FSMA: Produce Safety Rule - Implementation

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FDA/CFSAN and USDA/AMS

March 2015
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
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Legend:
- Suppl. Prop.: Green
- Final: Purple
- Large: Dark Blue
- Small: Light Blue
- V. Small: Light Purple
- Water: Light Cyan
Phase 2: Governance

High-level FDA Oversight

Steering Committee

Internal Advisory Team

Intentional Adulteration

Import Controls

Preventive Controls
  Human Food
  Animal Food

Produce Safety

Sanitary Transportation

ORA, CFSAN, CVM and State representation.
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
FDA Strategic Program Planning: 5 Steps

1. Develop Strategic Goals
2. Develop Strategic Framework
3. Develop Performance Measures
4. Monitor Implementation
5. Conduct Evaluation & Strategic Refresh

Planning Process → Implementation Process → Monitoring and Evaluating Process → Update Strategic Planning Materials
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
      – Farm protocol and etiquette
    • Continuing education
Key Activities: Relationship Building

• Develop working relationships with farms
  – Federal, state, academia, and farm partnerships
  – Conduct inspections with expanded emphasis on education and outreach
    • Pre-assessment program
  – Develop an incentive program for compliance
  – Develop a program to evaluate application of the rule to identify inconsistencies
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 for Industry

- 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

Internal Technical Assistance Network
- CVM Info Center
- FSPCA External Technical Assistance Network
- External Specialists
- Land Grant Universities

External Technical Assistance Network
- CFSAN FCIC
- Produce External Technical Assistance Network
- PSA / Extension Specialists
- SSA

Imports
- KMS
- NIFA/ National & Regional Centers
- VQIP

Regulators and Industry
Joint GAPs Review Project

- USDA AMS, FDA CFSAN and ORA, and State partners

- Primary Goals
  - Review GAPs materials & make recommendations for revisions resulting in alignment with the FDA (final) Produce Safety Regulation

- Secondary Goals
  - Gain better understanding the public health implications of common farming activities and operations via the perspective of FDA personnel;
  - Gain a variety of farm-based experiences via USDA GAP audits;
  - Provide examples, scenarios, and materials to be incorporated into training programs for both agencies; and
  - Enhance the working relationships among both agencies and stakeholders
Thank you