross between \$25,000 and \$500,000 in annual food sales (adjusted for inflation) **and** sell the majority of their products directly to consumers or to regional businesses may be eligible for a qualified exemption from the FSMA Produce Safety Rule. Qualified exempt farms need to comply with modified parts of the Produce Safety Rule, which are substantially less intensive than the full requirements for "covered" farms. These farms will not be inspected.

Qualified exempt farms must meet both requirements (a) and (b).

(a). Does your farm sell less than \$500,000 in annual food sales?

Food sales include not only produce, but also all food products including dairy products, eggs, meat, animal/pet feed, food ingredients or additives, beverages including alcoholic beverages, live food animals, baked goods, canned foods, candy and snacks. See the FDA Food Drug and Cosmetic Act §201(f) for further detail. The \$500,000 sales threshold is adjusted for inflation; see the table below.

Threshold value of gross annual food sales to meet qualified exemption, adjusted for inflation each year

Qualified Exemption

| | |
|---|-----------|
| Baseline value for cut-offs (2011) | \$500,000 |
| Value in 2016 | \$539,121 |
| Value in 2017 | \$548,654 |
| <p>The value for years 2018 and beyond will be published online by the FDA when they become available at fda.gov/food/guidanceregulation/fsma/ucm554484.htm. Click the drop-down menu for Produce Safety to see the threshold value of food sales for a "Qualified Exemption." Link here</p> <p>and</p> <p>(b). Is a majority of the food (by value) sold directly to a "qualified end-user"?</p> <p>A majority means more than 50% of sales, by dollar value.</p> <p>A "qualified end-user" is either:</p> <ul style="list-style-type: none"> • The consumer of the food (not a business); or • A restaurant or retail food establishment (including grocery stores, convenience stores, and farm-operated businesses selling food directly to consumers as their primary function) that is located in the same state or Indian reservation as, or within 275 miles from, the farm that produced the food. <p>Note: Some, but not all, food hubs count as a "qualified end-user." It depends on the business structure of the specific food hub, and whether it meets the FDA definition of a retail food establishment. It matters who owns the produce along the supply chain and what type of customers the food hub sells to (individual consumers versus other businesses). Each food hub should be considered on a case-by-case basis. You can contact the WSDA Produce Safety Program at producesafety@agr.wa.gov for assistance determining whether your food hub can be considered a qualified-end user.</p> | |

Modified requirements for qualified exempt farms

Qualified exempt farms must follow a modified (and significantly reduced) set of requirements of the Produce Safety Rule, and are exempted from all other aspects of the Rule.

Qualified exempt farms must:

1) Keep sales records and annually verify and document their qualified exempt eligibility status. The template provided in this document is an example of a qualified exemption form you can use to document your eligibility status.

This recordkeeping requirement went into effect January 2016.

2) Prominently label their products with the name and complete business address of the farm where the food was grown. If a food packaging label is required, the farm name and address must be printed on the label. If there is no packaging label (for example, selling loose produce items at a farmers market), the farm name and address must be displayed at the point of purchase, such as on a banner, sign, invoice, etc.

This labeling requirement goes into effect January 1, 2020.

Qualified exempt farms may transition out of this status in any given year if their average annual food sales exceed the \$500,000 threshold (adjusted for inflation), or their sales channels shift away from a majority of qualified end-users. Once a farm loses its qualified exempt status, it must immediately comply with the full set of requirements of the Produce Safety Rule. In addition, the FDA retains the right to remove a farm's qualified exempt status if it determines the farm poses a significant risk to public health, for example by being identified as the source of a foodborne illness outbreak.

Questions?

For more information, refer to the WSDA's Bridging the GAPs Farm Guide, Second Edition, available by searching at agr.wa.gov. See the chapter "Overview of the FSMA Produce Safety Rule." For the exact text of FSMA Produce Safety Rule pertaining to farm and product exemptions, see sections §112.1 through §112.7 of the Rule. [Direct link here](#)

You can also contact the WSDA Produce Safety Program with questions at producesafety@agr.wa.gov.

**FSMA Produce Safety Rule
Qualified Exemption Review Form**

Farm name: _____

Farm address: _____

Date: _____

ANNUAL FOOD SALES - VALUE

Annual food sales are based on a rolling average of the total food sales of the previous three years. Total food sales include sale of produce, meat, eggs, dairy, live food animals, animal feed, value-added food products, and all other food and beverage sales.*

| | |
|-----------------------|--------|
| 2018 Total food sales | \$0.00 |
| 2017 Total food sales | \$0.00 |
| 2016 Total food sales | \$0.00 |

Average annual total food sales: \$0.00

*To be eligible for qualified exemption, the average annual value of total food sales must be less than \$500,000.
Note that this number is adjusted annually for inflation.*

ANNUAL FOOD SALES - BUYERS

Qualified exempt farms must show that the majority of food (by value) is sold directly to qualified end-users. Qualified end users are either consumers, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation.*

| | |
|--|--------|
| 2018 Food sales to qualified end-users | \$0.00 |
| 2017 Food sales to qualified end-users | \$0.00 |
| 2016 Food sales to qualified end-users | \$0.00 |
| Average annual food sales to qualified end-users | \$0.00 |

Percent annual food sales to qualified end-users: #DIV/0!

To be eligible for qualified exemption, the average annual percent of total food sales made to qualified end-users must be greater than 50.0%

Reviewed by: _____

Title: _____ Date: _____

**Sales receipts or other records must be retained to support this record.*

Growers must perform an annual review and verification of records (i.e. sales receipts) supporting the farm's continued eligibility for qualified exemption from the Produce Safety Rule. This record and supporting documents must be reviewed, signed, and dated by a supervisor or responsible party within a reasonable time after the record is made.

Refer to FSMA Produce Safety Rule sub-sections §112.5, §112.6, and §112.7

FSMA Produce Safety Rule Qualified Exemption Review Form

Farm name: _____

Farm address: _____

Date: _____

ANNUAL FOOD SALES - VALUE

Annual food sales are based on a rolling average of the **total food sales** of the previous three years.*
Total food sales include sale of produce, meat, eggs, dairy, live food animals, animal feed, value-added food products, and all other food and beverage sales.

| | |
|-----------------------|--|
| 2018 Total food sales | |
| 2017 Total food sales | |
| 2016 Total food sales | |

| | |
|---|-------|
| Average annual total food sales: | _____ |
|---|-------|

[SUM of 2018, 2017, and 2016 total food sales] ÷ 3

*To be eligible for qualified exemption, the average annual value of total food sales must be less than \$500,000.
Note that this number is adjusted for inflation annually.*

ANNUAL FOOD SALES - BUYERS

Qualified exempt farms must show that the majority of food (by value) is sold directly to **qualified end-users**.* Qualified end-users are either consumers, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation.

| | |
|--|--|
| 2018 Food sales to qualified end-users | |
| 2017 Food sales to qualified end-users | |
| 2016 Food sales to qualified end-users | |

| | |
|--|--|
| Average annual food sales to qualified end-users | |
|--|--|

[SUM of 2018, 2017, and 2016 food sales to QEU] ÷ 3

| | |
|--|-------|
| Percent annual food sales to qualified end-users: | _____ |
|--|-------|

[Average annual food sales to QEU ÷ Average annual total food sales] x 100

To be eligible for qualified exemption, the average annual percent of total food sales made to qualified end-users must be greater than 50.0%

Reviewed by: _____

Title: _____ Date: _____

**Sales receipts or other records must be retained to support this record.*

Growers must perform an annual review and verification of records (i.e. sales receipts) supporting the farm's continued eligibility for qualified exemption from the Produce Safety Rule. This record and supporting documents must be reviewed, signed, and dated by a supervisor or responsible party within a reasonable time after the record is made.

Refer to FSMA Produce Safety Rule sub-sections §112.5, §112.6, and §112.7