Proposed Rules under the FDA Food Safety Modernization Act
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
- Address small business issues
- Extensive government, stakeholder Input
FDA Proposed Rule on Produce Safety
Key Principles

• Considers risk posed by practices, commodities

• Science- and Risk-based
  – Focus on identified routes of microbial contamination
  – Excludes certain produce rarely consumed raw
  – Excludes produce to be commercially processed
    (documentation required)

• Flexible
  – Additional time for small farms to comply
  – Variances
  – Alternatives for some provisions
Standards for Produce Safety

Focus on identified routes of microbial contamination

- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Worker health and hygiene
- Agricultural water

- Growing, harvesting, packing and holding activities
- Biological soil amendments of animal origin
- Specific requirements for sprouts
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 $25,000 or less per year
- Qualified exemption and modified requirements
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.
Variances 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
- Not covered: Farms with sales ≤$25,000/year

**Compliance Dates**

- **Very small farms**
  - Average annual value of food sold >$25,000 and ≤$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 ≤ $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
Key Principles

• Confirms industry’s primary role on food safety
• Prevention of hazards
• Risk-based
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

1. Hazard Analysis
2. Preventive Controls
3. Monitoring Procedures
4. Corrective Actions
5. Verification
6. Recordkeeping
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; 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

• “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

- 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

• Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment

• Certain storage facilities such as grain elevators that store only raw agricultural commodities intended for further distribution or processing
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

- [http://www.regulations.gov](http://www.regulations.gov)
- Link to rules on [http://www.fda.gov/fsma](http://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 and Technical Assistance Will Continue

- Public meetings
- Presentations
- Listening sessions

- Alliances
  - Produce Safety Preventive Controls Sprouts Safety
- Guidance documents

Partnerships will be essential
More Information Available

- Web site: [http://www.fda.gov/fsma](http://www.fda.gov/fsma)
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov