

The Food Safety Modernization Act Produce Safety Rule

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Introduction

An estimated one in six Americans get sick each year with foodborne illnesses, sometimes resulting in death. [1] With most foodborne outbreaks originating from fecal-related pathogens including viruses and bacteria, the Food and Drug Administration (FDA) has established a new rule that deals with food safety at the farm level:

- **Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.** <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>

This rule gives standards for growing, harvesting, packing and holding of fresh produce.

Although the American food supply is safer than ever, the country continues to experience foodborne illness outbreaks. Most of these outbreaks are the result of bacterial or viral contamination, with norovirus contributing to over 50% of illnesses. [2] *Salmonella* Typhi, Nontyphoidal *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC), *Shigella* spp., and *Clostridium perfringens* make up the other top sources of food-borne outbreaks. *Listeria monocytogenes* is not in the top outbreaks but is responsible for the greatest number of



deaths. [6] According to the Center for Disease Control and Prevention, most food-borne illnesses during the past two decades have been traced back to contamination that occurred early in the process, such as during harvesting, packing or transportation.

Certain fresh fruits and vegetables are more susceptible to contamination because they are typically eaten raw and are not processed in a manner that kills pathogenic microorganisms. Recent outbreaks have involved romaine lettuce, cantaloupes and spinach. [3] [4] [5] Contamination may be associated with poor agricultural practices during growing, harvesting, packing or holding activities at some point from farm to table.

There are certain practices that growers can undertake to reduce the contamination and spread of harmful bacteria. These practices are known as Good Agricultural Practices (GAP). Through the Food Safety Moderniza-

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tion Act (FSMA), the FDA is now requiring farmers to implement certain GAPs on-farm to minimize contamination of fresh produce. This will help shift the national focus around outbreaks from reaction to prevention.

Components of the Produce Safety Rule

The Produce Safety Rule requires growers to implement specific food safety practices during growing, harvesting, packing and holding activities. The areas include: (1) worker health and hygiene, (2) pre- and post-harvest agricultural water, (3) wildlife and domestic animals, (4) biological soil amendments of animal origin and (5) sanitation of equipment, tools and buildings. Contamination sources from past outbreaks have been traced back to these five major areas and are thus the areas of focus for produce safety regulations.

Effective Dates

Compliance dates vary depending on the size of the farming operation. All farms with an average annual monetary value of produce sold during the previous 3-year period of more than \$25,000 is a “covered farm”. Water-related compliance dates are later than the rest of the regulation compliance dates. [7] Please note that the monetary values listed below were established in 2011 and should be adjusted for inflation. [8]

- Large farms, defined as farms with more than \$500,000 in annual food sales (food sales include all human and animal food sold by the farm), needed to be in compliance by 1/26/18 and in compliance with water regulations by 1/26/22.
- Small businesses, defined as farms with annual food sales of more than \$250,000 and up to \$500,000, needed to be in compliance by 1/28/19 and in compliance with water regulations by 1/26/23.
- Very small farms, defined as farms with annual food sales of more than \$25,000 and up to \$250,000, needed to be in compliance by 1/27/20. They must comply with water regulations by 1/26/24.

Exclusions from the Rule

The Produce Safety Rule has several stipulations for exclusions. Exclusion from the Produce Safety Rule includes the following:

- Farmers earning less than \$25,000 in produce sales averaged over the last three years (adjusted for inflation with base of 2011).
- Produce classified as “Rarely Consumed Raw” according to the Produce Safety Rule.
- Produce that undergoes commercial processing that “adequately reduces the presence of microorganisms of public health significance”.
- Produce grown for personal or on-farm consumption.
- Produce that is not a raw agricultural commodity.

Qualified Exemptions

If your farm meets certain criteria, you may be eligible for a qualified exemption from the rule. In order to have the qualified exemption status, your farm must meet the two following criteria:

- During the past three-year period, more than 50% of the average annual monetary value of all food sold (including livestock, meat, row crops, rarely consumed raw produce and covered produce) was sold directly to qualified end-users.
 - Qualified end-users are the consumers of the food, a restaurant or retail food establishment. Selling to a wholesaler who then sells to a grocery store is NOT a qualified end-user. In order for a restaurant or retail food establishment to be a qualified end-user, they must be located in the same State or Indian reservation as the farm or not more than 275 miles from the farm. Examples of qualified end-users include customers at farm stands or farmers markets, direct sales to restaurants and direct sales to grocery stores.
- The average monetary value of all food sales over the last three years is less than \$500,000, adjusted for inflation. [8]

If your farm meets the criteria for a qualified exemption, you must comply with the following modified requirements:

- If the produce would be covered by the Produce Safety Rule if you were not exempt and would normally require a food packaging label, you must “include prominently and conspicuously on the food packaging label the name and complete business address of the farm where the produce was grown”.

- If the produce would normally be covered by the Produce Safety Rule if you were not exempt and would not require a food packaging label, you must “prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown on a label, poster, sign, placard or documents delivered” with the produce.
- You must keep records to prove that you are qualified exempt.

Conclusion

The FSMA Produce Safety Rule was passed with the intention of reducing foodborne illness outbreaks caused by fresh produce. Navigating the regulations can be daunting, but the Local, Regional and Safe Foods Team is here to help. If you have questions or need technical assistance on your farm, visit www.uaex.uada.edu/producesafety for more information and contact information.

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