

Implementing the Produce Rule

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**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

Produce Background

- FDA is conducting rulemaking to establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables (including sprouts).
- Sprout operations will be required to comply with all applicable requirements of this regulation (unless otherwise exempt), including sprout-specific provisions in Subpart M

Proposed Definitions

- “Farm means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both.”
- For the purpose of this rule, we propose to define the term “produce” to mean any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs.

Farms Excluded from Coverage

- Proposed Rule (2013)
 - Rule would not cover farms that have an average annual value of food sold during the previous three-year period of \$25,000 or less
- Supplemental Proposed Rule (2014)
 - Rule would not cover farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less
- Qualified exemptions are based on market channels and annual food sales

Small and Very Small Farms

- FDA Action in Supplemental Proposed Rule
 - Monetary thresholds for small business and very small business farms have also been changed to be based on produce sales, rather than food sales.

FSMA Implementation

- Phase 1: Set standards
 - Develop regulations, guidance, policy
- Phase 2: Develop plans for promoting industry compliance with FSMA Rules
 - Design strategies and frameworks
- Phase 3: Implement, monitor and evaluate

FSMA Operational Strategy

- Provides a foundation for fully developing and implementing FSMA standards
- Captures in broad, high-level terms our current thinking on strategy and guiding principles

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>

Key Principles

- Utilize a risk-based approach to prioritize and allocate resources for implementation activities
- Invest in specialized training and implement produce safety in a way that:
 - Promotes consistency in regulatory approach and decision making
 - Allows the flexibility needed to recognize the diversity and complexity of the produce farming community

Key Principles

- Work closely with the farming/sprouting community, government agencies, academia, and other partners
- Recognize the role of the marketplace in influencing and expanding industry compliance with the produce safety rule
- Develop meaningful public health metrics to measure success, such as reductions in produce-related foodborne illnesses

Inspections and Compliance

- By increasing education and accessibility to technical assistance, the agency intends to foster and facilitate compliance.
- Inspectional approach includes new ways to enhance collaboration and assist states to adjust and perform the majority of on-farm activities (as funding permits), while FDA provides scientific support and assistance, as needed.

Training: Rule Requirements

- FDA is working with two organizations to develop training on the regulatory requirements of the Produce Safety Rule
 - The Produce Safety Alliance (PSA), centered at Cornell University, is developing a curriculum to help the farming community understand the requirements in the rule and how to comply with these requirements
 - The Sprout Safety Alliance (SSA), centered at the Illinois Institute of Technology, is developing a curriculum to assist sprout growers

Technical Assistance

- Two elements to technical assistance:
 - Compliance assistance
 - Science / technical support
- Partners in providing technical assistance
 - FDA Technical Assistance Center
 - Regional FDA Produce Safety Network
 - USDA/AMS
 - Land-Grant University Cooperative Extension Services
 - PSA/SSA
 - State and foreign governments

Federal Register: Open Docket

The screenshot shows the Federal Register website interface. At the top, there is a navigation bar with links for Sections, Browse, Search, Policy, Learn, Blog, and My FR. A search bar is also present. Below the navigation bar is the Federal Register logo and the text "FEDERAL REGISTER The Daily Journal of the United States Government". A blue banner highlights the word "Notice".

The main content area features the title: "The Food and Drug Administration Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards; Public Meeting and Establishment of Docket". Below the title, it states "A Notice by the Food and Drug Administration on 03/24/2015". There are social media icons for Facebook, Twitter, and Email, and a "SUBMIT A FORMAL COMMENT" button.

Under the title, there is a section for "ACTION" with the text "Notice Of Public Meeting And Establishment Of Docket." and a "SUMMARY" section. The summary text reads: "The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to obtain comments that will inform our development of FDA Food Safety Modernization Act (FSMA) implementation work plans. FDA is also announcing a public meeting entitled 'FDA Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards.' At the public meeting, we will share our current thinking on our operational strategy for implementation work plans. We will also provide interested persons an opportunity to provide input on this".

On the right side of the page, there are navigation links for "Previous Document" and "Next Document", a "LEGAL DISCLAIMER" section, "Font Controls" with plus, minus, and text size icons, and a "PUBLIC INSPECTION" section with options for PDF, DEV, PRINT, and PUBLIC INSPECTION. The "Publication Date" is listed as "Tuesday, March 24, 2015".

Thank You

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