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Food

What You Need to Know: Proposed Rule on Standards for Produce Safety Under the FDA Food Safety Modernization Act (FSMA)

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Proposed Rule At-A-Glance

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 certain produce: 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 below 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.

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 (the effective date is 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; for some water requirements, they would have six years.
- 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 [Produce Safety Standards under the FSMA²](#).
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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, as shown below, the rulemaking process will take time, and plenty of time would be 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 *WE ARE HERE***
2. Public has until (insert date) (120 days) to comment and FDA holds three public meetings during this time.
3. FDA considers comments received and considers revising the 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.

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Proposed Standards for Produce Safety - Coverage and Exemptions/Exclusions for Proposed 21 PART 112

Does your farm grow, harvest, pack or hold produce?
 Sections 112.1 and 112.3(c)

YES



NO → You are NOT covered by this rule.

Is your produce rarely consumed raw? Section 112.2(a)(1)

NO



YES → This produce is NOT covered by this rule.

Is your produce for personal/on-farm consumption? Section 112.2(a)(2)

NO



YES → This produce is NOT covered by this rule.

Does your farm manufacture/process, pack, or hold produce that is not a *Raw Agricultural Commodity (RAC)? Section 112.2(a)(3)

NO



YES → Produce that is not a RAC is NOT covered by this rule.

Is your produce intended for commercial processing with a "kill step"?
 Section 112.2(b)(1)

NO

YES → This produce is NOT covered by this rule, EXCEPT as per Sections 112.(b)(2) and



(3)

Does your farm on average (in the previous 3yrs) have < \$25k annual food sales? Section 112.4(a)

NO



YES → You are NOT covered by this rule.

Does your farm on average (in the previous 3yrs) as per Section 112.5:

- have < \$500k annual food sales, AND
- a majority of the food (by value) sold directly to "qualified end-users"?

"Qualified End-User" Section 112.3(c) means:

- the consumer of the food ("consumer" is not a business) OR
- a restaurant or retail food establishment that is located—
 - (i) in the same State as the farm that produced the food; OR
 - (ii) not more than 275 miles from such farm.

YES → You are EXEMPT from this rule except as per Section 112.6

NO



You are COVERED by this rule.

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