



FSMA Produce Safety Rule: Qualified Exemption

An Eligibility and Annual Determination Worksheet

At a Glance

Many farms in Hawai'i may be eligible for a qualified exemption from the Food Safety Modernization Act Produce Safety Rule.

All farms, regardless of size or exemption status, should follow Good Agricultural Practices (GAPs) to minimize the risk of microbial contamination on fresh produce. Growing and selling safe produce is every farm's responsibility. However, the size, scale of production, and distribution or marketing channels can influence a farm's impact on public health. Growers in Hawai'i use a variety of means to market and distribute their produce, with varying levels of risk associated with their supply chains.

For example, a farm that ships its produce to multiple states, where the produce is then sold and distributed by wholesalers, has a higher level of risk due to the potentially serious and widespread impact on public health if an outbreak were to occur. Conversely, a farm that primarily sells its produce at farmers markets and to local restaurants has a limited geographic reach and a much simpler supply chain, and therefore would have a lesser impact on public health if an outbreak were to occur. The latter describes many farms in Hawai'i.

The Food Safety Modernization Act Produce Safety Rule (FSMA PSR) provides a qualified exemption with modified requirements. Certain farms are eligible for a qualified exemption based on total food sales, and to whom these sales are made.

Eligibility for a Qualified Exemption

Eligibility for a qualified exemption is determined annually using the following criteria:

- The farm must have gross total food sales averaging less than \$500,000 per year adjusted for inflation during the previous three years; AND
- The farm's direct sales to qualified end-users must exceed sales to all other buyers combined during the previous three years.

Modified Requirements for Qualified Exempt Farms

Recordkeeping Requirements (21 CFR § 112.7)

Qualified exempt farms must keep records to establish their eligibility and demonstrate that the farm meets the criteria for a qualified exemption. These include documentation, such as sales receipts and invoices with dates, as well as written records of an annual review and verification of the farm's continued eligibility for a qualified exemption. The annual review must be reviewed, dated, and signed by a supervisor or responsible party. The determination tool (see "Annual Determination" below) can be used as documentation to support a farm's eligibility.

Labeling Requirements (21 CFR § 112.6 (b))

Qualified exempt farms are subject to the modified requirement relating to produce labeling and signage:

- When a farm uses packaging for any produce that would be considered "covered produce," the farm name and complete business address must be displayed prominently and conspicuously on the label.
- When selling "covered produce" that does not require a label, you must prominently and conspicuously display the farm name and complete business address at the point

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of purchase. This could be on a poster, sign, banner, or documents delivered with the produce. This information could also be included in receipts and as a notice on the company's website for Internet sales.

- The complete business address must include the street address or post office box, city, state, and zip code.

FDA Withdrawal of Qualified Exemption (21 CFR § 112.201)

All farms, even those with a qualified exemption, may have farm food safety issues that lead to recalls or foodborne illness outbreaks. In these situations, FDA may withdraw a farm's exemption if:

- There is an active investigation of a foodborne illness outbreak that is directly linked to a farm.
- It is necessary to protect public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm relevant to the safety of "covered produce."

Determination and Documentation

Qualified exemptions are determined annually using sales records from the previous 3-year period. Each farm is responsible for establishing its eligibility and documenting its annual reviews along with sales records. For these reasons, it is critical that farms keep its sales records organized and easily accessible.

For more information, please contact the CTAHR Farm Food Safety Team at ctahrgap@hawaii.edu.

Key Definitions

Food Sales: includes all food for human beings (e.g., produce, value-added or processed foods, meats, seafood, dairy), feed for animals, and sales of livestock.

Qualified End-User: (a) the consumer of the food (in any location) 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. Restaurants and retail establishments located in another state or country may be qualified end users if they are within 275 miles of the farm.

Annual Determination for a Qualified Exemption from the FSMA Produce Safety Rule

using the following "FSMA Produce Safety Rule: Qualified Exemption Annual Review Worksheet"

Before completing this worksheet:

- Read and review the eligibility criteria and modified requirements for a qualified exemption.
- Read and understand the definitions of "food sales" and "qualified end-user."
- Gather all sales records for the previous 3-year period and organize them by customer type.

How to complete this worksheet:

Step 1: Enter the farm's name, address, date, and year of review

Step 2: Complete Table 1

1. Enter each of the three years this review encompasses.
2. Enter the gross total food sales for each year. 'Average Total Food Sales' should be calculated automatically.
3. Determine the inflation-adjusted cutoff for the \$500,000 total food sales requirement of the Produce Safety Rule qualified exemption by visiting the FDA and scrolling down to the "Produce Safety Rule" tab.
4. If your average total food sales is less than the inflation-adjusted cutoff, continue to Table 2. If it is higher, the farm is not eligible for a qualified exemption.

Step 3: Complete Table 2

1. Enter gross total food sales by customer type (qualified end-users and other food sales) for each year.
2. The 'Average Total Food Sales by Customer Type' should be calculated automatically.
3. If your average total sales to qualified end-users exceeds sales to other customer types, the farm is eligible for a qualified exemption.

Step 4: Review and Document

1. A farm should meet the requirements for a qualified exemption if:
 - * Total gross food sales average less than \$500,000 per year, adjusted for inflation, during the previous three years; and
 - * Direct sales to qualified end-users exceed sales to all other food sales combined during the previous three years.
2. The farm owner, operator, or manager must review and sign this document.
3. Save this worksheet and document it with sales records for the corresponding three-year period.



FSMA Produce Safety Rule: Qualified Exemption Annual Review Worksheet

Farm Name: _____	Date: _____
Farm Address: _____ _____	Review for the year: _____

Table 1: Total Food Sales in the Previous 3 Years

Year 1	\$ _____
Year 2	\$ _____
Year 3	\$ _____
Average Total Food Sales	\$ _____
Inflation-adjusted cutoff	\$ _____
Is the average total food sales from the previous 3 years is less than the \$500k cutoff, adjusted for inflation?	
Yes (Continue to Table 2)	No (Farm does not meet criteria for Qualified Exemption for this year)

Table 2: Comparison of Food Sales to Qualified End Users and Other Food Sales

	Sales to Qualified End Users	Other Food Sales (to non-qualified end users)
Year 1	\$ _____	\$ _____
Year 2	\$ _____	\$ _____
Year 3	\$ _____	\$ _____
Average Total Food Sales by Customer Type	\$ _____	\$ _____
Is the average total food sales to Qualified End Users greater than sales to non-Qualified End Users?		
Yes (Review and sign document)		No (Farm does not meet criteria for Qualified Exemption for this year)

Based on this information, this farm meets the criteria for a qualified exemption from the FSMA Produce Safety Rule

Reviewed by:

Print Name: _____	Sign: _____
Title: _____	Date: _____

