FSMA: Produce Safety Rule - Implementation

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FDA/Center for Food Safety and Applied Nutrition

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Food Safety Modernization Act

- Signed into law January 2011
- 50 new rules, guidance documents, reports
- Cornerstone: Prevention
Prevention Standards

Sec. 105. Standards for Produce Safety

– Establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables

– Applies to raw agricultural commodities for which FDA determines that such standards minimize the risk of serious adverse health consequences or death.
FSMA Implementation

• Phase 1: Set standards
  – Develop regulations, guidance, policy
• Phase 2: Implement standards
  – Design strategies to implement standards
• Phase 3: Monitor, evaluate, refresh
• Stakeholder engagement throughout the process
<table>
<thead>
<tr>
<th>Regulation</th>
<th>Proposal</th>
<th>Final (consent decree)</th>
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<tbody>
<tr>
<td>Preventive Controls (Human Food)*</td>
<td>Jan 16, 2013</td>
<td>Aug 30, 2015</td>
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<tr>
<td>Foreign Supplier Verification Program*</td>
<td>Jul 29, 2013</td>
<td>Oct 31, 2015</td>
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<tr>
<td>Intentional Adulteration</td>
<td>Dec 24, 2013</td>
<td>May 31, 2016</td>
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*Supplemental proposals published September 2014
Compliance Dates by Business Size

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<td>Produce Safety</td>
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Legend:
- Green: Suppl. Prop.
- Purple: Final
- Black: Large
- Light Blue: Small
- Light Purple: V. Small
- Blue: Water
Phase 2: Governance

High-level FDA Oversight

Steering Committee

Internal Advisory Team

Intentional Adulteration

Import Controls

Preventive Controls
  Human Food
  Animal Food

Produce Safety

ORA, CFSAN, CVM and State representation.

Sanitary Transportation
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
FSMA Operational Strategy: Produce Safety

• Broad, collaborative effort to foster awareness and compliance through guidance, education, and technical assistance
Key Principles

• Inspection, compliance functions specialized
• Invest in regulator training to promote consistent inspections, decision making
• Investigators and subject matter experts work together to drive compliance
Key Principles

• Robust data integration, analysis and information sharing
• Public health metrics
• Work closely with government counterparts and other food safety system stakeholders
Phase 2: Charge

- Develop a framework and multi-year implementation plan for ensuring compliance with regulations:
  - Inspections, compliance and enforcement
  - Data collection, analysis, updated IT
  - Performance goals and metrics
  - Training for regulators
  - Education, outreach and technical assistance for industry
Key Activities: Skilled Workforce

• Build a workforce with specialized skill set focused on produce.
  – Requires experienced regulatory personnel in field and HQ
  – Staffing dependent upon overall production, risk-based commodity/practice assessments
  – Work closely with regulatory partners (USDA, states) and other stakeholders (cooperative extension).
Key Activities: Skilled Workforce

• Build a workforce with specialized skill set focused on produce.
  – Comprehensive, Hands-On Regulator Training
    • Include PSA core curriculum training requirement
    • Regulator course with on-farm component
    • Continuing education
Key Activities: Relationship Building

• Develop working relationships with growers
  – Federal, state, academia, and farm partnerships
  – Conduct inspections with expanded emphasis on education and outreach
    • Pre-assessment program
  – Develop an incentive program for compliance
Stakeholder Engagement

• Transparency Remains a Priority

• Next Phase: Inclusive/Coalition Approach
  – Engage stakeholders to help determine reasonable and practical ways to implement provisions and concepts before rules become final.

• Future: Partnerships/Collaboration Key
  – Establish mechanisms to foster industry understanding of standards and encourage firms to comply and initiate any corrections on their own.
Education, Outreach, and Technical Assistance

• Collaboration with industry, academia and researchers to provide training and educational materials to industry and regulatory officials

• Alliances
  – Produce Safety Alliance
  – Sprouts Safety Alliance

• FDA/NIFA grants
FDA Food / Feed Internal and External Tech Assistance Networks

FSPCA External Technical Assistance Network

Land Grant Universities

Extension Specialists

Internal Technical Assistance Network

CVM Info Center

CFSAN FCIC

Imports

VQIP

KMS

Produce External Technical Assistance Network

PSA / Extension Specialists

SSA

NIFA/ National & Regional Centers

NASDA

Regulators and Industry
Public Information Available

- Web site: [http://www.fda.gov/fsma](http://www.fda.gov/fsma)

Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)
Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards
May 2, 2014
Thank you