

# The Food Safety Modernization Act Proposed Food Safety Rules

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## Introduction

An estimated 48 million Americans get sick each year with foodborne illnesses, sometimes resulting in death. With most foodborne outbreaks originating from fecal-related pathogens including viruses and bacteria, the Food and Drug Administration (FDA) has proposed two new rules that deal with food safety at the farm and manufacturing level:

- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food** (<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>) – This rule deals with food manufacturing facilities.
- **Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption** (<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>) – This rule deals with safe handling of fresh produce.

Although the American food supply is safer than ever, the country continues to experience foodborne outbreaks. Most of these foodborne outbreaks are the result of a virus known as norovirus followed by three bacteria – Salmonella, *Listeria*



*monocytogenes* and *Escherichia coli* O157:H7. According to the Center for Disease Control and Prevention, most foodborne 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 not processed in a manner that kills pathogenic microorganisms. Recent outbreaks have involved cantaloupes, spinach and tomatoes that were contaminated with fecal matter at some step in the farm-to-table process.

There are certain practices that growers can undertake to reduce the contamination or spread of harmful bacteria. These practices are known as Good Agricultural Practices, or GAP. Through the Food Safety Modernization Act, the FDA is embracing GAP practices to help shift the national focus from responding to problems to preventing problems.

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The agency's proposed regulations would require growers to develop a food safety plan that addresses their on-farm food safety practices.

## Food Safety Plans

The proposed regulations would require growers to develop food safety plans that address specific areas of possible contamination. The areas include the following: (1) agricultural water, (2) worker health and hygiene and sanitation, (3) domestic and wildlife animals, (4) biological soil amendments of animal origin and (5) equipment, tools and buildings.

## Effective Dates

The FDA will take comments on the proposed regulations until May 16, 2013. It is expected that the final rules will be published by May 2014 and become effective July 2014. Compliance dates will vary depending on the size of the farming operation.

- Very small farms, defined as farms with annual monetary value of less than \$250,000, will have four years to comply after the rule's effective date.
- Small businesses, defined as farms with an annual income of less than \$500,000, will have three years to comply after the rule's effective date.
- Large farms, defined as farms with more than \$500,000 in annual income, will have two years to comply after the rule's effective date.

## Rule Application

Items covered by the proposed regulations currently include lettuce, spinach, tomatoes, sprouts, mushrooms, onions, peppers, cabbage, walnuts, cantaloupes, apples, peaches, strawberries, watermelons, citrus and other fruits. These are foods that are not generally cooked prior to consumption.

## Exemptions

The proposed regulations have several exemptions that allow producers to opt out of the food safety regulations. Exemptions include the following:

- Farmers earning less than \$25,000 in annual income.
- Certain produce that constitutes the lowest risk with respect to biological hazards (such as potatoes and fruits and vegetables for further processing, such as canning).
- Grains are exempt.
- Produce for personal or on-farm consumption.
- Qualified End-User Exemption – Farms whose total annual food sales fall below \$500,000 AND whose annual sales of food directly to “qualified end-users” exceed the annual value of food sold to all buyers. (A “qualified end-user” is defined as a consumer of the food OR a restaurant or retail food establishment that is located in the same state as the farm or not more than 275 miles from the farm.)

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