

FSMA Homepage: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

<http://wayback.archive-it.org/org-1137/20180907212840/https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm304045.htm>

Produce Safety Standards

Information available related to Produce Safety Standards under the FDA Food Safety Modernization Act (FSMA).

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Prevention is Key for Produce Safety Standards

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. FDA has compiled from CDC

data information regarding produce associated outbreaks which occurred between 1996 and 2010 where contamination is likely to have happened early in the production chain, during growing, harvesting, manufacturing, processing, packing, holding, or transportation. This FDA data set demonstrates that from 1996 to 2010, approximately 131 produce-related reported outbreaks occurred, resulting in 14,350 outbreak-related illnesses, 1,382 hospitalizations and 34 deaths. These outbreaks were associated with approximately 20 different fresh produce commodities. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, 2011, enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur.

As a key element of this preventive approach, FDA was mandated under FSMA to establish science-based, minimum standards for the safe growing, harvesting, packing, and holding of produce on farms to minimize contamination that could cause serious adverse health consequences or death.

Guidance and Rules

- [Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules](#)
- Final Rule
- Docket Number: [FDA-2011-N-0920](#), [FDA-2011-N-0921](#), [FDA-2011-N-0922](#), [FDA-2011-N-0143](#)
- [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#)
- Final Rule
- Docket Number: [FDA-2011-N-0921](#)

Full Text of the Law Relating to Produce Safety Standards

- [SEC 105. Standards for Produce Safety](#)

Alliances

Produce Safety Alliance

FDA and the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) established the Produce Safety Alliance to provide produce farmers, along with other groups, the information they need to ensure the safety of fresh produce for consumers. The Produce Safety Alliance is providing fundamental, on-farm food safety knowledge and will assist farmers with the information that they will need to comply with FDA's produce safety regulation. It is housed at Cornell University through a USDA Agricultural Marketing Service grant funded cooperatively by both USDA and FDA. Cornell's national Good Agricultural Practices (GAPs) program has been a leader in the development of education outreach materials on GAPs and in dissemination of food safety knowledge to the agricultural community. For more information, visit the [Produce Safety Alliance's page](#) .

Sprout Alliance

FDA has also supported the establishment of a Sprout Safety Alliance in cooperation with the Institute for Food Safety and Health, Illinois Institute of Technology to conduct education and outreach to promote the safe production of fresh sprouts. FDA is launching this specific initiative in light of a number of outbreaks that have been attributed to sprouts, and because specific requirements for sprouts are included in the proposed rule on produce safety. The Alliance will develop and identify new and existing educational materials to help industry, particularly small companies, grow safe sprouts. Also, this effort

will help prepare sprout farms to comply with the proposed produce safety rule. [Read more on the Sprout Alliance.](#)

Coordination with USDA on Produce Safety

FDA has worked with the U.S. Department of Agriculture throughout the development of the proposed produce safety regulations. Through this collaboration, FDA was able to gather information and expertise on specific issues, such as the National Organic Program, while USDA was briefed on the progress of the draft proposals. In addition, FDA and USDA's Agricultural Marketing Service have worked together with Cornell University to develop the Produce Safety Alliance – the primary mechanism for reaching out to and educating farmers. This public-private partnership will develop and disseminate training and education programs to provide produce farms across the country with fundamental food safety knowledge.

FDA Outreach on Produce Safety

Since early 2010, FDA and USDA technical experts, scientists, and other staff participated in listening sessions and meetings in 13 states. In some of those states, we were able to tour farms large and small and talk with people who have the “on-the-ground” knowledge that FDA realizes must be reflected in the proposed rule. The states visited have included: Arizona, California, Delaware, Florida, Georgia, Maryland, Nevada, New York, North Carolina, Ohio, Oregon, Pennsylvania, Texas and Washington.

Public Meetings & Webinars

- [Final Rules for Produce Safety, Foreign Supplier Verification Program \(FSVP\), and Third Party Auditors \[ARCHIVED\]](#)
- Webinar Series

- November 2015
- [Proposed Rules to Establish Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Portland, OR](#)
[ARCHIVED]
- Public Meeting
- March 27, 2013
- [Proposed Rules to Establish Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chicago, IL](#)
[ARCHIVED]
- Public Meeting
- March 11, 2013
- [Proposed Rules to Establish Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Washiongton, DC](#)
[ARCHIVED]
- Public Meeting
- February 28, 2013