

Proposed Rules under the FDA Food Safety Modernization Act

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FDA FOOD SAFETY
MODERNIZATION ACT



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What can we do for you?

- US-FDA-LAO@fda.hhs.gov
- Act as liaisons
- Provide clarification
 - Pesticide residues
 - Inspection issues
- Share knowledge
- Work together to improve inter-country and intra-country work processes

What we can't do (today)

- Provide specific recommendations about requirements that have not been issued
- Predict what future proposed rules will contain
- Answer questions about specific import alerts

Five Proposed Rules Establish Food Safety Framework

- Produce Safety Standards - **Published Jan. 2013**
- Preventive Controls for Human Food - **Published Jan. 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

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
- Produce 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

Hazard Analysis and Risk-Based Preventive Controls

Human PC

Preventive Controls Required

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan
- In addition, seeking comment on supplier approval and verification program

Verification Required

- Validation
- Calibration
- Review of records
- In addition, seeking comment on review of complaints, finished product and environmental testing

Updated Good Manufacturing Practices

- Protection against allergen cross-contact
- Updated language (e.g., “must”)
- Certain provisions containing recommendations would be deleted
- Comments requested on mandating training and whether rule should require, rather than recommend, certain provisions

Exemptions and Modified Requirements -1

- “Qualified” facilities:
 - Very small businesses (3 definitions being proposed—less than \$250,000, less than \$500,000 and less than \$1 million in total annual sales)
 - OR
 - Food sales averaging less than \$500,000 per year during the last three years AND
 - Sales to qualified end users must exceed sales to others

Exemptions and Modified Requirements - 2

- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages

Exemptions and Modified Requirements - 3

- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment
 - Certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification and records

Exemptions and Modified Requirements- 4

- Certain storage facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing are exempt from hazard analysis and risk-based preventive controls.
 - Also exempt with respect to CGMPs

Exemptions and Modified Requirements- 5

- Facilities such as warehouses that store raw agricultural commodities that are fruits and vegetables are NOT exempt from hazard analysis and risk-based preventive controls.
 - They are exempt with respect to CGMPs

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

Effective and Compliance Dates

Effective date:

60 days after the final rule is published

Compliance Dates

- **Small Businesses**—a business employing fewer than 500 persons would have two years after publication.

Compliance Dates (cont.)

- **Very Small Businesses**—a business having less than \$250,000 (or alternatively \$500,000 or \$1 million) in total annual sales of food would have three years after publication to comply.
 - Very small businesses are considered “qualified” facilities and subject to modified requirements
- **Other Businesses**—a business that does not qualify for exemptions would have one year after publication of the final rule to comply.

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
- Comment period is 120 days; exact due date will be in the Federal Register
- 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 shows the FDA website's navigation and content for the Food Safety Modernization Act (FSMA). The top navigation bar includes links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Radiation. The main content area is titled "Food" and features a breadcrumb trail: Home > Food > Food Safety > Food Safety Modernization Act (FSMA). A table of contents lists: Food Safety, Food Safety Modernization Act (FSMA), About FSMA, Full Text of the Law, Implementation & Progress, and Dockets Open for Comment. A featured article titled "The New FDA Food Safety Modernization Act (FSMA)" is displayed, with a sub-headline "The New FDA Food Safety Modernization Act (FSMA)". The article text states: "The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in over 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the focus from responding to contamination to preventing it." Below the text is a link: "Get FSMA Updates by E-mail".

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Food Safety
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About FSMA
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 [Get FSMA Updates by E-mail](#)

