

FSMA Produce Safety Rule FAQ's

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On behalf of the New York State Department of Agriculture and Markets (Department), this article presents information on the Food Safety Modernization Act (FSMA) Produce Safety Rule and answers frequently-asked questions from producers.

The Produce Safety Rule is the first mandatory federal food safety standard for the production of fruits and vegetables in the United States. In July 2017, New York State adopted the Produce Safety Rule under a grant-funded cooperative agreement with the U.S. Food and Drug Administration (FDA). The Produce Safety Rule will affect many of New York's growers, harvesters, packers and holders of produce. The rule addresses the areas of: personnel health, hygiene and training; agricultural water, including for irrigation and washing; biological soil amendments of animal origin and human waste; domesticated and wild animals; equipment, tools, buildings and sanitation; and sprouts.

The following are frequently-asked questions from producers on the Produce Safety Rule.

1. Which portions of FSMA will impact my farm?

The Produce Safety Rule affects growers, harvesters, packers and holders of produce whose average produce sales over three years exceed \$25,000. The Produce Safety Rule is one of seven rules outlined in FSMA.

2. Where can I determine if I might qualify for any exemptions to the Produce Safety Rule?

There are certain exemptions from the Produce Safety Rule that would subject farms to recordkeeping requirements, but not to on-farm inspections. There are three potential exemptions for farmers: qualified exemption, rarely consumed raw exemption and processing exemption.

1. Farms may be eligible for a **qualified exemption** if they generate less than \$500,000 in average annual food sales. A majority of these food sales must also be to a qualified end user. A qualified end user is defined as a consumer, a retail store or a restaurant within the same state or within 275 miles of where the food was produced. The FDA defines food as all human and animal food, including items such as chewing gum, bottled water and dietary supplements.
2. Farms may be eligible for an exemption if they only sell produce that is defined by the FDA as **rarely consumed raw**. Rarely consumed raw produce includes: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed);

eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; water chestnuts; and milk. This is considered an exhaustive list. Produce not included in the above list is considered covered produce and subject to the Produce Safety Rule. If a farm sells both rarely consumed raw produce and covered produce, the part of the operation that grows and handles covered produce will be subject to inspection.

3. Lastly, farms may be eligible for an exemption if they only sell produce destined for further **processing** that includes a validated kill step to reduce pathogens. For example, a farm that sells grapes to a facility that makes wine would be eligible for the processing exemption. If a farm sells both produce destined for further processing and other covered produce, the covered produce and the associated farm operation will be subject to on-farm inspections.

Producers can complete an information survey, which will help determine coverage rates and compliance dates: <https://www.surveymonkey.com/r/9HM3NTP>.

3. Where can I find out how soon my farm will be subject to the Produce Safety Rule?

Farms that average \$25,000 in produce sales over three years must meet staggered compliance dates. However, farms will not have to meet agricultural water guidelines at these designated dates. FDA has recently announced its intention to delay the requirements of Subpart E- Agricultural Water until four years after the above compliance dates for each of the farm size categories. Farms with over \$500,000 in total produce sales, or “other farms,” must comply with the Produce Safety Rule first. These farms have a compliance date of January 26, 2018.

Farms with over \$250,000, but less than \$500,000 in total produce sales are considered “small farms” and have a compliance date of January 26, 2019. Lastly, farms with over \$25,000, but less than \$250,000 in total produce sales are considered “very small farms” and have a compliance date of January 26, 2020.

4. When will Produce Safety Rule inspections begin?

The Department will not begin inspections before Spring 2019. Current efforts will be concentrated on outreach and education to the industry.

5. Who will be conducting these inspections?

The Department’s Division of Food Safety and Inspection will be conducting inspections. The Department adopted the Produce Safety Rule into its own laws so that New York State inspectors would be conducting outreach, education, and inspections on New York State farms rather than the FDA. We expect cooperation with the FDA and do not expect them to be conducting inspections.

6. How do these inspections differ from Good Agricultural Practices (GAP) audits?

Produce Safety Rule inspections are mandatory and required under FSMA. These inspections are free and encompass all covered commodities and covered activities on the farm. In

comparison, GAP audits are voluntary and driven by the market. Producers must pay for the audit and choose what commodities and what scopes are included.

7. Can GAP audits and Produce Safety Rule inspections be combined into one inspection?

The Produce Safety Rule aims to refine these voluntary GAP audits and provide a standardized food safety inspection for produce. However, producers that are exempt from the Produce Safety Rule may still be required by their buyer to undergo a third-party food safety audit, such as USDA's GAP, Harmonized GAP or Safe Quality Food (SQF) Institute. The third-party, GAP audit will always be driven by the buyer. There have been discussions with states, USDA and FDA to address this issue. The USDA Harmonized GAP audit is currently being aligned with the Produce Safety Rule so that all aspects of the Produce Safety Rule will be contained in the Harmonized standard.

8. Will the Department be providing mock inspections?

The Department will be performing On-Farm Readiness Reviews (OFRR) in conjunction with Cornell Cooperative Extension (CCE) to producers willing to participate. This will not be a mock inspection, but rather an educational visit. The OFRR will consist of a walk-through of farm operations to observe what areas may or may not be compliant with the Produce Safety Rule.

9. How can I sign up for this educational visit?

An OFRR may be scheduled by contacting Aaron Finley at (518) 457-3846 or Aaron.Finley@agriculture.ny.gov. Aaron is the Department's Produce Safety Program Office Administrator based in Albany. Steve Schirmer is also an administrator of the program and serves as the Department's Produce Safety Program Field Administrator based in Syracuse. Steve can be contacted at Steve.Schirmer@agriculture.ny.gov. Producers can also indicate on their Farm Information Form that they want to participate in an OFRR. Farm Information Forms have been distributed at grower trainings and by produce associations.

10. How often will I have to perform water quality testing for my agricultural water?

Guidelines and compliance dates for the use of agricultural water are currently under review by FDA. Agricultural water includes both production and postharvest water used in contact with covered produce. Producers should consider the source, quality, application method and timing of the application of their water.

There is no requirement to test water from a public water supply. However, documentation must be provided of test results or current certificates of compliance. Ground and surface water must be tested. Samples must be representative of use and must be collected as close in time as practicable to, but before, harvest. Ground water will need to be tested four or more times during the growing season or over the period of a year. Additionally, one or more samples must be rolled into a profile every year after the initial year. Surface water must be tested twenty or more times over a period of two to four years. Additionally, five or more samples must be rolled into a profile every year after the initial survey.

Updated information on agricultural water requirements will be distributed by the Department as received by the FDA.

For more information on FSMA, the Produce Safety Rule in New York State and to determine your farm's coverage or exemption under the rule, please visit the Department website at: <https://www.agriculture.ny.gov/FS/general/fsma.html>. Questions can also be sent to Aaron.Finley@agriculture.ny.gov and Steve.Schirmer@agriculture.ny.gov.