

FSMA Facts

Produce Safety: Does this Rule Apply to You?

What is FDA doing?

FDA is issuing a proposed rule to establish science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms. The proposed rule is required by the FDA Food Safety Modernization Act (FSMA).

Who would be covered?

- The proposed rule would apply to farms that grow, harvest, pack or hold most fruits and vegetables when those fruits and vegetables are in their raw or natural (unprocessed) state.
- The proposed rule would not apply to produce that is rarely consumed raw (such as potatoes), produce that will receive processing including a kill-step (with certain documentation), and produce for personal or on-farm consumption.
- The proposed rule would not apply (or would only partially apply) to certain farms. See the Decision Tree for more information.

What would the proposed standards cover?

They would focus on commonly identified routes of microbial contamination of produce, including: (1) agricultural water (2) farm worker hygiene (3) manure and other additions to the soil (4) animals in growing areas, and (5) equipment, tools and buildings. There are also specific proposed standards for sprouts.

How can I comment on the proposed rule?

The proposed rule was published on January 16, 2013, and comments are due by November 15, 2013 and can be submitted at <http://www.regulations.gov>.

When would the new requirements be effective?

If you are covered by the rule (see flowchart) you would have the following amount of time after the effective date (60 days after the **FINAL** rule is published in the Federal Register) to comply.

- Very small businesses, defined as having an average annual value of food sold during the

previous three years of no more than \$250,000, would have four years after the effective date to comply and six years for some water requirements.

- Small businesses, defined as having an average annual value of food sold during the previous three years of no more than \$500,000, would have three years after the effective date to comply; for some of the water requirements, they would have five years.
- Other businesses would have to comply two years after the effective date. They would have four years to comply with some of the water requirements.

What if I need more information?

Go to www.fda.gov/fsma

Produce Safety Rule Process: It Won't Happen Overnight

The process of issuing a rule takes time. FDA must follow several steps before a final rule is issued. Even when a final rule is issued, it may have an effective or compliance date in the future. In the case of the proposed Produce Safety Rule, the rulemaking process will take time, and plenty of time is allowed after a final rule is issued for those covered by the rule to comply.

1. FDA proposes rule on January 4, 2013 and requests Comments; original comment period closes May 16, 2013; FDA extends the Comment period until September 16, 2013
2. FDA holds three public meetings and more than 150 webinars, listening sessions, and other outreach activities during the comment period
3. FDA reviews comments received and considers revising proposed rule based on the comments
4. FDA issues final rule, setting dates for companies to comply, with additional time for small and very small businesses, and even more additional time to comply with proposed agricultural water requirements.

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