



Pennsylvania
Department of Agriculture

FSMA PRODUCE SAFETY RULE APPLICATION PACKET

PRODUCE FARMS EXEMPTION VERIFICATION

Any facility growing, harvesting, packing, and holding produce grown for human consumption that is claiming an exemption status

The Pennsylvania Department of Agriculture produce farm application is required for produce farms and/or any entity that grows, harvests, packs, or holds covered produce for human consumption as defined in 21 CFR Part 112. This application allows PDA to provide education, technical assistance, and compliance information to regulated farms and businesses, and prioritize inspections.

The Food Safety Modernization Act Produce Safety Rule (PSR) requires covered farms to take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of or exposure to covered produce including those measures reasonably necessary to prevent the introduction of know or foreseeable hazards into covered produce. It also provides reasonable reassurance that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (FD & C Act). Requirements for the rule (21 CFR Part 112) focus on major routes of contamination including health and hygiene, biological soil amendments of animal origin, domesticated and wild animals, equipment, tools, buildings, and sanitation. The PSR also addresses personnel qualifications and training and growing, harvesting, packing, and holding activities performed by the operation.

In accordance with 21 CFR Part 112, various forms of exemption under the Produce Safety Rule may be attained. This Produce Farm Exemption Verification application is to be completed to support the determination of any applicable exemption and shall be submitted to the Department after every 3 years of business to verify exemption status. Please complete and return this form in its entirety including all necessary accompanying documentation to verify the exemption status of your produce farm from complying with 21 CFR 112 Produce Safety Rule (PSR). An internal audit of a facility's exemption status is recommended to be completed annually. If the facility is found to no longer fall under the requirements of the exemption, the facility shall contact the Pennsylvania Department of Agriculture to update the facility's exemption status and determine the next applicable steps.

Inspection of produce farms covered under 21 CFR 112 are conducted by the Pennsylvania Department of Agriculture as part of financial assistance award (FAIN) funded 100 percent by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS).

Your information will not be shared with any entities or persons outside of the FDA and the Pennsylvania Department of Agriculture.

All material must be fully completed and returned with any necessary accompanying documentation to:

RA-AGPLANREVIEW@pa.gov

or mail / fax to:

**Pennsylvania Department of Agriculture
Bureau of Food Safety and Laboratory Services
Attn: Produce Safety Program Specialist
2301 N. Cameron St, Room 112
Harrisburg, PA 17110
Fax: 717-787-1873**

SECTION 1: FACILITY INFORMATION

FACILITY ID#: _____

NAME OF FARM: _____

SECTION 2: EXEMPTION VERIFICATION

REQUIREMENTS FOR BASIC EXEMPTION: Please check all boxes that apply. One of the following requirements must be met to qualify as an exempt farm:

Micro-exemption (or non-covered farm exemption) 21 CFR Part 112.4: during the previous 3-year period, preceding the year this application is submitted, a farm's average of all produce sales was \$25,000 or less (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment. Please fill out the "Produce Sales" lines with the supporting produce sales figures to support this determination.

Produce Sales, Year 1: _____

Produce Sales, Year 2: _____

Produce Sales, Year 3: _____

Average Produce Sales of 3-year period: _____

ONLY grow produce that is rarely consumed raw, specifically the produce on the following exhaustive list: asparagus, black beans, great Northern beans, kidney beans, lima beans, navy beans, pinto beans, beets, garden (roots and tops) beets, sugar beets, cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill (seeds and weed), eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, mature southern field peas (such as black-eyed peas, cowpeas, crowder peas, purple hull peas, sea island peas, silver peas, and speckled peas), winter squash, sweet potatoes, and water chestnuts.

Produce grown is used only for **personal consumption** or produced for consumption on the farm or another farm under the same management.

Produce grown receives **commercial processing** that adequately reduces the presence of microorganisms of public health significance. (21 CFR 112.2(b))

A farm facility is eligible for a processing exemption when the produce grown at the facility is intended for commercial processing at another facility in the distribution chain. Examples of commercial processing include (but not limited to) refining, distilling, or other processing to eliminate spore-forming microorganisms.

Additional requirements include:

- You must disclose in documents accompanying the produce that the food is "not processed to adequately reduce the presence of microorganisms", in accordance with the practice of the trade.
- Additionally, you must annually receive written assurance that the customer receiving your product will perform said commercial processing or that an entity in the distribution chain, subsequent to your customer, will perform commercial processing to reduce pathogenic microorganisms.

Farm qualifies for Qualified Exemption (see below).

REQUIREMENTS FOR QUALIFIED EXEMPTION:

Determination of a Qualified Exemption is based on total food sales, not just produce. This total includes livestock; meat; dairy products such as milk; hay; grains; and wine; and other foods (for both human and animal). Review and complete the **Qualified Exemption section below**.

A farm is eligible for a Qualified Exemption and its associated modified requirements in a calendar year if both of the following conditions are met:

- During the previous 3-year period, preceding the year this application was submitted, the average annual monetary value of the food the farm sold directly to qualified end-users (QEU's) exceeds the monetary value of food sold to all other buyers during that period.
 - o Per 21 CFR Part 112.3, a Qualified End-User is a consumer (not including a business), a restaurant, or a retail food establishment that is:
 - In the same state or same Indian reservation as the farm that produced the food; or
 - Not more than 275 miles from said farm.
- The average monetary value of all food the farm sold during this 3-year period is less than \$500,000, adjusted for inflation, using 2011 as the baseline year.

Food Sales, Year 1: _____ Food Sales to QEU's, Year 1: _____

Food Sales, Year 2: _____ Food Sales to QEU's, Year 2: _____

Food Sales, Year 3: _____ Food Sales to QEU's, Year 3: _____

Total Accumulative Food Sales: _____ / 3 years to calculate average: _____

As a Qualified Exempt Farm you are:

- Required to maintain records verifying the status as Qualified Exempt that may be inspected by the Pennsylvania Department of Agriculture and/or the FDA.
- Required to review records annually to verify they continue to meet both the sales value of food and sales to a Qualified End User requirement. Review must be documented.
- Required by law to provide the name and complete business address of the farm where the produce was grown either on a label or at the point of sale while operating under the Qualified Exempt category.
- Qualified Exempt status may be revoked if there is an active investigation of food borne illness linked to my/our farm and/or it is determined necessary by PDA and/or FDA to protect public health.
- Qualifying for this exemption does not preclude the farm from following the requirements of the FDA FSMA Produce Safety Rule.
- Qualifying for this exemption does not exempt any farm from complying with all adulteration and other applicable provisions under the U.S. Food, Drug and Cosmetics Act.
- Qualifying for this exemption does not exempt the farm from complying with other applicable laws and regulations.

Note: A farm is not required to claim the Qualified Exemption and can choose to follow the full FSMA PSR requirements including an inspection.

By signing this application, I attest that this information is accurate for my intended operations, and I meet all qualifications for the desired exemption. I will notify the Pennsylvania Department of Agriculture if my farm is no longer eligible for this exemption, so that any requirements can be reassessed to ensure continued compliance with the Produce Safety Rule.

Any exemption status is liable to be withdrawn from any facility at the discretion of the FDA and/or the Pennsylvania Department of Agriculture in accordance with 21 CFR Part 112 Subpart R.

Name of Applicant: _____ **Title:** _____

Applicants Signature: _____ **Date:** _____