

Proposed Rules under the
FDA Food Safety
Modernization Act
-- Focus on Produce --

FDA FOOD SAFETY
MODERNIZATION ACT



Version 1/15/2013

Five Proposed Rules Establish Food Safety Framework

- Produce Safety Standards
 - Published Jan. 16, 2013
- Preventive Controls for Human Food
 - Published Jan. 16, 2013
- Foreign Supplier Verification Program
- Preventive Controls for Animal Food
- Accredited Third Party Certification



Key Aspects of Proposals

- Confirm industry's primary role on food safety
- Risk-based and flexible
 - Burden commensurate with risk
- Address small business issues
 - Additional time for small farms, businesses, to comply
- Extensive government, stakeholder Input

Produce

FDA Proposed Rule on Produce Safety



Regulatory Framework

- Framework considers many factors associated with produce farming community
 - Examples include diversity of operations and broad range of crops and practices
- Proposing integrated approach that draws on past experiences
 - Examples include CGMPs, HACCP, shell egg regulation

Who Would be Covered?

- Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities)
- Farms and “farm” portions of mixed-type facilities
- Domestic and imported produce
- Farms with annual sales > \$25,000 per year
- Limitations on coverage are proposed

Covered Produce

- “Produce” defined as fruits and vegetables
 - Includes mushrooms, sprouts, herbs and tree nuts
- Produce does not include grains
- Some limitations on covered produce

Limitations on Coverage

- Produce for personal or on-farm consumption
- Produce not a Raw Agricultural Commodity
- Certain produce rarely consumed raw
- Produce that will receive commercial processing
- Farms with sales of \leq \$25,000 per year
- Qualified exemption and modified requirements

Standards for Produce Safety

Focus on 5 identified routes of microbial contamination

1. Agricultural water
2. Biological soil amendments of animal origin
3. Worker health and hygiene
4. Equipment, tools, buildings and sanitation
5. Domesticated and wild animals

Other requirements

- Sprouts
- Growing, harvesting, packing and holding activities

Alternatives Permitted

- Farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin
- Alternatives must be scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration

Variations Provide Flexibility

- A state or foreign country may petition FDA for a variance from some or all provisions if deemed necessary in light of local growing conditions.
- Practices under the variance would need to provide the same level of public health protection as the proposed rule without increasing the risk of adulteration.

Recordkeeping Required But Not Burdensome

- The proposed rule would require certain records, for example, to document that certain standards are being met
 - Example: agricultural water testing results
- Records already kept for other purposes need not be duplicated

Qualitative Assessment of Risk Reflects Science Behind Rule

- Draft qualitative assessment of risk helps to inform proposed rule
- Provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce
- Available for public comment as part of the proposed rule

Compliance Dates Staggered

- **Effective Date:** 60 days after final rule is published

Compliance Dates

- **Very small farms**
 - Average annual value of food sold $> \$25,000$ and $\leq \$250,000$
 - Four years after the effective date to comply
 - For some water requirements, six years

Compliance Dates

- **Small farms**
 - Average annual value of food sold $>$ \$250,000 and \leq \$500,000
 - Would have three years after the effective date to comply
 - Would have five years for some water requirements
- **Other covered farms**
 - Other covered businesses would have to comply two years after the effective date
 - Would have four years for some water requirements

Preventive Controls for Human Food



Summary of Requirements

- Hazard Analysis and Risk-Based Preventive Controls
 - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Updated Good Manufacturing Practices

Who is Covered?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- Applies to domestic and imported food
- Some exemptions and modified requirements are being proposed

Farm-Related Exemptions

- Activities within the definition of “farm,” including farm activities that are covered by the proposed produce rule
- Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods

Risk Assessment

- Draft qualitative risk assessment announced in a separate notice of availability
- Addresses activities outside the farm definition conducted in a facility co-located on a farm.
- Comments being accepted separate from the proposed rule

How to Comment on the Proposed Rules

- www.regulations.gov
- Link to rules on www.fda.gov/fsma
- Comments are due by May 16, 2013 (120 days)
- Comment periods on major FSMA proposals will be coordinated to enable comment on how the rules can best work together.

Outreach Will Continue

- Public meetings
- Presentations
- Listening sessions

Partnerships will be
essential



Technical Assistance

- Alliances
 - Produce Safety
 - Preventive Controls
 - Sprouts Safety
- Guidance documents
- National technical assistance network

Partnerships will be essential



More Information Available

- Web site:
<http://www.fda.gov/fsma>
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov



The screenshot displays the FDA website's navigation and content for the Food Safety Modernization Act (FSMA). At the top, the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health" are visible. Below this is a horizontal menu with tabs for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Radiation. The "Food" tab is selected, leading to a page titled "Food". A breadcrumb trail shows the path: Home > Food > Food Safety > Food Safety Modernization Act (FSMA). A sidebar on the left lists "Food Safety" topics: Food Safety Modernization Act (FSMA), About FSMA, Full Text of the Law, Implementation & Progress, and Dockets Open for Comment. The main content area features the heading "The New FDA Food Safety Modernization Act (FSMA)" and a text box stating: "The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of years, was signed into law by President Obama on January 4, 2011. It aims to shifting the focus from responding to contamination to preventing it." Below this text is a red envelope icon and the text "Get FSMA Updates by E-mail".

