



Qualified Exemption Status Review and Verification - Instructions

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This information and the accompanying worksheets are meant to help with understanding some parts of the Produce Safety Rule and related rules, and documenting compliance with the rule. It has not been reviewed by the FDA, or approved by the FDA.

These worksheets were in collaboration with University of Wisconsin Extension. I would like to thank UW Extension for their support.

The Food Safety Modernization Act Produce Safety Rule provides for two exemptions from the rule:

1. Farms with an average annual monetary value of produce sold during the previous three years of \$25,000 or less are not a “covered farm” under the Produce Safety Rule (§ 112.4);
2. Farms with more than \$25,000 of produce sales but less than \$500,000 of food sales *may be* eligible for a “qualified exemption” from the rule, with modified requirements (§ 112.5).

Please note that the Produce Safety Rule has strict definitions for “produce” and “food”, which are addressed in full at the end of this document. In brief, *produce* means any fruit, vegetable, mushrooms, sprouts, peanuts, tree nuts, and herbs; *food* means anything used for food or drink for people or animals.

Please note that the dollar figures above should be adjusted for inflation from a 2011 basis. Instructions for making this inflation adjustment are included in Step 3 of this document.

If your farm is eligible for the qualified exemption, you still have to comply with parts of the rule pertaining to the general provisions, records, compliance and enforcement, and rules governing the of the withdrawal of the qualified exemption (§ 112.6)

In addition, farms eligible for the qualified exemption must meet modified requirements for product labeling at the point of sale (§ 112.6). This document does not address these requirements.

Purpose of the Accompanying Record Forms

If your farm is eligible for a qualified exemption, you must provide a written record reflecting that you have performed an annual review and verification of your farm’s continued eligibility for the qualified exemption.

The accompanying records are designed to help you:



- Determine and document whether your customers meet the definition of a “qualified end-user”;
- Determine whether your sales numbers meet the criteria for the qualified exemption; and
- Provide documentation of your review and verification of your farm’s continued eligibility for the qualified exemption.

These record-keeping forms do not help you determine if your farm is a “not-covered farm” due to produce sales of less than \$25,000.

These instructions refer to two accompanying record forms which are meant to be used in conjunction with each other:

- The Annual Summary of Farm Sales of Food; and
- Annual Review and Verification of Qualified Exemption from FSMA Produce Safety Rule

These records are one way to complete the documentation requirement, but they are not the *only* way. Using these particular forms is not required by the Produce Safety Rule.

Users of these records have final responsibility for understanding the rules surrounding the qualified exemption, and how the exemption applies in their individual situation. The details of the eligibility requirements for the qualified exemption are spelled out in §112.5 of the Produce Safety Rule.

While parts of the accompanying forms may seem self-explanatory, please refer to these instructions as you complete them - there are some important details and explanations that simply didn’t fit on the form.

COMPLETE THE ANNUAL SUMMARY OF FARM SALES OF FOOD

The qualified exemption considers food sales for each of the three previous calendar years. If this is the first time that you have completed an annual review and verification of your qualified exemption from the Food Safety Modernization Act Produce Safety Rule, you will need to complete one Annual Summary of Farm Sales of Food for each of the three previous calendar years, unless you have already completed one for a given year.

Step 1: Enter Your Farm’s Data

Start by entering the calendar year for the sales you are summarizing where indicated at the top of the form; the Produce Safety Rule specifies that for the qualified exemption, sales are considered on the basis of the three previous calendar years.

Enter the following information under Step 1:

- Your farm’s name: the Produce Safety Rule requires that your farm name appear on all records.
- Your farm’s address: the Produce Safety Rule requires that your location appear on all records.

- Your farm’s state: we ask for your state separately because it is important for determining whether a customer is a qualified end-user.
- If your farm is located on an Indian reservation, enter the name of that reservation here.

Also, sign your name and date the document for the date you are completing this summary. The Produce Safety Rule requires a signature and date as part of the annual review and verification of a qualified exemption.

Since you can use the Annual Summary of Farm Sales of Food for multiple reviews (e.g., you can use the Annual Summary of Farm Sales of Food from 2016 when you do your annual review and verification in 2017, 2018, and 2019), you should sign and date this document separately.

If this is your first year in business, FDA guidance indicates that you should estimate your sales for the coming year.

Step 2: Enter Sales Data

For each customer, follow the instructions below. There are several potential steps to determining if a customer is a qualified end-user. This form is designed so that as you fill in the information from left to right, as soon as you determine that a customer *is* or *is not* a qualified end-user, you can move to entering their sales information. You don’t need to complete every column for every customer.

Please note that for each customer, you will complete either Column E or Column F; a given customer is either a qualified end-user or is not.

IMPORTANT: The qualified exemption is based on your farm’s sale of **food**, not produce. *Food*, according to the FDA, is anything used for food or drink for people or animals. When you enter sales numbers in Step 2, those sales numbers must be for the value of all food sold by your farm.

How to Complete Step 2:

1. Column A: Enter the customer’s name. For direct-to-consumer sales, you will probably want to summarize your sales as follows (in other words, you don’t need to list individuals involved in direct-to-consumer sales):
 - For Farmers Market, enter the name of the farmers market; e.g., Wednesday Hillsdale Market, or Saturday Dane County Farmers Market.
 - For your farm’s own CSA customers, enter the name of your farm and “CSA”; e.g., “Rocky Falls Ranch CSA”.
 - For sales at a farm stand owned by your farm, enter the location of the farmstand; e.g., “Rocky Falls Ranch Hwy 151 Farmstand”.
 - For other sales directly to the consumer of the food, identify the way that you sold the food (for example, “Internet sales to consumers”).
2. Column B: Enter the customer type: Consumer, Restaurant, RFE, or Other:

- **Consumer:** A person not representing a business; generally limited somebody purchasing food to eat for themselves or their family. The term *consumers* does not include businesses.
 - **Restaurant:** A facility that prepares and sells food directly to consumers for immediate consumption. See the complete definition at the end of this document.
 - **Retail Food Establishment (RFE):** A retail food establishment's primary function is to sell food products directly to consumers. Examples include: grocery stores, or other outlets serving a similar function, such as a farm stand that you don't own that sells food to consumers; another farm's CSA; or a home delivery service. See the complete definition at the end of this document.
 - **Other:** Any customer that does not fit the above three categories, such as a wholesale distributor.
 - **Regarding produce auctions:** If you sell your produce *through* a produce auction or food hub instead of *to* an auction or food hub, the customer who purchased the food will need to be identified as either a Consumer, Restaurant, RFE, or Other. What do we mean by "through" instead of "to"? As long as a produce auction or food hub is simply a location for buyers and sellers to meet and transfer produce, and as long as the food is not stored, the farmer is selling *through* the auction or food hub.
3. If the customer is not a consumer, restaurant, or RFE (retail food establishment), draw a dash in Columns C,D, and E, and enter your total food sales to this customer in Column F; you have completed this row. Otherwise, continue to the next step.
 4. If the customer is a consumer, draw a dash in Columns C and D, and enter your total food sales to this customer in Column E; you have completed this row. Otherwise, continue to the next step.
 5. Column C: Enter the customer's state. If the state is the same as your farm's state, enter a dash in Column D; enter your total food sales to this customer in Column E¹; you have completed this row. Otherwise, continue to the next step.
 6. Column D: Enter the distance from your farm to the customer in miles. If the distance is less than 275 miles, enter your total food sales to this customer in Column E. If the distance is 275 miles or more, enter your total food sales to this customer in Column F.

Please note that the Produce Safety Rule requires that you enter actual values for data; in other words, if you need to complete column D, you must enter the actual miles to that customer, rather than, for example, "<100".

When you have entered sales for each customer, enter the totals for Columns E and F at the bottom of the table.

¹ If you farm on an Indian reservation and the customer is not in the same *state* as your farm but *is* in the same Indian reservation, note that in Column C, enter a dash in column D, and enter your total food sales to that customer in Column E.

COMPLETE THE ANNUAL REVIEW AND VERIFICATION OF QUALIFIED EXEMPTION

Where indicated at the top of the form, enter the calendar year for which you are conducting this review.

Step 3: Enter Sales Data for Three Previous Years

To complete the review, you will need to have completed the Annual Summary of Farm Sales of Food for each of the three previous calendar years (in other words, if you are doing this verification in January, 2018, you will need to have completed an Annual Summary of Farm Sales of Food for 2017, 2016, and 2015).

How to Complete Step 3

1. For Rows 1, 2, and 3, use the data from the Annual Summary of Farm Sales of Food to complete Columns A, B, and C. If any value is 0 for a given year, enter a "0".
2. In Row 4, enter the average of the sales above in Column B and Column C.
 - a. The calculation for an average is: add together the values from Rows 1, 2, and 3, and divide that sum by three.
 - b. If your farm is just beginning operations and does not have a history of food sales, you may use a projected estimate of revenue when you begin operations.
 - c. If your farm has only had food sales for one or two previous years, you may make the average calculation using only the previous years in which you have food sales.
3. In Row 5, Column C, enter the sum of the two values in Row 4.
4. If the value you entered in Row 5, Column C is less than \$500,000, enter \$500,000 in Row 5, Column B; otherwise, follow the instructions below to find the correct value to enter.

Inflation Adjustment in Cell B5

One of the two eligibility requirements for the qualified exemption is that the average annual monetary value of all food sold in the three-year period preceding the applicable calendar year be less than \$500,000; however, that \$500,000 is adjusted for inflation using a baseline year of 2011. This complicates things a little bit but does mean that the number will be consistently adjusted upwards as time goes on.

If the average of your food sales for the past three years is less than \$500,000, you don't need to worry about finding the inflation-adjusted value. Simply enter \$500,000 and move on.

If the average of your food sales for the past three years is \$500,000 or more, you will need to find the current inflation-adjusted value of \$500,000 in 2011. The FDA provides these values at <https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>; the actual number appears when you click on the Produce Safety header. Use the "Average 3 Year Value" listed at the right end of the table.

FSMA Inflation Adjusted Cut Offs

Implicit Price Deflators for Gross Domestic Product (GDP)

Several FSMA rules have provisions in which a value is adjusted for inflation and averaged over 3 years. We provide the values based on Price Deflators for Gross Domestic Product (GDP) and the average for the most recent 3 years for the applicable rules below. The GDP deflator is not a static number, and changes monthly. We intend to update the values at the end of March each year.

	2011	2012	2013	2014	2015	2016
GDP Deflator	103.435	105.338	107.038	108.547	110.09	111.528

Produce Safety

Qualified Exemption: A farm is eligible for a qualified exemption if the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, and sales to qualified end-users during such period exceeded the average annual monetary value of the food sold by such farm to all other buyers.

Baseline Value for Cut-offs (2011)	Value in 2012	Value in 2013	Value in 2014	Value in 2015	Value in 2016	Average 3 Year Value for 2014 - 2016
\$500,000	\$509,199	\$517,417	\$526,645	\$532,170	\$539,121	\$532,645

Not covered farm: A farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of less than \$25,000 (on a rolling basis).

Baseline Value for Cut-offs (2011)	Value in 2012	Value in 2013	Value in 2014	Value in 2015	Value in 2016	Average 3 Year Value for 2014 - 2016
\$25,000	\$25,460	\$25,871	\$26,332	\$26,608	\$26,956	\$26,632

When you have this information, enter it in Row 5, Column B.

Step 4: Determination

In Step 4, you will evaluate the data you compiled in Table 2 to determine if you are eligible for the qualified exemption. Simply circle the answer for each question in Table 3.

To be eligible for the qualified exemption, your answers must be as follows:

- Question 1: Yes
- Question 2: Yes
- Question 3: No

If ALL of your answers to questions 1, 2, and 3 match the answers above, your farm IS ELIGIBLE for the qualified exemption. Proceed to Step 5.

If one or more of your answers does not match the answers above, your farm is NOT eligible for the qualified exemption, and this documentation is not required. Your farm must meet the full requirements of the Food Safety Modernization Act Produce Safety Rule.

Step 5: Review and Sign

If your farm is eligible for the qualified exemption, check the box to confirm that you have reviewed and verified this farm's eligibility for the qualified exemption, and determined that it does meet the requirements.

Enter your name and title where indicated. The FDA expects that this review will be conducted by the owner, operator, or agent responsible for this farm.

Enter your farm name and address where indicated. The Produce Safety Rule requires that your farm name and location appear on all records. As this is a separate form from the Annual Summary of Farm Sales of Food, we recommend that you enter this information again here.

Sign and date the document. The Produce Safety Rule requires a signature and date as part of the annual review and verification of a qualified exemption.

A NOTE ABOUT SALES RECORDS

The Produce Safety Rule requires you to keep sales records to demonstrate your eligibility for the qualified exemption. This spreadsheet is NOT A SUBSTITUTE for those records. This spreadsheet provides a review of your sales records; you are still required to maintain the sales records from which you derive the data you are going to enter here.

Sales records are required to include the date of the sale, but do not have to be signed.

The Produce Safety Rule does not describe requirements for documenting individual transactions at farmers market; if you do not use a point-of-sale system at farmers market, we recommend that you document total sales of food each time you attend a farmers market. If you use a POS system for credit and debit cards, include those sales.

Additional Documentation of Customer Addresses

FDA guidance indicates that you should document the address of the entities you are selling to. You don't need to do that on this form. (Please note: for sales to *consumers*, you don't need to document addresses, because their location does not matter with regards to their status as a qualified end-user.)

If you use QuickBooks or other program to invoice customers, you can track their address there - as long as you clearly use the same name on the spreadsheet and in your invoicing program.

If you don't use bookkeeping software, you will need to record customer addresses in some other way.

If you sell your produce through a produce auction or food hub (please see Step 2, part 2, regarding produce auctions), you will need documentation of the customer who purchased the food, the customer's address, and the dollar amount sold to each customer.

DEFINITIONS

Food

In brief, *food* is anything used for food or drink for people or animals.

According to the FDA, *food* has the meaning given in section 201 (f) of the Federal Food, Drug, and Cosmetic Act: 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.

The FDA provides further examples in 21CFR1.227: “Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.”

Produce

In brief, *produce* means any fruit, vegetable, mushrooms, sprouts, peanuts, tree nuts, and herbs.

According to the Produce Safety Rule § 112.3, *produce* means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). **Produce does not include** food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include 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).

Restaurants and Retail Food Establishments

According to the FDA regulations (21CFR1.227), these are the definitions for a *restaurant* and a *retail food establishment*:

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

- (1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and
- (2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.