

[Home](#) [Food Safety](#) [Food Safety Modernization Act \(FSMA\)](#)

Food

Overview of the FSMA Proposed Rules on Produce Safety Standards and Preventive Controls for Human Food

Related Resources:

- Proposed Rule under FSMA for Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food¹
- Proposed Rule under FSMA for Produce: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption²

Summary

FDA has released for public comment a proposed rule on Preventive Controls for Human Food and a proposed rule on Standards for Produce Safety. These rules are two of the proposed rules that are key to the preventive food safety approach established by the 2011 FDA Food Safety Modernization Act. The proposed rules build on existing voluntary industry guidelines for food safety, which many producers, growers and others currently follow. FDA expects to soon issue its proposed rule on importer foreign supplier verification; future proposed rules will address preventive controls for animal food, and accreditation of third-party auditors.

Proposed Standards for Produce Safety

The proposed produce rule covers all fruits and vegetables except those rarely consumed raw, produced for personal consumption, or destined for commercial processing that will reduce microorganisms of public health concern. The proposed rule is based on science and risk-analysis, and therefore focuses on areas of risk, most noticeably:

- agricultural water;
- biological soil amendments;
- health and hygiene;
- domesticated and wild animals; and
- equipment, tools and buildings.

The proposed produce rule is the result of extensive outreach by FDA with consumers, government, industry, researchers, and many others. The proposed rules build on existing voluntary industry guidelines for food safety, which many producers, growers and others currently follow. The produce rule is aimed at being flexible for different-sized farms, at complementing conservation laws and rules, and at not conflicting with laws and rules for organic farming.

Certain farms would be exempt from most of the requirements if their sales average less than \$500,000 per year during the last three years (adjusted for inflation) and their sales to qualified end-users exceed their sales to others during the same period.

The exemption can be revoked under certain circumstances. In addition, farms whose average annual value of food sold during the previous three-year period is \$25,000 or less would not be covered by the rule. Such farms would still be responsible for the safety of their produce. In addition, states and foreign countries can seek variances from provisions of the rule because of local growing conditions.

While the effective date for this rule would be 60 days from publication of the final rule, the general

compliance date would be two years after the effective date. For small businesses, the compliance date would be three years after the effective date, and for very small businesses four years after the effective date. Additional time would be allowed for compliance with certain water requirements.

Preventive Controls for Human Food

The proposed rule on preventive controls for human food would apply to facilities that manufacture, process, pack or hold human food. In general, with some exceptions, the new preventive control provisions would apply to facilities that are required to register with FDA under FDA's current food facility registration regulations. A number of exemptions and modified requirements have been established.

The rule proposes firms have written plans in place to identify potential hazards, put in place steps to address them, verify that the steps are working, and outline how to correct any problems that arise.

The rule proposes each covered facility to prepare and implement a written food safety plan, which would include the following:

- hazard analysis;
- risk based preventive controls;
- monitoring procedures;
- corrective actions;
- verification; and
- recordkeeping.

Publication of Related Proposed Rules

Future proposed rules will address importer foreign supplier verification, preventive controls for animal food, and accreditation of third party auditors.

Extensive Outreach

FDA has conducted extensive outreach to industry, the consumer community, other government agencies and the international community to gain input and perspective on how best to implement the proposed rules required by FSMA. That input and perspective is helping to shape the proposed regulations in a way that will help to ensure practical and flexible as well as effective proposals. We also invite all interested stakeholders to comment on these proposed rules.

Since January 2011, FDA staff has made more than 350 presentations to industry and consumer groups, farmers, state and local officials, and the research community. In addition, FDA has participated in 70 meetings with global regulatory partners and industry stakeholders. Three public meetings were held on FSMA-related topics including preventive controls, the import provisions, and inspections and compliance. FDA also held a series of 14 farm tours around the country, as well as visited several food and feed facilities (large and small). FDA will be holding several additional meetings, including regional public meetings, during the comment period to explain the proposal and to provide additional opportunity for input.

Rulemaking Process and Submitting Comments

The public is encouraged to review and submit comments to the proposed rules. The proposed rule is published in the Federal Register and filed in FDA's official docket on <http://www.regulations.gov>³. FDA will review comments on the proposed rule and consider revising the rule, before issuing a final rule. Comments are due within 120 days of the rules' publication in the Federal Register.

Assistance to Industry

FDA intends to publish various guidance materials to help industry in meeting the new requirements. In addition, FDA is working with stakeholders through organizations known as "Alliances" focused on produce in general, sprouts, and preventive controls. The alliances are developing training and outreach programs and will focus on the needs of small and very small

operations.

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1. </Food/FoodSafety/FSMA/ucm334115.htm>
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3. <http://www.regulations.gov/>