

**Determine where your farm falls under the Produce Safety Rule (PSR)
Template for 2021**

Name and address of farm: _____ **Date:** _____

The objective of this document is to help farms determine their status within the Produce Safety Rule. The questions outlined follow a specific order so that the reader can have the pertinent information required to determine if the farm is not covered, eligible for a qualified exemption and modified requirements or a covered farm. If you need assistance, contact information for NCSU Produce Safety Team is listed on page 6.

Definition of Produce

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).

1. Do you **only** grow produce for personal or on-farm consumption?

Yes _____ No _____

If your answer is **Yes**, then you are not covered by the Produce Safety Rule.
If your answer is **No**, go to question 2.

2. Use sales receipts or records to determine **produce** sales for the farm over the previous 3 years. Count **all** produce sold by the farm regardless of the fact the produce may be covered or not covered by the PSR or exempt.

Year 1 (Sales year: 2018)	\$ _____	
Year 2 (Sales year: 2019)	\$ _____	
Year 3 (Sales year: 2020)	\$ _____	
Add produce sales for Years 1-3	\$ _____	divide this number by 3
Average total produce sales for years 1-3	\$ _____	

Based on published FDA inflation rates for 2021*, if the average produce sales for the past three years are under \$28,561* the farm is not covered by the PSR. If you need further assistance, go to page 6.

If the average produce sales for the past three years are greater than \$28,561* go to question 3.

*Source: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

Created by: _____ **Date:** _____

Farms that are not covered by the PSR are not required to have a written record but this record is helpful in reassuring the status under the law.

3. Do you **only** grow “rarely consumed raw” produce?

Yes _____ No _____

Rarely consumed raw (RCR) produce are fruits and vegetables that are almost always cooked before being consumed. FDA considers that the following commodities are **rarely consumed raw**: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts. This is an exhaustive list. Note that **rarely consumed raw** produce is also referred to as **not covered produce** in the Produce Safety Rule. For more information on this subject, search for [FDA’s Fact Sheet Rarely Consumed Raw Produce](#).

If you answered **Yes**, the farm **only** grows **rarely consumed raw** produce then the farm is **exempt from the Produce Safety Rule** but is still subject to the provisions of the Federal Food, Drug and Cosmetic (FD&C) Act. In other words, the farm is responsible for making sure the produce is safe for human consumption.

If you answered **No**, go to question 4. Note that if you grow, pack or hold any **rarely consumed raw** commodities these will not be inspected if you operate a **covered farm** during routine inspections. A covered farm can voluntarily follow practices outlined in the PSR for **rarely consumed raw** commodities but if the farm chooses not to follow practices, these have to be separated from all other crops that are subject to inspection while being packed or on hold at a packing house.

4. Do you grow produce that is intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?

Yes _____ No _____

If you answered **Yes**, then the farm must annually obtain a written assurance from either the customer performing the commercial processing or from your customer that an entity in the distribution chain subsequent to customer will perform commercial processing. Produce for which the grower has a written assurance that it will be commercially processed with a “kill” step is exempt from the PSR. Enforcement discretion for this guideline is in place (April 2021). Growers will need to have a written assurance once FDA terminates the period for enforcement discretion. To learn more visit: <https://www.fda.gov/media/110052/download>

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/ dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.

Produce sold to restaurants that will be later cooked should not be included in this category.

If you answered **No**, go to question 5.

5. Determine if a farm is eligible for a Qualified Exemption and Modified Requirements.

To be eligible for this category, a farm must meet both requirements:

Requirement 1: Average food sales must be under \$571,214* for years 2018-2020.

Requirement 2: The majority of food sales must be made to Qualified End Users (QEU) for years 2018-2020.

The dollar amounts listed here are based on the adjusted inflation rates published by FDA for 2021.

*Source: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

Requirement 1. Determine food sales for the farm.

Food is defined as articles used for food or drink for man or animals, or articles used to make components of it. It includes seeds and beans used to grow sprouts. 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. Livestock and meat are both food within this definition. Consider that cotton, tobacco and timber are not considered food.

If you operate a poultry or hog farm for an integrator typically the grower does not own the animals. Growers' payments are for day to day care of the animals and therefore are not considered food. Verify this information before proceeding.

Use sales receipts or records to determine **total food** sales over the previous 3 years. Count **all** produce sold by the farm regardless of the fact the produce may be covered, rarely consumed raw or exempt (further processed) by the PSR.

Year 1 (Sales year: 2018)	\$ _____	
Year 2 (Sales year: 2019)	\$ _____	
Year 3 (Sales year: 2020)	\$ _____	
Add food sales for Years 1-3	\$ _____	divide this number by 3
Average total food sales for years 1-3	\$ _____	

Are the average food sales over \$571,214 for the last three years?

Yes ___ No ___

If the answer is **Yes**, then the farm cannot claim a qualified exemption and is likely to be a covered farm. A covered farm is subject to inspections and must follow the practices outlined in the Produce Safety Rule. Go to page 6 for a list of resources if you need assistance.

If your answer is **No**, then go to requirement 2.

Requirement 2: The majority of food sales must be made to Qualified End Users (QEU) during the last three years.

Determine **food sales to qualified end users (QEU) over the last three years**. Qualified end users are people who will consume/eat the food they are buying from the farm. Such consumers include those that buy from you at a farm stand, farmers market, through Community Supported Agriculture, through the internet or any other direct marketing channel. This also includes sales the farm made to retail food establishments (grocery stores that you deliver to directly) and restaurants within 275 miles of your farm.

	2018	2019	2020	Average food sales (2018-2020)
Sales to Qualified End Users (QEU)				
Directly to consumers (regardless of location)				
Retail food establishments within 275 miles of the farm (grocery stores) or restaurants				
Others	↓	↓	↓	
A- Total Food Sales to QEU by year	A1	A2	A3	A4=(A1+A2+A3)/3
Sales to businesses (not Qualified End Users)				
Brokers				
Distribution centers				
Retail food establishments or restaurants farther than 275 miles from the farm				
Processors				
Packers				
Others	↓	↓	↓	
B- Total Food Sales to businesses (not QEU)	B1	B2	B3	B4=(B1+B2+B3)/3

(A4) Average sales to QEU _____

(B4) Average sales to businesses (non QEU) _____

Are the average food sales to QEU **(A4)** greater than sales to businesses **(B4)** that are not considered Qualified end users? Yes _____ No _____

If the answer is **Yes**, then the farm has met the second requirement to be eligible for a qualified exemption.

If the answer is **No**, then the farm cannot claim the exemption and is likely to be a **covered farm**. A covered farm is subject to inspections and must follow the practices outlined in the Produce Safety Rule.

Further verification

$$(\$ \underline{\hspace{2cm}} \div \$ \underline{\hspace{2cm}}) \times 100 = \underline{\hspace{2cm}} \%$$

(A4) Average food sales to qualified end users (years 1-3)	Average total food sales (years 1-3)	Percent sales to qualified end users
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If you follow this template and the sales to qualified end users are 51% or more, then the farm has met both requirements listed to be eligible for a qualified exemption and modified requirements.

*Sales receipts must also be retained to support this record.

Created by:
Date:

Reviewed by:
Date:

FSMA PSR Reference § 112.7(b) Confidential Record

Responsibilities for farms under the Produce Safety Rule

1. Farms not covered: It is recommended to have a financial record to reassure produce sales are under the threshold established by FDA. A written record is not required by the Produce Safety Rule.
2. Farms that are eligible for a Qualified Exemption and Modified Requirements.
 - a. The farm must establish and keep adequate records necessary to demonstrate that the farm satisfies the criteria for a qualified exemption, including a written record reflecting that an annual review has been performed and verification of the farm’s continued eligibility for the qualified exemption. A sample record is provided on pages 3-5. In addition to the review, receipts must accompany this record. All farms that fall under this category will need written financial records annually. The records do not need to be sent to NCDA Produce Safety Office, they are for the farm to have in the event they are contacted about the status of their farm under the PSR.
 - b. Modified labeling: The labeling requirement consists of including the name and complete business address of the farm where the produce was grown either on the label of the produce, display the same information at the point-of-purchase or in documents delivered with the produce during a shipment. The labeling requirement became effective January 20, 2020 for all farms that claim a qualified exemption. This labeling requirement does not apply to covered farms. For more information on labeling, see link below.
 - c. Grow produce under sanitary conditions and not place in commerce **adulterated food**. FDA can withdraw a qualified exemption if produce is adulterated. Produce is adulterated when it has been grown, harvested, packed or held in a farm under such conditions that it is unfit for food or if it has been prepared, packed or held under unsanitary conditions where it can be contaminated with filth or have been rendered injurious to health.

A qualified exemption can be withdrawn in the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm; or if FDA determines that is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm that are material to the safety of the food.

For more information about qualified exemptions and modified requirements go to:

<https://ncfreshproducesafety.ces.ncsu.edu/what-are-the-requirements-for-small-and-medium-scale-farms/>

3. Covered farms. Covered farms are farms whose average food sales over the past 3 years are greater than \$571,214 or that even when the sales are below that threshold they sell most of the food they grow, harvest, pack and/or hold to non-qualified end users (through brokers, distribution centers, etc.).

a. A covered farm must have a responsible party attend the Produce Safety Alliance training.

b. The farm must implement the practices outlined in the Produce Safety Rule.

c. The farm must be ready for inspections. In North Carolina, inspections will generally be conducted by personnel from the NCDA C&S Produce Safety Program even though FDA inspectors can also do inspections. These are announced inspections where a farmer will be contacted and notified that they will be undergoing an inspection in the near future.

If after filling out this template, you need help understanding how the Produce Safety Rule impacts your farm contact your local County Extension Agent <https://www.ces.ncsu.edu/directory/> or Area Specialized Agents- Food Safety – Fresh Produce with NC Cooperative Extension. More information can also be found at <https://ncfreshproducesafety.ces.ncsu.edu>

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